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Enablers for change

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

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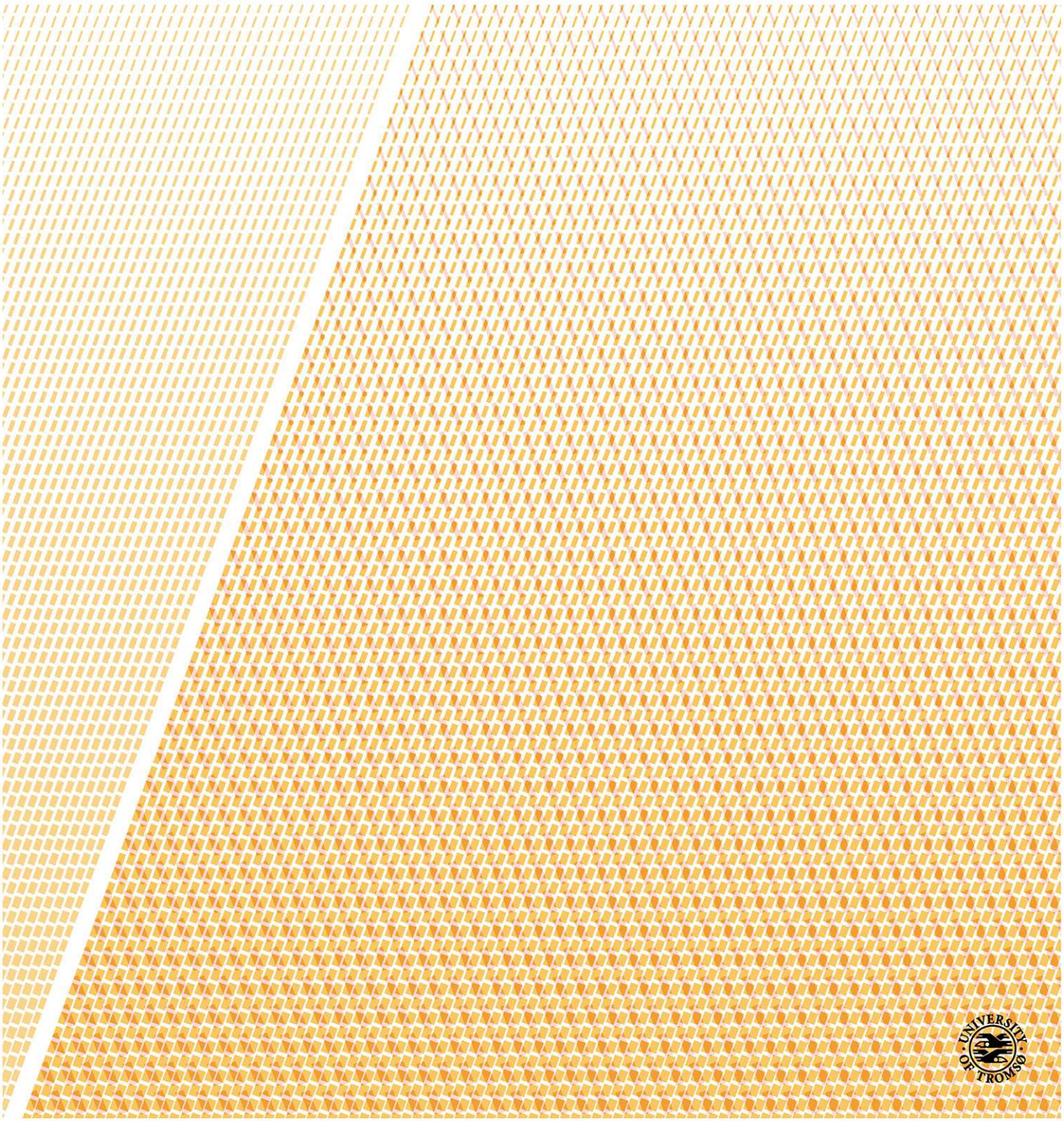
Hege Andersen

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

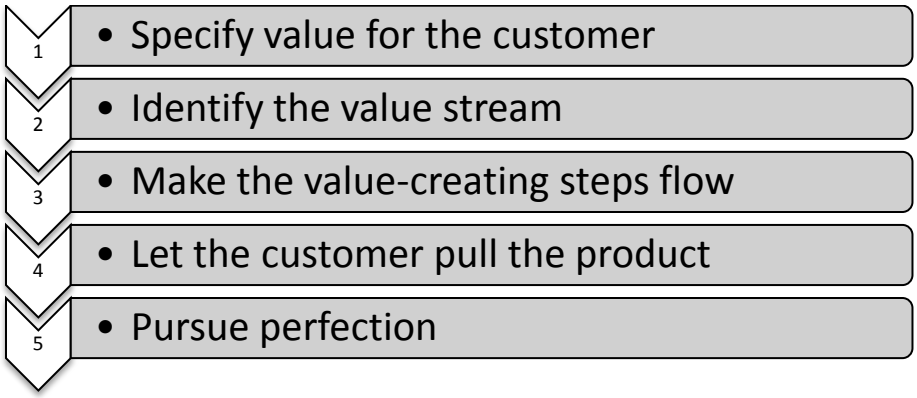
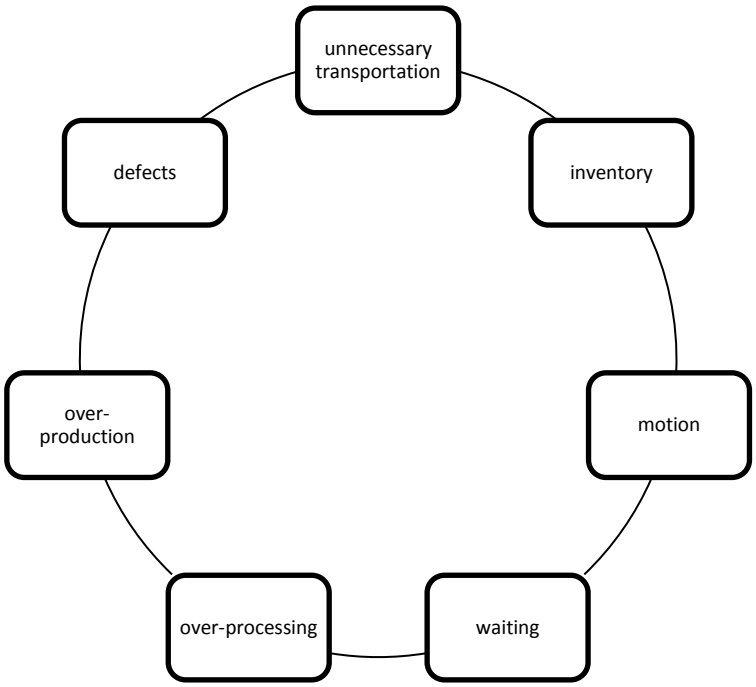


Figure 2: The seven wastes of Lean



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.

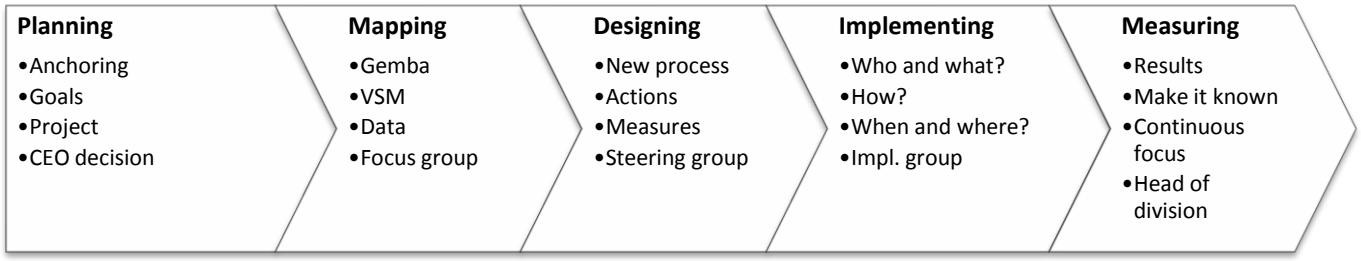
Each Lean intervention was organized as a project, including a steering group, a focus group, and, if necessary, a project and/or implementation group. A department-internal project manager (Lean consultant), who was trained in Lean philosophy and improvement techniques and tools, was responsible for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

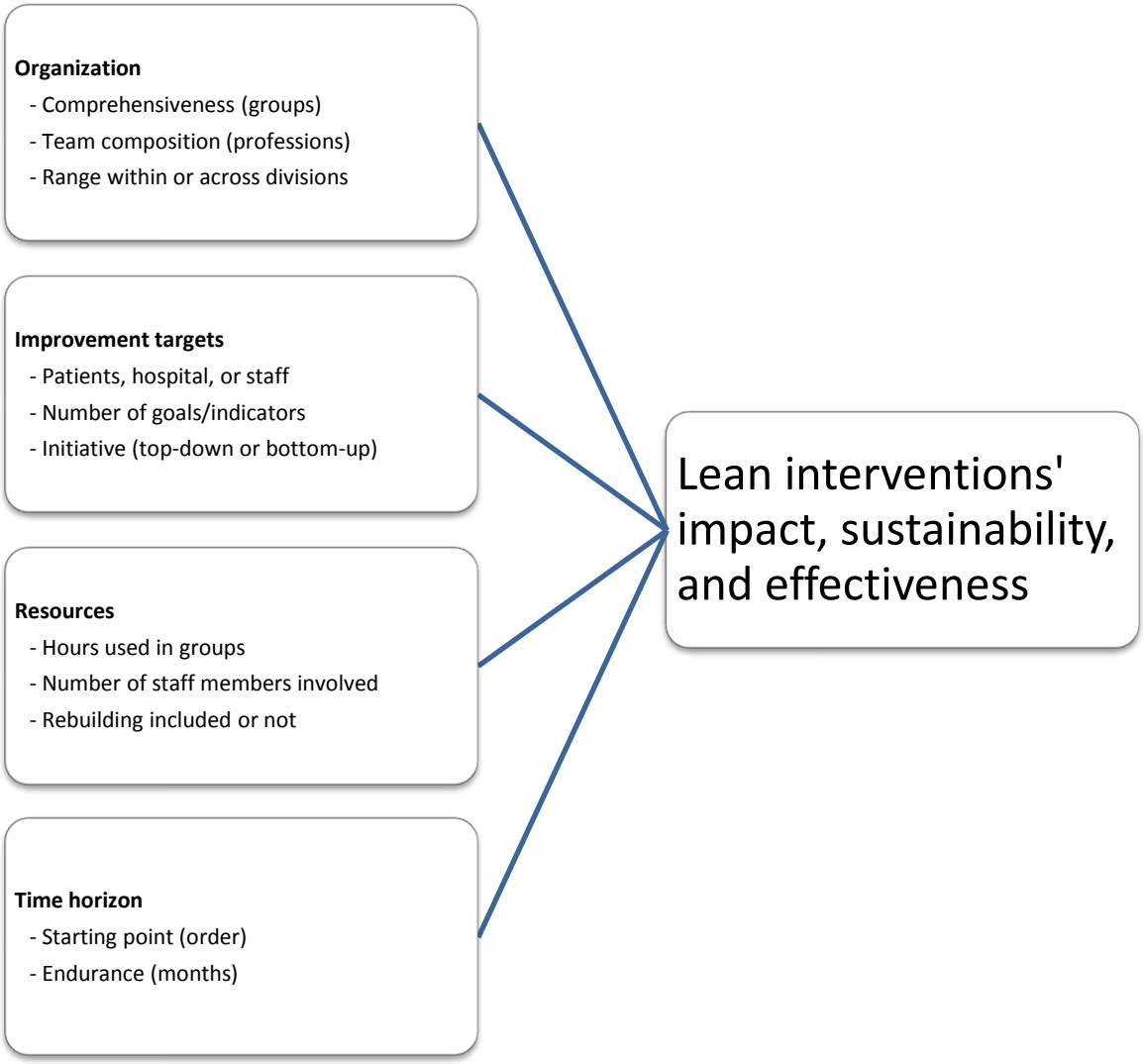
	Domains of the intervention	**Context** Situation and organization	**Content** Characteristics of the intervention	**Application** Local delivery process	**Outcomes** Results and maintenance
Dimensions of capability	Cultural	Underlying beliefs, values, norms and behavior			
	Technical	Training and information-support 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



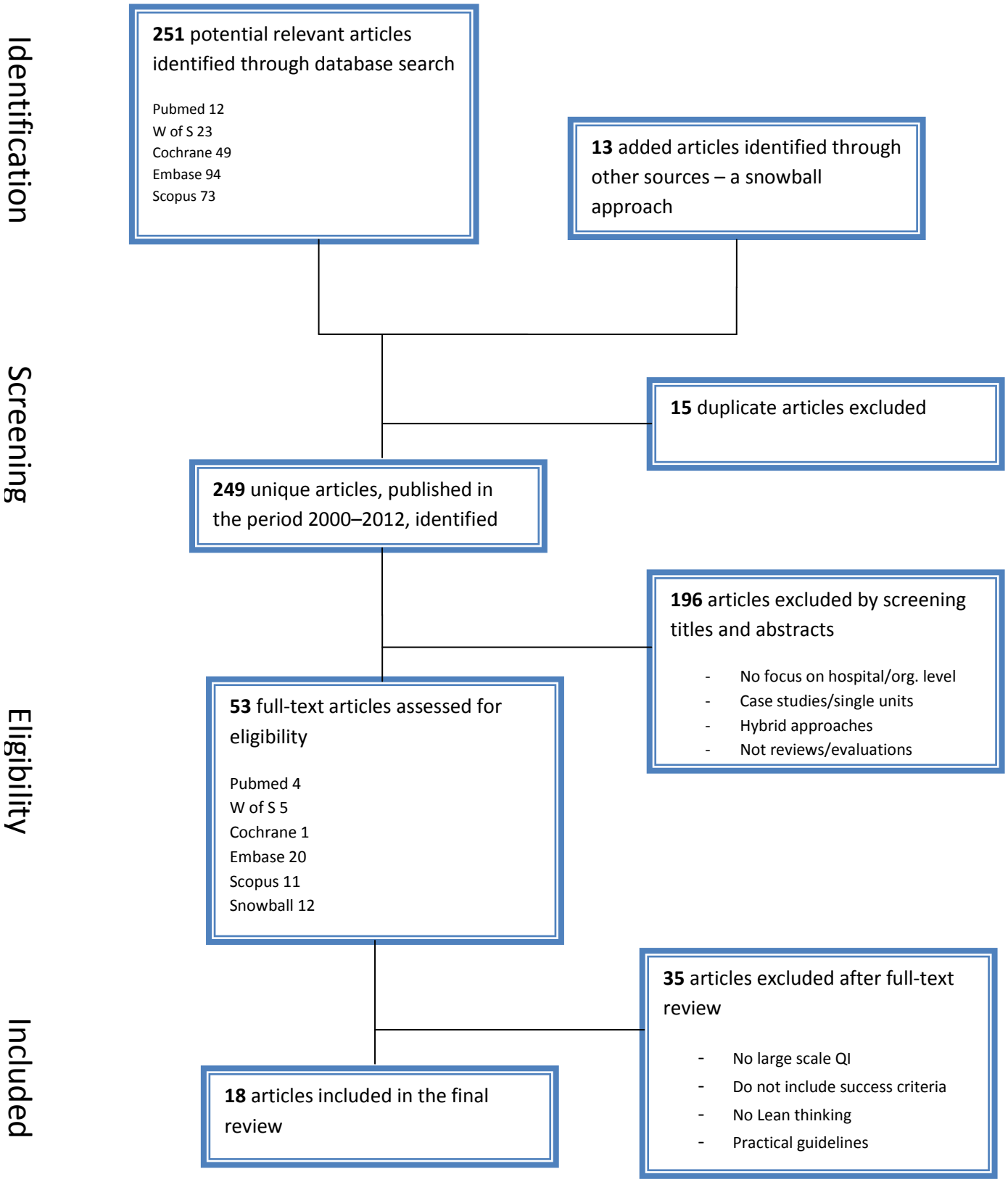
The dependent and independent variables are described more closely in Chapter 4.5.3.

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.

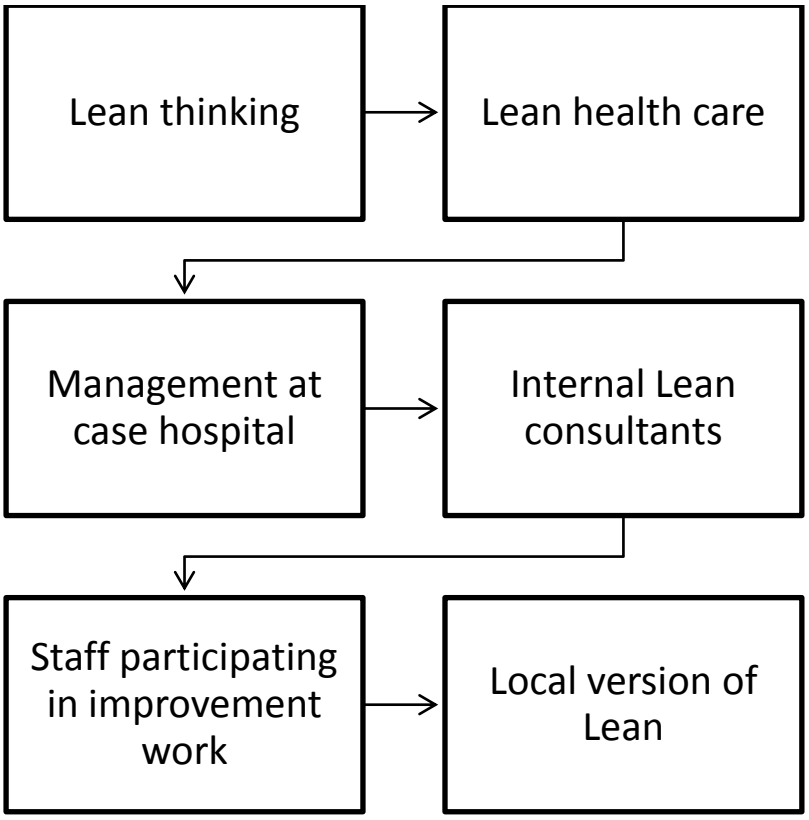
Possible translation rules and regularities are deduced by comparing and analyzing the findings from the literature review, the focus groups, and the survey, making it possible to draw tentative conclusions in relation to whether varying outcomes are a matter of translation. Neither the principles nor 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

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Lean thinking in hospitals: is there a cure for the absence of evidence? A systematic review of reviews

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ABSTRACT

Objective: Lean interventions aim to improve quality of healthcare by reducing waste and facilitate flow in work processes. There is conflicting evidence on the outcomes of lean thinking, with quantitative and qualitative studies often contradicting each other. We suggest that reviewing the literature within the approach of a new contextual framework can deepen our understanding of lean as a quality-improvement method. This article theorises the concept of context by establishing a two-dimensional conceptual framework acknowledging lean as complex social interventions, deployed in different organisational dimensions and domains. The specific aim of the study was to identify factors facilitating intended outcomes from lean interventions, and to understand when and how different facilitators contribute.

Design: A two-dimensional conceptual framework was developed by combining Shortell's *Dimensions of capability* with Walshes' *Domains of an intervention*. We then conducted a systematic review of lean review articles concerning hospitals, published in the period 2000–2012. The identified lean facilitators were categorised according to the intervention domains and dimensions of capability provided by the framework.

Results: We provide a framework emphasising context by relating facilitators to domains and dimensions of capability. 23 factors enabling a successful lean intervention in hospitals were identified in the systematic review, where management and a supportive culture, training, accurate data, physicians and team involvement were most frequent.

Conclusions: In the absence of evidence, the two-dimensional framework, incorporating the context, may prove useful for future research on variation in outcomes from lean interventions. Findings from the review suggest that characteristics and local application of lean, in addition to strategic and cultural capability, should be given further attention in healthcare quality improvement.

Strengths and limitations of this study

- This review of reviews sums up the major findings regarding facilitators for lean interventions in healthcare in the latest decade.
- The immaturity of the research field makes it hard to find substantial evidence for effective lean interventions in healthcare.
- The fact that lean is a social, complex and context-dependent intervention calls for a shift from cause–effect to conditional attributions in research.

INTRODUCTION

Lean thinking has been introduced in healthcare during the latest decades as a quality-improvement method.[1] Lean can be challenging to adopt in a medical environment, where professionals require evidence before taking action.[2–4] Researchers remark a profound gap and tension between the medical approach and lean thinking.[5 6] The call for scientific proof for lean as an efficient and effective quality-improvement method is strong.[7] The lack of evidence may lead to resistance and hinder speed-up and spread of quality initiatives in healthcare.[1 8–10]

Lean interventions aim to improve quality by reducing waste and facilitate flow in care processes.[11] Lean techniques include value stream mapping of start-to-end processes, identification and elimination of activities that do not add value and streamlining of value-adding activities.[12] A focus on measurements and continuous improvement is expected to promote implementation and sustainability.

In a recent review, Mazzocato *et al*[13] concluded that lean has been applied successfully in healthcare institutions worldwide. However, most studies have a narrow technical application with a limited organisational reach. Many are single case studies, some quite anecdotal, while others are biased or characterised by a weak study design. Some reviews suggest that inappropriate analyses, a lack of alternative hypotheses and other methodological limitations undermine the validity.[2 5 14] This makes it difficult to rule out confounding explanatory factors,

to measure the outcomes and generalise the results from lean interventions.[6]

Advocates for experimental designs question results from qualitative studies, and argues that randomised controlled trials are necessary to isolate effects.[15 16] Many studies using an experimental design did not find any significant effect of lean and other quality-improvement interventions.[1 2 6 9 10 17] Experimental methods are not very helpful in understanding interventions' effectiveness because they rule out context, content and application variables.[9] We cannot be sure that the specific intervention —and not other factors—produced the observed change.[2 10]

The key problem is the adaption of study designs that do not allow drawing solid conclusions, particularly as they fail to take into account contingency factors that are needed to translate the findings from one setting to another. Is there a cure for this lack of evidence? On a paramount level, one must ask whether the absence of evidence justifies inaction.[18] The *quality chasm* between the healthcare we have and the healthcare we should have is well documented.[1 19 20] In other words, the call for action is still there, and, these obstacles to quality improvement must be crossed.

Lean as social, complex and context-dependent interventions

Shortell *et al*[21] emphasised the need to link evidence-based medicine and what they refer to as evidence-based management, arguing that medicine must take into account the complex organisational and social context in which care is delivered. Such integration of the intervention and its context seldom happens in quality-improvement research.[22]

Lean interventions operate differently from the clinical interventions affecting biological systems, in which a linear cause–effect relationship controlling the influence of context is assumed. A context is simply defined as all surrounding factors that are not part of the intervention itself.[8 23] However, the boundaries between the intervention and its surroundings may be relatively arbitrary, as lean interventions are social, complex and inherently context-dependent.[24 25] Lean interventions consist of multiple, reciprocally interacting elements. They evolve over time in response to continuous feedback as situation-dependent cumulative processes, and are therefore intrinsically unstable and difficult to standardise. Lean and other quality-improvement methods are often adjusted, mixed, implemented and used simultaneously.[5 10 26 27] This fact challenges the strict distinction between lean and other quality-improvement methods. Finally, lean interventions are open systems that feed back on themselves, so that with learning, they may change the conditions that made them work in the first place.

There is a growing literature on lean facilitators. According to Grimshaw *et al*,[28] systematic reviews provide the best evidence on the effectiveness of quality improvement. We observe a growing consensus that characteristics such as management, resources and culture matter, but the current knowledge base lacks specification on when and how the different facilitators work. This vagueness partly rests on insufficient methodological attention to the context in which lean interventions work. To understand and assess variation in lean intervention success, there is a need for a conceptual framework defining facilitators for change at the stages and levels where they are activated. These facilitators, also named enablers, determinants for effectiveness and so on, may be defined as contingency factors which help the progress of lean interventions,[8 22 29] and shift the focus from cause–effect to conditional attributions.

The University Hospital of North Norway underwent a complex merger and restructuring process between 2007 and 2010.[30] An enterprise-wide lean programme for improvement was launched. The programme aimed to accomplish quality improvement in parallel with the organisational change to counteract the transitional setbacks in quality that large-scale change may entail.[31] A research programme was established to evaluate the effects. The proposed framework represents a theoretical tool to understand more of how and when lean interventions work at the hospital. Our approach incorporates the complex social and organisational context in which the interventions are applied and the different stages of adoption. We suggest that the emerging knowledge could guide decision-makers considering lean interventions, assessing the organisations' readiness for change.[22 32] The specific aim of the study was to identify contingency factors influencing intended outcomes of lean interventions, and to understand when and in which dimension different factors contribute.

METHODS

A systematic narrative review[33] of reviews of quality improvement in hospitals was conducted. One reviewer performed the systematic review, supervised by the two coauthors. Any confusion was resolved by discussion involving all three authors. The initial inclusion criteria were English language articles published in a peer-reviewed journal in the period 2000–2012. The search words included hospital, healthcare, quality improvement, lean thinking, lean management and review/evaluation. By searching PubMed, Web of Science, EMBASE, Cochrane and Scopus, 251 articles were identified. A snowball approach was used to search for supplementary articles, adding 13 articles. Fifteen duplicate articles were removed. The titles and abstracts of these 249 articles were screened according to the *Prisma guidelines* for reporting reviews and meta-analysis (see online supplementary material).[34] One hundred and ninety-six original articles were excluded. Exclusion criteria included the absence of a hospital or organisational focus, single-unit case studies and hybrid quality-improvement approaches. As a result, 53 articles were assessed for eligibility. After a full-text

review, another 35 articles were excluded by the criteria that neither large-scale quality improvement, success criteria nor lean thinking were issued. Articles that mainly represented practical guidelines were also excluded. The final review included 18 articles.[10 13 17 22 23 26 27 31 35–44]

Data analysis

The 18 articles were systematised according to the number of studies included in each review. Eight articles reviewed a number of definite cases, varying from 4 to 90 (median 33). The remaining articles were expert evaluations, narrative or unsystematic reviews, all covering lean interventions in hospitals. Half of the articles review only lean interventions, while the others include lean and corresponding methods such as *Productive ward* and process-oriented redesign. Lean was extracted and treated separately as far as possible, though confined by the observed mix, similarity and simultaneous use of different quality-improvement methods in hospitals.[5 22 26 27] The methods used in the original studies were qualitative, quantitative or a mixed-method approach. Most studies were based on cases originated in the USA, Australia and Great Britain.

The next step was to search for facilitators, defined as contingency factors predicted to promote quality improvement, as opposed to barriers that hinder improvement.[37] The decision to concentrate on facilitators and not on barriers to lean improvement was based on the fact that the research literature at this field chiefly pays attention to facilitators and not to barriers.[5 8 10 13 17 22 23 38] In most cases, the facilitators were quite easy to identify in the texts despite different annotations used, including *enablers*, *conditions*, *factors* and *key facilitators*, *critical elements*, *determinants of effectiveness*, and *contextual characteristics*. Using the method of feature maps, which enable localisation of similarities and differences among studies,[33] the articles were systematically analysed and recorded in a standardised format, according to the facilitators. The procedure was conducted by creating a worksheet categorising every article according to the author, year of publishing, type of review, other quality-improvement methods comprised (in addition to lean), research method, labelling of facilitators and facilitating factors. The complete worksheet is attached as an online supplementary material.

All the identified facilitators were assigned to larger categories. This classification was carried out to develop a more specific and practically focused state of knowledge concerning facilitators for lean thinking, as the need for an overview necessitated reducing the information to manageable amounts. All the identified facilitators concerning management and leadership were placed in the category *management*, covering subjects such as management support, commitment and ownership. Cultural issues were all categorised as *supportive culture*, including views, norms, beliefs and behaviours supporting the principles and practice of quality improvement. All facilitators concerning local translation were put in the category *adaption*, as all facilitators dealing with prior involvement in quality-improvement work were grouped under the heading *experience*, and so on. After examining all the 149 facilitators, grouping them with similar ones, we ended up with a list comprising 23 facilitators. The different facets of these facilitators are all listed in box 1. Finally, the frequency of each of the facilitators in the 18 reviews was accounted for.

Box 1 Facilitators for change: description

Adaption: Local translation of the lean intervention
Measurement: Audits local performance metrics on regular basis as evidence
Holistic approach: Lean as an entire value system, embracing every day improvement
Belief: In staff and patient, benefits encourage willingness and motivation
Experience: Prior quality improvement using a successful, mature method
Administrative support: Practical facilitation by a project management
Competence: In tools, assumptions and methods assure capability
Communication: With and between patients and staff, including feedback to both
Alignment: Consistency to strategic objectives and priorities of strategic importance
IT-systems: Adequate IT support and infrastructure established
Continuous improvement: A long-term plan, securing endured and sustained attention
System-wide scope: Multifaceted interventions across silos and functional divides
Vision: Targets of urgency and direction, but realistic, simple and practical solutions
Customer focus: Includes patient and workforce value creation and improvements
External support: Expert change agents, networks and sponsorship trigger change
Staff involvement: Commitment, engagement and empowerment by staff participation
Resources: Available, sufficient and accessible capacities
Accurate data: Robust and timely, evidence-based data as a impetus to change
Physicians: Clinical leadership and champions' engagement, support and collaboration
Teamwork: Multiskilled and disciplinary team collaboration including decision-making
Training: Accessible, substantial, practical and relevant training for immediate use
Supportive culture: Views, norms and beliefs that support quality improvement
Management: Leadership support, ownership and commitment

A theoretical and methodological framework

Lean interventions consist of several different phases, from planning and preparation to implementation and sustainability, involving different organisational capabilities. The facilitators for improvement were analysed and reorganised in a table combining Shortell's *dimensions of capability*[2 45] and Walshe's *domains of an intervention*.[9]

Shortell categorised improvement factors according to cultural, technical, strategic and structural dimensions of an intervention. The *cultural* dimension refers to the underlying beliefs, values, norms and behaviours of the organisation. The *technical* dimension covers training and information system issues, while the *strategic* dimension emphasises the conditions that offer the greatest opportunities to change. This dimension touch on the degree of integration of quality improvement in the hospital's strategic plans, and to which extent improvement efforts are devoted to processes central to strategic priorities. The *structural* dimension relates to mechanisms that facilitate learning and disseminate best practices throughout the organisation. The four dimensions are multiplicative, inter-related and equally necessary for lasting quality improvement according to Shortell. Varying lean success can be understood as a result of the interplay of dynamic processes related to the four dimensions.[45]

Walshe's differentiated domains in quality interventions are labelled as context, content, application and outcomes. The context involves the situation, setting or organisation in which the intervention is deployed. Context may vary widely, within and between hospitals. The *content* describes the nature or characteristics of the intervention itself. The content of lean may be standardised and repeatable or modified and easy to redesign. The *application* covers the process through which the intervention is delivered. This process may be protocol-driven or widely varying depending on local actors. *Outcomes* are the results of the intervention, including the maintenance phase after implementation. All of these domains may be characterised by low or high variance. High levels of variance in the settings, content and application may explain interventions of varying success. Variances also reduce the ability to generalise empirically, and to draw conclusions about effects from one specific context to another. The complex relationship between context, content, application and outcomes must be unpicked to develop a situational understanding of effectiveness.[9]

By combining Shortell's dimensions and Walshe's domains, this two-dimensional framework made it possible to classify identified facilitators for quality improvement, as emerging in different domains in a multistage process and by different organisational dimensions. The framework was used to describe and understand the contextual factors encountered in an organisational-wide quality-improvement effort.

RESULTS

Among the 18 reviewed articles, 149 facilitators for lean interventions were found. The reviews identified 3–16 (median 7) facilitators for improvement. All were identified in several reviews, varying from 3 to 14 (median 7) times. The facilitators were categorised into 23 extensive classes, covering the range of all the identified facilitators.

Figure 1 shows how frequent the different facilitators were identified in the 18 reviews.

DISCUSSION

Table 1 shows how the different facilitators were found relevant in different intervention domains and affected organisational dimensions.

Context: situation and organisation

Prior experience, accompanied by success stories demonstrating the benefits for patients and staff, enables improvement.[23 31 37] This relates to the organisation's cultural capability and the influence of the underlying beliefs, values, norms and behaviours. Motivation influences the willingness to participate.[13 17 37 38 40 41 44] IT systems' infrastructure and competence,[17 23 31 36–38] as well as external experts sponsoring, strengthen the technical and structural capability. Sponsorship triggers learning and contribute to dissemination of best

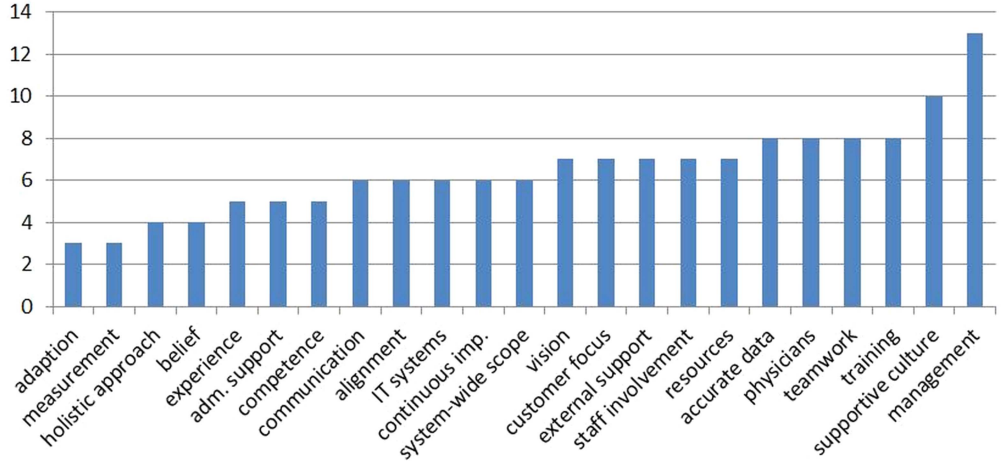

Figure 1 Frequency of different facilitators identified in 18 reviewed articles.

Table 1 Facilitators for change, literature reviews 2000–2012

	Domain of the intervention			
	Context	Content	Application	Outcomes
Dimensions of capability	Situation and organisation	Characteristics of the intervention	Local delivery process	Results and maintenance
Cultural Underlying beliefs, values, norms and behaviour	Experience Belief	Adaption Customer focus	Teamwork	Supportive culture
Technical Training and info support systems	IT systems Competence	Training	Administrative support	Communication
Strategic Strategic importance and opportunity to change	Alignment Vision	Resources	Physicians Management	Holistic approach Continuous improvement
Structural Mechanisms to facilitate learning and disseminate best practices	External support	Accurate data	Staff involvement	Measurement System-wide scope

practices throughout the organisation.[17 31 35 38–40 44] Competence in tools and methods supports the assumptions of lean, and increases the potential for change.[26 27 36 38] Ambitious targets aligned with the hospital's overall goals and strategies strengthen the strategic capability.[17 31 36 38 41 44] The goals have to be of strategic importance, but at the same time realistic, based on simple and practical solutions.[17 22 31 36 40 44]

Content: characteristics of the intervention

Adaption and translation to local conditions are a precondition for success.[26 35 37] A methodology communicating a clear patient and workforce focus supports the cultural dimension. Emphasis on patient processes, value creation and patient's needs facilitates quality improvement in healthcare.[10 13 23 35 37 42 44] Access to and accomplished substantial training in methods and tools strengthen the organisations' technical capability,[10 17 22 26 31 35 36 38 44] as sufficient and available resources, financial as well as staff time, affect the strategic dimension.[10 17 22 23 31 35 36 38 44] On the structural dimension, accurate and robust data represent an impetus to learning and spread of best practices. Timely data contribute to an evidence-based quality-improvement initiative.[13 17 36 37 39 40 44] Availability and sufficiency of training, data and other resources are among the most frequent facilitators in the reviewed articles, and thereby probably among the most important drivers for change.

Application: local delivery process

Collaborating multidisciplinary and multiskilled teams facilitates local application of lean.[23 31 35–38 42 43] Strengthening the improvement culture presupposes workforce stability, team leadership and decentralised decision-making. Administrative project management and practical support secures backing, and contributes to the technical capability.[22 31 36 44] Strategically, involvement of physicians and management encourage change. Management engagement includes frontline and senior managers, maintaining urgency, setting direction, reinforcing expectations and providing resources.[10 13 17 22 23 31 35 36 38–42 44] Physicians represent champions and clinical leadership, and their involvement, engagement and collaboration are important at the strategic level as role models and peers for others.[10 17 23 31 36 38 40 43] The management and physicians' involvement are among the most frequently identified enablers jointly with teamwork. Key factors to disseminate best practices are staff participation, engagement and empowerment. Staff commitment, responsibility and ownership are required for achieving longstanding outcomes.[26 35 38–42 44]

Outcomes: results and maintenance

To secure maintenance, a hospital depends first and foremost on a supportive culture characterised by norms, beliefs and behaviours supporting the principles and practice of quality improvement.[10 22 23 35–38] In a supportive culture, employees feel that they can make use of their skills and creativity, take initiative and cause things to happen.[35] At the technical dimension, communication and feedback between patients and staff are enablers.[31 35 38 43 44] Strategically, a holistic approach based on continuous improvement and sustained attention affects the ability to accomplish change. A holistic approach emphasises that lean is not only a strategy to promote everyday improvement but also a philosophy of ongoing quality improvement within the hospital's value system.[13 17 27 35 41] A long-term plan should be established to secure continuous improvement.[10 13 17 26 27 37] Local audits and measurements conducted on a regular basis relate to the organisation's structural capability, which strengthens the evidence for lean interventions.[36 37 39 40] A system-wide multifaceted approach, across functional divides, allows best practices to be learned and disseminated.

Analysis based on the conceptual framework suggest that understanding which facilitators influence the

intervention at different domains and dimensions of capability is probably more important than a quantitative approach.[8 17] This represents a shift from cause–effect to conditional attributions.[45] Each domain and dimension is influenced by the status of other ones. Our results summarised in table 1 indicate that a number of facilitators may interact within and between the domains and dimensions. The four dimensions, domains and the associated facilitators are inter-related and probably all necessary to achieve longstanding results.[2] Finally, we elaborate our interpretation of these findings.

Our analyses of data from previous review articles within this new framework show that successful lean interventions share some common features. We identified 23 facilitators associated with successful interventions. Unfortunately, little is known about which facilitators are most important.[8 22] Management and leadership engagement were identified as important by 13 of the 18 reviewed reviews. The other facilitators most frequently identified were a supportive culture, accurate data and training, along with physician and team involvement. This is in accordance with the conclusions from relevant research, and may indicate that these facilitators are vital to accomplish quality improvement.[13 23 31 35] Two recent reviews conclude that leadership, culture, maturity and data infrastructure have a stronger evidence base than other factors.[23 38] Our results, nevertheless, suggest that successful interventions must utilise multiple facilitators from the four dimensions of capability, interplaying as the change processes that touch on different domains. The observation the facilitators identified in this study were in accordance with those promoted in other broader theories of implementation concerning uptake of evidence and innovations in healthcare[4 23 46] strengthens the findings.

The most frequent facilitators belong to the *content* or *application* part of the intervention. This may indicate that policymakers should pay special attention to the content of lean and the local delivery process. Sufficient resources, accurate data and training are crucial for lean interventions to succeed. Lean interventions are not a recipe that can be implemented locally if the training or available resources are inadequate. The need for local resource allocation should not be underestimated. This is in accordance with Radnor *et al*,[27] who advocated that lean interventions must be contextualised, rather than transplanted like a recipe.

This assertion is supported by the frequently identified facilitators labelled physicians and management. Leadership and clinical leadership are keys to understand why, or why not, lean interventions make contributions to healthcare.[47] Finally, the local application of lean in hospitals depends heavily on teamwork by multiskilled and multidisciplinary teams. Work-floor staff must be engaged and empowered. Womack and Jones,[12] who initially advocated lean thinking in healthcare, emphasised the multiskilled teams as a main advantage for hospitals, making lean interventions suitable for healthcare.

The cultural and strategic dimensions of capability embrace most of the frequent facilitators. A supportive culture is fundamental to achieve quality improvements.[38] The organisational culture and the strategic importance of the patient path exposed to the improvement initiative are essential to understand variation in outcomes of lean interventions. Available resources, physicians' and managements' involvement indicate and affect the strategic importance, and thereby the opportunity to change. These findings are supported by other recent hospital-based studies, like Rozenblum *et al*.[47]

Limitations

Making these interpretations from a systematic review of reviews must take the methods' limitations into consideration. The facilitators were grouped with similar ones, and sometimes renamed, risking that the original meaning could be misread and mistranslated by our interpretation. Transparency is promoted by conducting feature maps and presenting all the identified facilitators in appendices.

It could be argued that facilitators identified in large reviews should be given more weight than those identified in smaller ones. However, our analysis identified the same facilitators across small and large reviews. Therefore, weighting was not conducted, even though we suggest that facilitators identified in many studies are significant.

Including qualitative and quantitative studies eliminates the possibility of quantifying the findings and predicting the effects of the various facilitators by meta-analysis. The inclusion of both types of studies broadens the scope, increase the ability to identify an ampler spectre of facilitators and contribute to understanding the role of context in lean interventions.

Directions for future research

A critical review concluded that most of the research on hospital quality is dominated by questions of *what* and does not go further to investigate the *how, when* and *why*.[48] They called for approaches that incorporate structure, process and outcomes. The fact that we know so little about the relationship between these makes it difficult to recommend ways of organising that could improve patient care.[49]

The facilitators identified and the two-dimensional framework proposed in the present work incorporate structure and process. Still, the facilitators are characterised by vagueness, as broad and comprehensive determinants, that needs further specification and practical content to guide future effective quality improvements to healthcare organisations.[8 22 38 50] In addition to contextual preconditions, success are dependent on how an organisation utilises, combines and sequences organisational resources and routines.[32] A logical next step will be to measure and analyse outcomes in the context of this framework, with the identified facilitators as explanatory variables. Possible measures of outcomes

could be related to the healthcare providers' performance (adherence to recommended practice), patient's outcome (as quality of life or mortality), surrogate outcomes (as re-admission) and organisational outcomes (such as resource use or sustainability).[36] At the University Hospital of North Norway, more than 5 years of lean experience and more than 20 implemented lean interventions leave us with a sufficient amount of empirically based cases to assess due to varying success.

Conclusion

The findings contribute to reduce the gap between theory and practice, by a shift in focus from cause-effect to conditional attributes or characteristics of an effective organisation-wide quality intervention. The review of reviews identified 23 inter-related facilitators for lean in hospitals, where management engagement, cultural support, accurate data and training, along with teamwork, physician and staff involvement were most frequent. The findings suggest that characteristics of lean and the local application should be given attention, in addition to the organisations' cultural and strategic capability.

The main contribution of this review is a two-dimensional framework for identification and analysis of facilitators for lean interventions in healthcare. This framework incorporates the complex social and organisational context in which lean interventions are applied. These findings coincide with recent research calling for more attention to the influence of organisational context when trying to understand variance in interventions in healthcare.[23] We suggest that it will prove useful in future research aiming for a better understanding of how the likelihood to accomplish success in lean interventions can be increased.[14] The framework will also be used in future research locally at the hospital, as a practical tool to assess variation in adoption of lean.

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Lean thinking in hospitals: is there a cure for the absence of evidence? A systematic review of reviews

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Appendix 2. *Articles comprised by the review* (web only)

Author/ year	**Review/ size**	**QI/ research method**	**Labels**	**Factors**
Poksinska B. 2010	Review 30 articles	Lean. Theoretical/ case studies.	Enablers	Commitment/participation from staff that owns and drives it Training and responsibility to staff (empowerment) Consultants/trainers from health care Management support, ownership and resources Organization culture An holistic approach - lean is not a toolbox Improve the entire system, involve several units Adaption, not adoption Clear view of the customer Teamwork, collaboration and communication
Powell A, Rushmer R, Davies H. 2008.	Review 59 articles	QI, including Lean. Observation, interviews, action research.	Necessary but not sufficient conditions for successful implementation	Alignment with strategic objectives Quality as part of everyday life/every ones work Long time approach Active health professionals/doctors engagement Belief that staff/patient will benefit Strong leadership and clear vision Sustained active participation from board and senior management Multifaceted interventions sustained action at different levels Substantial investment in training and development (including IT and training of staff) Support from ”change agents” to provide skills Robust and timely data Resources
Vos L, Chalmers SE, Dûckers MLA et al. 2011	Review 10 articles	Process oriented redesign including Lean. Uncontrolled before-after evaluations.	Factors for success	Senior management support Clinical leadership and involvement Team-based problem solving Adequate information and communication technology support Administrative support Ambitious targets External facilitators Organizational readiness Selection and execution of projects in order of urgency Using a change strategy that already proved to be successful Good communication and training in QI techniques

Brennan S, McKenzie J, Whitty P, et al 2009	Review - protocol	QI, including Lean. Qualitative and quantitative.	Dimensions of capability thought necessary for successful implementation	Views, norms, beliefs, and behaviors that support the principles and practice of QI Competency in QI methods and tools Alignment of QI activities with the organizations priorities Management structures and systems that support QI, including appropriate data and analysis systems. Leadership support for QI at all levels. Ability to work as a team (team performance), team member participation, Presence of a champion Physician support and participation, team members technical competence, training in theory, methods, and tools, support to facilitate implementation and use, the nature and complexity of the targeted change
de Souza LB, Pidd M. 2011	Review 90 articles	Lean. Case studies.	Success factors	Clarify the nature of lean healthcare, provide evidence that it works, focus on patient processes, translate it, make a culture, data – evidence based, continuous improvement, multidisciplinary teams across silos, local performance measurement, technical support, success stories (small pilots)
Kaplan HC, Provost LP, Froehle CM, et al. 2012	10 QI-experts identification based on review	QI, including Lean. Qualitative and quantitative studies	Contextual factors influencing QI success	External motivators (environmental pressure and incentives) Project sponsorship (personnel, expertise, facilities from outside) QI leadership (senior management board) Senior leader project sponsor (to champion and support) Culture support Program maturity/sophistication of QI Data infrastructure Resource availability Workforce QI focus/training/engaged Micro system leadership (personally involved) Culture support; teamwork, communication, freedom to improve Capability (team ability to use QI methods) Motivation/willingness Team diversity Physician involvement Expert (subject matter)

				Team tenure (worked as a team before) Prior QI experience Team leadership Team decision making processes Team norms of behavior Team QI skills Trigger (a specific event stimulates a new emphasis) Tasks strategic importance to the organization
Kaplan HC, Brady PW, Dritz MC, et al 2010	Review 47 articles	QI including Lean. Observation, controlled design, meta-analysis.	Factors important for QI success	Leadership from top management/board Organizational culture Organizational structure (clinical integration across departments) Data infrastructure and information systems Years involved in QI (experience) Customer focus Physician involvement Micro system motivation to change Resources for QI QI team leadership
Mazzocato P, Savage C, Brommels M et al. 2010	review 33 articles	Lean. Qualitative and quantitative.	Contextual characteristics of relevance	Senior management involvement Work across functional divides Pursue value creation for patients Nurture long term holistic culture of CQI A need to improve A willingness to improve
Kim CS, Spahlinger DA, Kin JM et al. 2009	UMHS-USA evaluasjon	Lean. Qualitative and quantitative.	Key factors	Expert guidance for initial efforts leadership - clinical champions and senior management support frontline worker engagement in the QI processes Use metrics to develop and track interventions Define a realistic project scope
Lukas CVD, Holmes SK, Cohen AB et al. 2007	12 healthcare system doc. review	QI including Lean Longitudinal case-studies, mixed method evaluation.	Interactive elements that appear critical to successful transformation of patient care	Impetus to transform leadership commitment Actively engage staff in meaningful problem solving Alignment to achieve consistency of organization goals Integration to bridge traditional intra-organizational boundaries among individual components.
Kollberg B, Dahlgaard JJ, Brehmer PO. 2007	Unsystematic review	QI including Lean. Qualitative and quantitative.	Critical success factors	patient focus active involvement and multi-skilled teams

Radnor ZJ, Holweg M, Waring J. 2012	4 multilevel studies NHS	Lean. Case studies including interviews	-	holistic system approach, Understanding pathways across the organization. a culture of continuous QI, structured problem solving, understanding the underlying assumptions
Walshe K. 2009	Unsystematic review	Lean Theoretical, qualitative and quantitative studies	-	Adoption of a QI method, stick with it; develop skills and experience, build up engagement, commitment Organizational capacity.
Walshe K, Freeman T. 2002	unsystematic review	Lean. Research evaluations.	The determinants of effectiveness	Leadership, direction, culture, training, resources, Practical support.
Winch S, Henderson AJ. 2009	Un-systematic review	Lean. Qualitative and quantitative.	-	teamwork, collaboration between health professionals and patients, Communication.
Øvretveit J, Gustafson D. 2002	Un-systematic review and recommendation for evaluation	QI including Lean. Theoretical, qualitative and quantitative.	Conditions for effectiveness or critical success factors	Senior management commitment, sustained attention, the right type of management roles at different levels, focus on customer needs, physician involvement, sufficient resources, careful program management, practical and relevant training which personnel can use immediately, the right culture
Morrow E, Robert G, Maben J et al. 2012	Evaluation program NHS	Productive ward (Lean). Mixed method evaluation including interviews and surveys.	Key facilitators	Regional level support Alignment with organizational targets Clear vision, good information about the initiative Dedicated project leadership Strong support from senior staff (champions/steering groups) External support (facilitation, networks) Enthusiasm from middle managers

				Communication and feedback to staff and patients Need for change, valuing the initiative Simple, practical solutions to real problems Accessibility of recourses and teaching modules Self-nomination (units to take part) Local ownership and empowerment Sufficient resources, support and time (staff cover)
Kim CS, MBA, DAS, Billi JE. 2009	Unsystematic review	Lean. Qualitative and quantitative.	Critical Elements	Senior management support. Expert guidance for their initial projects. A well-structured set of metrics, on a regular basis, readjusted Aligning individual goals, projects, and metrics Provide flexibility for frontline workers to experiment at the site and time they identify a problem. Frontline management need to avail themselves to the area

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RESEARCH ARTICLE Open Access

Lost in translation: a case-study of the travel of lean thinking in a hospital

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Abstract

Background: Lean thinking as a quality improvement approach is introduced in hospitals worldwide, although evidence for its impact is scarce. Lean initiatives are social, complex and context-dependent. This calls for a shift from cause–effect to conditional attributions to understand how lean works. In this study, we bring attention to the transformative power of local translation, which creates different versions of lean in different contexts, and thereby affect the evidence for lean as well as the success of lean initiatives within and among hospitals.

Methods: We explored the travel of lean within a hospital in Norway by identifying local actors' perceptions of lean through their images of enablers for successful interventions. These attributions describe the characteristics of lean in use, i.e. the prevailing version of lean. Local actors' perceptions of enablers for lean interventions were collected through focus group interviews with three groups of stakeholders: managers, internal consultants and staff. A questionnaire was used to reveal the enablers relative importance.

Results: The enablers known from the literature were retrieved at the case hospital. The only exception was that external expert change agents were not believed to promote lean. In addition, the stakeholders added a number of new and supplementary enablers. Two-thirds of the most important enablers for success were novel, local ones. Among these were a problem, not method focus, a bottom-up approach, the need of internal consultants, credibility, realism and patience. The local actors told different stories about local enablers and had different images of lean depending on their hierarchical level.

Discussion: By comparing and analyzing the findings from the literature review, the focus groups and the survey, we deduced that the travel of lean within the hospital was affected by *three principles of translation*: the practical, the pragmatic, and the sceptical. Further, *three logics of translation* were in play: translation as a funnel, a conscious sell-in, and a wash-out. This resulted in various local versions of lean.

Conclusions: We conclude that lean, introduced by the management, communicated by the internal consultants, and used by the staff, is transformed more than once within the hospital. Translation is part of the explanation for the lack of evidence for lean, and translation can be decisive for outcomes.

Keywords: Quality improvement, Lean thinking, Healthcare, Context, Implementation, Translation, Hospital, Norway

Background

Quality improvement by the use of *lean thinking* is introduced in many hospitals worldwide [1]. Lean thinking is a systematic quality improvement approach to identify and eliminate non-value-adding activities in work processes [2]. It is argued that lean's focus on zero defects, no delay, continuous improvement and *just in time* make lean especially suited for healthcare [3, 4]. However, in practice, lean interventions are characterized by high variance; that is, high heterogeneity of the context and the intervention itself - the content, the application and the outcomes of lean [5–9]. Studies that apply an experimental design have trouble finding significant effects of lean, and qualitative studies showing positive effects are characterized by a narrow application and limited organisational reach [6, 10–15]. In sum, there is a lack of evidence for lean impact in healthcare.

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A recent review of enablers for successful lean interventions conclude that more attention should be paid to local application and translation [16], echoing other studies that assert the importance of context to understand variations in outcomes of such interventions [6, 17–19]. The common argument for a context approach is that outcomes vary because contexts are different. Thus, one must map contexts to understand why similar interventions produce different outcomes. Our approach is complementary, maintaining that actors in different contexts translate and transform a lean intervention differently, thereby creating different versions of lean, and thus, different interventions in different contexts. To understand variations in outcomes of lean interventions, one must also understand why and how the intervention itself is changed. This implies a shift from cause–effect to conditional attributions and to the transformative power of local translation processes [20–22].

The aim of this study is to explore the travel of lean into and within one case hospital in Norway by emphasizing how local interpretation at three different hierarchical levels at the hospital leads to the emergence of various versions of lean. Our two main research questions are:

- Is lean, defined by enablers for 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 or regularities?

The answers to the two research questions may contribute to suggest to what extent variations in outcomes can be considered a consequence of how lean interventions are translated.

Methods

This study's empirical basis is a lean initiative at a university hospital in Norway. The hospital underwent a complex merger and restructuring process between 2007 and 2010 [23], during which lean was introduced as an enterprise-wide program intended to improve patient pathways, including quality of care and work conditions, and increase hospital efficiency. The lean techniques used included value stream mapping of work processes, identification and elimination of activities that did not add value, maintaining value-adding activities in work processes running without any delay [24, 25].

The hospital chose a strict approach to implementing lean, using trained internal lean consultants, standardized schemes and routines. The standards were anticipated to prevent comprehensive variations among the different interventions across the hospital. However, an evaluation after five years of lean experience documented that the lean impact, where improved standards were adopted, routinised, integrated, and the intended effects accomplished, varied considerably among the lean initiatives at the hospital [26].

Data collection

Enablers for lean interventions were identified by a systematic review of literature reviews concerning lean in hospitals (2000–2012) [16]. Local enablers for lean interventions were collected through separate, semi-structured focus group interviews with three groups of stakeholders: leaders of lean steering-groups (heads of divisions), internal lean consultants, and staff participating in redesigning patient pathways. All the participants had detailed first-hand experience of lean projects and processes.

Participation in the focus groups was restricted to employees involved in lean interventions implemented in the period from 2008 to 2012. The focus groups were considered to be a representative sample of relatively small populations; 8 of 10 steering-group leaders and 14 of 17 internal consultants attended. The 11 members of improvement groups that attended were collected from a list including all 258 former members. Two participants from each of the 17 projects were invited by drawing lots. The sample closure at 11 was reasoned by a judgment of a sufficient, representative sample size.

The focus group interviews were conducted in March 2013. Each interview lasted 2–3 h, and was taped and transcribed by the corresponding author, in consultation with the co-author. Both authors were running the focus groups. The critical incident technique (CIT) was used during the data collection, with emphasis placed on the incidents that had made the most significant contributions to the improvement activity [27]. The participants were asked to identify the two to three most important incidents that contributed to the lean project's success. Each incident was only registered once, even if it was mentioned several times. The participants were not briefed on the enablers identified by the literature review [16].

All the enablers were assigned to larger categories by using work-sheets to secure a systematic classification of data [28]. The classification was carried out to develop a more specific and practically focused state of knowledge. The analytical approach of developing broad conclusions was believed to increase the relevance of the study results [29]. After examining all the reported enablers and grouping them with similar ones, we ended up with a list comprising 44 enablers. They were systematized according to which domain of the intervention they touched upon: *context* covered the setting in which the intervention is deployed, *content* referred to the characteristics of the intervention itself, *application* related to the process through which the intervention was implemented, and *outcome* covered the results and maintenance phase after implementation [6].

To ensure that all relevant factors were identified, the respondents had an opportunity to launch additional enablers by e-mail two weeks after the interview. This to secure that the final list included all the enablers that the stakeholders believed was important to successful lean interventions.

In order to reveal the relative importance of the enablers, an electronic questionnaire was mailed to 363 registered former participants in lean projects, during the period from April to May, 2013. We used *Quest-back* in order to ensure the anonymity of the respondents. The questionnaire contained a list of the locally identified enablers. The respondents were asked to point out the three most important enablers for quality improvement concerning the setting, content, local application and outcomes of lean.

A total of 195 people completed the questionnaire, of which 165 were included in the survey, leaving out 30 that reported that they had no lean experience, as they never attended the lean project they were invited to. The remaining sample was organisationally and professionally representative, regarding the three hierarchical groups that constituted the population. Characteristics of the participants in the focus groups and the survey are given in additional files (Additional file 1).

Approval was obtained from the Data Protection Official for Research (PVO), who confirmed that a more comprehensive ethical approval or informed consent was not necessary.

Results

The enablers identified in the literature review were also reported at the hospital. The only exception was that external expert change agents, networks and sponsorships [30, 31] was not believed to trigger change by the stakeholders at the case hospital. However, the focus groups added a number of new and supplementary enablers not identified in the literature review.

Table 1 presents the enablers identified at the case hospital. They are organized according to whether they are retrieved from the literature review or novel, local ones. A further description of the local enablers is presented as an additional file (Additional file 2).

The findings from the survey contribute to knowledge of the enablers' relative contribution to lean success. Table 2 presents the 12 most important enablers according to the stakeholders at the case hospital.

Approximately half of the reviewed enablers were shared as important by the management, the consultants and the staff. Most of these related to the content of lean and the local application. When separated among the three groups, the preferred enablers and their relative importance diverged. The main results distributed across the three hierarchical levels are presented in the following paragraphs and detailed in additional files (Additional files 3 and 4).

Table 1 Local enablers for lean improvement

Part of intervention	Context	Content	Application	Outcomes
	Situation and organisation	Characteristics of the intervention	Local delivery process	Results and maintenance
Reviewed pre-conditions	Experience	Adaption	Teamwork	Supportive culture
	Belief	Customer focus	Administrative support	Communication
	IT-systems	Training	Physicians	Holistic approach
	Competence	Resources	Management	Continuous improvement
	Alignment	Accurate data	Staff involvement	Measurement
	Vision			System-wide scope
	External support[a]			
Local pre-conditions	Preparation	Bottom-up	Credibility	Compatible to professional values
	Need for change	Dedication to lean	Internal consultants	Data feedback
	Anchoring in management, department or staff	Process orientation	Group composition	Smooth transition
	Management structure support	Priority setting tool	Operational	Realism and patience
		Visual and simple, less resource demanding	Sufficient participation	Few, palpable measures
			Problem, not method focus	Follow-up structure

[a]Enabler only identified in the review

Table 2 The most important enablers for change, results from the questionnaire ($n = 165$)

Context	Content	Application	Outcomes
Management structure support	Customer focus	Team work	**Few, palpable measures**
Organisational structural support, coordination and continuity	Include patient and workforce value creation and improvements	Multi-skilled and multi-disciplinary team collaboration including decision-making	**Concrete, quick results and visual success-stories**
Vision	**Bottom-up**	**Credibility**	**Realism and patience**
Targets of urgency and direction, but realistic, simple and practical solutions	**Improvement suggestions from floor, voluntariness due to initiative**	**No bragging, trustworthiness, no camouflaged dismissals or cuts**	**Distinct mandate, demarcation, smaller projects, adjustments possible**
Need for change	**Problem, not method focus**	**Internal consultants**	Holistic approach
Perceived need, potential for improvement	**Lean as a meeting place**	**Project management skills, mentors and network**	Lean as a entire value system, embracing every day improvement

Bold: locally identified enablers

Management

In the management focus group, many of the reviewed enablers were shared. Exceptions, that is, enablers not mentioned, were belief in benefits as motivating, communication and feedback to staff, and a holistic lean approach. Among local enablers, the management did not launch a need for credibility or goals compatible to professional values. These findings are also reflected in the survey, as the management did not identify credibility or realism and patience as being among the most important enablers. They gave preference to their own role as management and the need for a smooth transition from project to everyday work.

Internal consultants

The internal consultants recognized all of the reviewed enablers except a need for prior experience in quality improvement. This group was the only one that pinpointed the need for a process orientation and a holistic approach, including the entire value system, which they denoted *a lean hospital*. They mentioned all the enablers that were identified by the other focus groups. However, they diverged from the other two groups by placing their own role as internal consultants at the top of the list of important enablers. They also diverged by ranking management-anchoring and benefits' motivating role above the need of a vision and perceived need for change among the staff.

Staff

The staff recognized only some of the reviewed enablers. They did not mention a need for prior experience, competence or alignment, all of which are contextual enablers. Nor were clinical leadership or leadership by management, adaption or a holistic approach brought up. The staff emphasized the need for decentralized decision-making, clinic-anchoring and continuity of staff. They viewed lean as a meeting point, rather than a method of problem-solving. They shared the consultants' emphasis on patient focus and bottom-up processes, but differed by stating that a conscious group composition was more important than internal consultants or management support. Assurances of sufficient and accessible resources were important for these stakeholders, as were credibility and trustworthiness concerning the lean initiative.

Discussion

What happens when popular management ideas, like lean, travel into and within an organisation? We conclude that lean, being introduced by the management, taught and communicated by the internal consultants, and used in practical improvement work by the staff, is transformed and translated more than once on its way through the hospital.

There are numerous empirical studies on the adoption and implementation of management ideas, and also several attempts to theorize such processes. For example, a vast literature stream theorizes on and investigates organisations' *absorptive capacity* and the role this plays in understanding variations in outcomes of adoption and implementation processes [32, 33]. There are also more rational and instrumental "how-to" theories, some of which argue for top-down implementation strategies [34, 35], while others consider bottom-up approaches as decisive for outcomes [36, 37]. At the other end of the spectrum are studies that consider management theories as fashions, and of organisations and their leaders as more or less dedicated fashion followers [38, 39]. Management fashions pass through populations of organisations as popularity curves of rapid upswings, followed by equally rapid downturns [40–42]. When conceptualized as fashion, management ideas are superficial phenomena that primarily affect organisations only on the surface, rather than impacting their core practices. Thus, a main assumption within this school of

thought is that fashionable management ideas primarily lead to temporary discourse within organisations, which often remains decoupled from action [43–45].

This paper is based upon an alternative theory: that of organisational translation of practices and ideas [46–50]. Translation theory focuses on how ideas and various representations of practices travel in time and space. It contrasts with theories of diffusion, in which the ideas that spread resemble physical and hardly changeable objects [51]. Inherent in the diffusion approach is also the image of adopters as passive receivers, and of an active central broadcasting point that provides all of the energy to the dissemination process [52]. In contrast, translation theorists conceive management ideas as immaterial accounts that are transformed as they spread. The power behind the travel does not stem from one single, powerful source, but is created from the richness of the interpretations the idea triggers in each actor within a network [53].

Especially important for 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 they had developed and applied at the local level – and how these versions eventually related to the outcome of the intervention. This approach provides a window into the local translations of lean, in terms of the extent to which, how, and why lean is transformed. The conclusions are founded on the assumption that enablers represent a way of defining the lean version applied at the specific site under study.

How lean is translated – the characterizing principles

Lean is, as indicated by our results, transformed at the hospital level. What characterizes local versions of lean? When the respondents were asked to identify the most important enablers for success, two-thirds was local, not identified in the literature review we conducted, which constitute the basis for this study. Among these were structural support from the management, palpable measures, a bottom-up approach, credibility, realism and patience. The top-three enablers for quality improvement identified in the review and supported locally were patient focus, teamwork, and a vision characterized by targets of urgency and direction. When it comes to what attributions make a considerable difference, according to the local stakeholders, local situational ones like credibility, bottom-up and problem, not method focus, dominates. This confirms previous research which has stated that lean interventions are social, complex and inherently context-dependent [8, 14, 54], and that local interpretation manifests in local versions of lean [55].

Based on the analysis of the enablers, we constructed three broad and intertwined guiding principles that characterize how local stakeholders translate lean. These three principles are the practical, the pragmatic and the sceptical way of handling lean.

The practical principle

The local version of lean is characterized as practical because it stresses preparation, process orientation, automatic data feedback to staff, and structural support from management. Lean is defined as a priority-setting tool that forces the organisation to rank activities according to their importance. When one specific quality improvement approach is chosen, the organisation must stick with it. In order to ensure continuous improvement, one single structure for monitoring, including a watchdog, is recommended.

The pragmatic principle

Lean is emphasized as a meeting place for problem solving, rather than a quality improvement method per se. For this reason, success depends on sufficient, but flexible, participation, and time and resources must be added when needed. A few palpable measures concerning professional issues and limited work processes will promote quick results and a smooth transition to everyday routine. Stakeholders state that an advantage of lean is that it is simple, flexible and less resource-demanding than other improvement tools. It represents a toolbox to pick from, quite accessible and straightforward.

The sceptical principle

Local stakeholders pay attention to the perceived need for change as a prerequisite for success. Lean must be comprehended as credible and trustworthy, and not as camouflage for dismissals and cuts. The outcomes should be evidence-based and compatible with professional values, without threatening the autonomy of professionals. A certain group composition that recognizes discord, includes critics and "owners" of the work processes at stake, and yet avoids enthusiasts, is suggested. Further on, the interventions must be results of a bottom-up approach that includes voluntariness and work-floor engagement. In addition, changes should be anchored in management, department and staff, facilitated by internal consultants recruited locally at the hospital. The improvement work should demonstrate realism and patience.

The logics of lean translation

By separating the enablers identified by the stakeholders, local versions of lean can be vaguely discerned. If the enablers identified in the literature review truly mirror lean in healthcare, then only the consultants can be said to have stayed true to lean, as they shared all the reviewed enablers. Management shared the most, except for benefits as a motivation, a need for communication and feedback, and a holistic lean approach. The staff noted fewer known enablers, leaving out a need for clinical and management leadership, prior experience, lean competence, alignment to overall goals, a holistic approach and adaption. Only the

consultants mentioned the need for a holistic *lean-hospital* mindset, and only the management saw the advantage of prior experience. The consultants and the management agreed on many issues, believing that lean is less resource-demanding than other quality improvement approaches, among other things. The staff and the management only had a few enablers in common. In the following, we outline and discuss three interrelated logics of the local translation of lean, which is believed to lead to the observed transformation.

"Whisper down the lane" – translation as a funnel

Translation can be understood as a multilayered process in which different parts of the organisation change the idea for their own use. The translation process functions as a funnel, or like the game "whisper down the lane," where the work-floor version of lean diverges from the original idea. The local actors translate the idea into a world they know, based on appropriateness and sense-making [49].

Some impediments are rather obvious when it comes to the idea of lean's travel within healthcare: the distinction between producing cars and giving care [56], the profound gap between evidence-based medicine and quality improvement storytelling [14], and the varying ability of hospitals to identify an idea, assimilate it, and exploit it to fulfil their own needs [33]. Szulanski [57] named these impediments as an arduous relationship, causal ambiguity and lack of absorptive capacity.

One important observation from the focus groups, in addition to the enablers the staff mentioned, was those that they did not mention. Classical enablers for quality improvement by lean were left out, such as the need for competence, alignment, adaption, process-orientation, and physicians and management engagement. The work-floor staff emphasized a belief in lean as a possible means for patient-directed problem solving, more than a method of quality improvement per se.

"Washed out" – copying the tools, leaving the philosophy out

A pragmatic way of implementing lean involve copying the tools, rather than the underlying philosophical elements [58]. Lillrank's conceptual model for the transfer of management ideas is based on the observation that the greater the cultural and social distance, the more the output of a transfer process differs from the input [55]. Tools have a low level of abstractions, and are easy to transfer, while the lean philosophy requires a higher level of abstraction, and is thereby more demanding to implement.

Liker and Kaisha [25] state that most attempts to implement lean have been fairly superficial, because most organisations do not recognize that lean is an entire system that not only consists of tools, but also entails continuous learning, respect for people, and a long-term philosophy. Only the consultants in our study believed that a holistic approach and a *lean hospital* promote change. During its travel within the hospital, lean tools were adopted while the philosophy-part was washed out. The fact that, in the focus groups, the management emphasized lean as a less resource-demanding toolbox to pick from, and the perception of lean as a functional meeting place supports this assumption. This is in accordance with other studies [12, 54].

A statement from one of the respondents in the survey illustrates the problem with the logic of washing-out lean: *"(there is) a danger of (creating) a one-sided focus on process leaving out the corresponding focus on change in structure (restructuring) and change management. The consequence may be that the projects are restricted by meeting resistance in the established structures."*

"Introductory sale" – conscious sell-in of the least controversial parts of lean

Manufacturing myths, a new vocabulary, differences in skills, professional or functional silos, hierarchy and resistance to change are among the barriers to lean in healthcare [59]. These barriers, which are caused by cultural and social distance may delay lean implementation in hospitals [54, 60]. Morris and Lancaster claim that management ideas have to be "boiled down" to be adaptable in a local setting [61]. Successful implementation of lean depends on effective adaption, and this in turn depends on translation [56].

Lean often leads to resistance, as do other industrial concepts and models of management [12, 54]. At the case hospital, the management relabelled lean as *patient pathway work*, perhaps as an attempt to weaken the coupling with industry and production, and thereby manage to reduce the anticipated resistance and *lean is mean* attitude reported elsewhere [12]. The internal consultants and the staff were told that quality improvements for the patients were the primary goal of lean, and that lean would not be used for economical savings or dismissals. In this way, the organisation left out the most controversial parts of lean in order to avoid resistance and to secure successful sell-in of the new idea [56].

A statement from one of the respondents in the survey may underline the logics of "sell-in:" *"With a declared patient-focus, it is also a paradox that the medical evidence-based literature is almost absent in lean. It is also strange how easily the 'new' terminology is adopted by management as matter of course, and then repeated – in constantly wider circles like ripples in water – without any knowledge of what we in fact know or do not know based on years of, often bitter, experience, and patient research. Lean may be an efficient management tool, but the terminology are and will always be out of place when employed*

for health services that are founded on a deeper and more nuanced value-base."

Translation makes a difference

This study indicates that translation of lean makes a difference, specifically in two interrelated ways. First, the study illustrates the transformative power of translation [50, 62]. The local translation of lean at different levels and units of the organisation leads to a transformation of lean into various local versions within the organisation. Due to different translation processes, the work-floor versions of lean diverge from the original idea. They may also differ from each other. While some versions are slightly modified compared to the original idea, for instance by adding or toning down some elements, other versions are more radically transformed throughout the local translation processes [63, 64]. This mechanism throws light on the problems of measuring effects of lean interventions. Bluntly, lean is not lean, but more often numerous materialized versions of the idea; that may have, in methodological terms, various causes when it comes to measuring and comparing effects of lean interventions. It may be hard to account for these different versions in effect studies. In fact, we believe that translation makes a considerable contribution towards explaining the lack of evidence for lean; that is, the immaturity of the research field [12, 14, 65].

Second, there are reasons to believe that the ways in which translations are performed can be decisive for outcomes [47, 66]. Some translations may lead to successful lean interventions, while others cause the interventions to fail. Outcomes may depend on the extent to which, and in what way, lean is tailored to meet local needs. Thus, future research should focus on the relations between local translation processes and the effects of the interventions. In doing so, researchers should closely study, for example, the decisions that local actors make when translating lean, and reveal how they, in practice, balance two main concerns: on the one hand, concern for adapting lean to fit the local context and needs, and on the other hand, concern for staying true to lean, and making sure that the core elements of the concept are not washed out when tailoring it to new contexts.

Strengths and weaknesses of the study

The focus on enablers was chosen for theoretical, as well as for analytical reasons. As a contribution to cure the lack of evidence for lean success, there is a growing body of literature on lean barriers and enablers [54, 67]. Observing that barriers often reflect a lack of enablers [59], we chose to focus on the latter. Enablers comprise the context and utilization, the content and outcomes of lean interventions, illuminating conditional attributions of the implementation process, i.e. the prevailing version of lean at the specific site.

A mixed-methods approach seemed best suited to explore the dissemination of lean within hospitals [68, 69]. Focus groups were used for exploring the stakeholders experience and attitudes towards lean. Group dynamics contributed to a more thorough exploration, taking the research in new and unexpected directions [69]. We argue that the design of three homogeneous focus groups encouraged a wider range of data to be detected, as well as it helped identifying group norms and social processes within those groups. By separating the three groups we were able to differentiate between three levels of the organisation; top-management, intermediate level, and work floor. In addition, we reduced the possibility for hierarchy to affect the data.

We suspected that the list of 44 broadly defined enablers lacked some clarity, and thereby were insufficient to guide policymakers how to achieve sustainable change [20]. The whole research field is characterized by these limitations [70, 71]. Some of this vagueness could be reduced by adding some specification of quantity to the dataset, i.e. how many, and who, hold which enablers as important. Given the fact that it is not appropriate to give percentages or frequency counts of focus group data [29], we decided to complement the data with a questionnaire, making it possible to state the relative importance of different enablers.

A relatively low response rate (49 pct.) may contribute to uncertainty about the results caused by sampling bias. The sample was representative regarding occupation and hierarchical level, but there may still be some unobserved imbalance in the sample.

By combining focus group interviews and the succeeding questionnaire, it was possible to cross-check reliability. And, by examination of whether the enablers identified in the literature review were retrieved at the hospital, we tested the validity of the former study. The findings from the two separate studies were anticipated to reinforce each other in a reciprocal manner.

Although the findings are based on a study at one single hospital, similar processes of translation can be expected at other sites, though they may result from other enablers than those identified here. The description and awareness of translation processes are relevant for organisations in general.

Conclusions

Ideas travel, and so do quality improvement ideas. Lean management travelled all the way from Toyota in Japan to a university hospital in Norway. This study concerns the travel of lean through a hospital, from the top management, via internal consultants, to the work-floor staff, based on

the assumption that local translation plays a key part in lean interventions.

The translation processes at the hospital were characterized by the practical, the pragmatic, and the sceptical principle, paying attention to the need of credibility, anchoring, realism and patience in lean interventions. Local attributions like these were the most important for local improvements. On its way through the hospital the idea of lean was translated, so that it eventually represented something different to the staff than it did to the top management that introduced it. The idea of lean was partly washed out, or edited, by management during their sell-in, and partly lost in translation via a funnel effect. We claim that translation is a considerable part of the explanation for why it is so hard to find proof of lean efficiency, and for the varying outcomes of lean interventions within and among hospitals.

The crux of lean-based quality improvement seems to be to capture the right balance between two main concerns: tailoring lean to local needs, and at the same time staying true to lean as a philosophy for change.

Additional files

Additional file 1: Table S1. Study sample and data collection method. (DOCX 10 kb)

Additional file 2: Table S2. The local enablers. (DOCX 12 kb)

Additional file 3: Table S3. Reviewed and local enablers identified by the focus groups. (DOCX 13 kb)

Additional file 4: Tables S4-S7. The three most preferred enablers by management, consultants and staff in focus groups, percent per part of the intervention. (DOCX 13 kb)

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
HA and KAR collaborated in drafting the study design and in the data collection. HA systematized the data and performed the analysis. KAR contributed to the interpretation, in addition to the theoretical and conceptual focus of the study. HA and KAR drafted different parts of the manuscript, cooperated in its completion before approving the final manuscript for submission. All authors read and approved the final manuscript.

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Additional file art II

Table A2: The local enablers

Enabler	Description
Preparation	Preparatory work, baseline established
Need for change	Perceived need, potential for improvement
Anchoring in management, department or staff	"lean management"
Management structure support	Organizational structural support, coordination and continuity in management and staff
Bottom-up	Improvement suggestions from floor, voluntariness due to initiative
Dedication to lean	Stick with lean and stay true to the method
Process orientation	work processes in focus
Priority setting tool	Enforce priorities
Visual and simple, less resource demanding	Tool box to pick from, spot check, not science
Credibility	No bragging, trustworthiness, no camouflaged dismissals and cuts
Internal consultants	Project management skills, mentors and network
Group composition	Include critics, recognize discord. "Owners" participate, roles clarification. Avoid enthusiasts
Operational	Professional issues at stake, intensive small cases
Sufficient participation	Sufficient, but flexible. Add resources and time when necessary
Problem, not method focus	Lean as a meeting place
Compatible to professional values	Outcomes; Not threaten autonomy, evidence based
Data feedback	Information to staff, high level analysis, automatic data collection
Smooth transition	From project to every day routine. Agreements commit
Realism and patience	Distinct mandate, demarcation, smaller projects. Adjustment possible
Few, palpable measures	Concrete, quick results and visual success-stories
Follow-up structure	One standard established, Focus and progress, watch dog ask for results

Table A3: Reviewed and local enablers identified by the focus groups

	Enabler	Management	Internal consultants	Staff
Reviewed enablers	Experience	X		
	Belief		X	X
	IT-systems	X	X	X
	Competence	X	X	
	Alignment	X	X	
	Vision	X	X	X
	External support*			
	Adaption	X	X	
	Customer focus	X	X	X
	Training	X	X	X
	Resources	X	X	X
	Accurate data	X	X	X
	Teamwork	X	X	X
	Administrative support	X	X	X
	Physicians	X	X	
	Management	X	X	
	Staff involvement	X	X	X
	Supportive culture	X	X	X
	Communication		X	X
	Holistic approach		X	
	Continuous improvement	X	X	X
	Measurement	X	X	X
	System-wide scope	X	X	X
Local enablers	Preparation	X	X	X
	Need for change	X	X	
	Anchoring in management, department or staff	X	X	X
	Management structure support	X	X	X
	Bottom-up	X	X	X
	Dedication to lean	X	X	
	Process orientation		X	
	Priority setting tool	X	X	X
	Visual and simple, less resource	X	X	

	demanding			
	Credibility		X	X
	Internal consultants	X	X	X
	Group composition	X	X	X
	Operational	X	X	X
	Sufficient participation	X	X	X
	Problem, not method focus	X	X	X
	Compatible to professional values		X	X
	Data feedback	X	X	X
	Smooth transition	X	X	X
	Realism and patience	X	X	X
	Few, palpable measures	X	X	X
	Follow-up structure	X	X	X

* Enabler only identified in the review

Table A4-7: The three most preferred enablers by management, consultants and staff in focus groups, percent per part of the intervention

Context	Management structure	Vision	Need for change	Anchoring in management	Belief in benefits
Total	59	48	36	36	17
Management	55	60	40		
Staff	60	47	39		
Consultants	61			44	39

Content	Costumer focus	Bottom-up	Problem, not method focus
Total	58	49	47
Management	48	50	58
Staff	59	48	43
Consultants	61	44	44

Application	Teamwork	Credibility	Internal consultants	Group composition	Management
Total	61	34	34	33	19
Management	58		38		38
Staff	63	34		32	
Consultants	48	30	61		

Outcomes	Few, palpable measures	Realism and patience	Holistic approach	Smooth transition
Total	66	45	43	29
Management	68		40	48
Staff	65	47	47	
Consultants	61	52	30	30

* Problem, not method focus was misplaced in Table 1 in the original article

ORIGINAL ARTICLE

How to design Lean interventions to enable impact, sustainability and effectiveness. A mixed-method study

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ABSTRACT

Objective: This study's aim was to assess how various organisational designs affect Lean interventions' success. Refinement of design and analytics contributes to the knowledge of organisational change management, and promote sound investment in quality improvement.

Methods: A panel of 11 experienced Lean consultants ranked the success of 17 Lean interventions implemented at a university hospital. This was done by assessing their impact on outcome, the sustainability of the improved work processes and the effectiveness regarding degree of goal achievement. The potential relationship between the interventions' rank, organisation, targets for improvement, and use of time and resources, was analysed by a linear mixed model.

Results: 30 percent of the interventions were assessed as successful, 60 percent as moderately successful, and 10 percent as unsuccessful. Employee and safety-staff representation (β 0.22 [CI 0.07–0.37]), top management attendance (β 0.14 [CI 0.10–0.18]), patient-related goals (β 0.13 [CI 0.06–0.20]) and hours in work-groups (β 0.01 [CI 0.00–0.01]) were related to impact on outcome. Interventions that ranged across divisions (β -0.45 [CI -0.75– -0.19]), employee and safety-staff representation (β 0.44 [CI 0.29–0.60]), comprehensive project organisation (β 0.22 [CI 0.08–0.36]) and patient-related goals (β 0.18 [CI 0.11–0.26]) were related to sustainability. Interventions that ranged across divisions (β -1.39 [CI -1.96– -0.81]), comprehensive project organisation (β 0.30 [CI 0.18–0.43]), employee and safety-staff representation (β 0.25 [CI 0.89–0.41]), limited top-management attendance (β -0.18 [CI -0.28– -0.08]), multi-disciplinary teams composed of several professions (β 0.16 [CI 0.08–0.24]) and patient-related goals (β 0.15 [CI 0.04–0.19]) were all related to a higher degree of effectiveness.

Conclusions: To achieve quality improvement in hospitals, policymakers are advised to invest in time and a comprehensive project organisation. Furthermore, the interventions should engage multidisciplinary teams including employee and safety-staff representatives and pursue improvement for patients, across divisions. The methods applied constitute a framework for future research.

Key Words: Quality improvement, Hospitals, Research health services, Organisational change, Lean thinking

1. INTRODUCTION

Lean thinking is a philosophy of continuous improvement of work processes by reducing non-valued activities and poor working conditions.[1] The improved processes are characterised by customer pull; avoiding queues and batching.[2] Finally, Lean's focus on measurement and continuous improvement are expected to facilitate the implementation of more efficient work processes and secure sustainability.[3,4] Lean was originally developed as a production philosophy.[5] In practice, Lean is often a toolkit, in which tools such as

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value stream mapping and 5S are used to improve the quality of services.[6]

In the last two decades, Lean thinking has been introduced worldwide in hospitals, despite limited evidence of its effectiveness.[5,7–11] A critical review concluded that the research field lacks empirical and theoretical coherence and a solid conceptual framework.[11] Approximately 20 years of Lean experience resulted in small pockets of best practices, in which most hospitals have implemented Lean tools in single units, rather than the whole philosophy throughout the entire organisation.[12,13]

Some interventions succeed while others fail, applying the same methodology, but in different settings.[14] These observations imply that Lean is not a context-free methodology.[15] Lean should be regarded as complex social interventions, which implies that they are not magic bullets.[16] The current knowledge-base lacks specification, as policymakers are advised to arrange "the right culture, the right people, the right processes and the right tools" to advance Lean efficiency.[17] Lean has considerable potential to improve organisational performance, but the outcomes may be limited by poor application.[9] Research should move away from the tool focus of Lean, toward a system-level approach, in which Lean is contextualised.[18] Varying outcomes of Lean may be a result of organisational and managerial weaknesses more than cultural resistance.

Previous research documented several factors that enable effective use of Lean tools.[17,19] Among these enablers are: Staff engagement and training, a focus on understanding patients' needs, resources and strong committed leadership.[1,12,20]

The aim of this study is to analyse 17 Lean interventions implemented within one hospital to gain knowledge of how various intervention designs affect success. Variables are chosen on the basis of literature reviews concerning facilitators for Lean success in health care (2000–2012), summarised in a umbrella review (see Table 1).[12]

Table 1. Independent variables – dimensions and descriptions

Dimension	Description
Organisation – features of the project organisation	Comprehensiveness in project design (use of steering-, project-, work-, or implementation groups)
	Team composition (number of professions represented)
	Organisational range (improvement within or across organisational divisions)
Improvement targets – characteristics of the chosen goals for improvement	Main target area (improvements for patient, hospital efficiency or staff)
	The number of goals and accompanying indicators
	Initiative made by management (top-down) or staff (bottom-up)
Resources – investment in time, people and rebuilding	Amount of hours used in work groups
	Number of participants in work groups
	Whether or not the intervention included rebuilding
Time horizon – experience and duration	Starting point of each project
	Endurance in months from start to implementation

A number of previous studies explored single Lean interventions, and some studied hospital-wide Lean initiatives. However, to my knowledge, this is the first study that systematically assesses a broad range of organisational factors, how interventions are designed, and their relationship to successful Lean initiatives over time. The research questions are: How do various intervention designs, improvement targets, resources and time horizons affect Lean interventions' impact, sustainability and effectiveness? And, are the applied methods suitable to test the implementation of change for quality improvement in hospitals?

2. METHODS

The research setting was a Norwegian university hospital with approximately 800 beds and 6,000 employees. Between 2007 and 2010, it underwent a complex merger and restructuring process.[21] Lean was introduced as an enterprise-wide program to improve the quality of care and working conditions, and increase hospital efficiency. Use of a standardised approach was anticipated to prevent comprehensive variations among different interventions. However, five years of experience documented that impact, *i.e.* improved standards adopted and integrated, and intended effects accomplished, varied considerably among the Lean initiatives at the hospital.

This study comprises 17 Lean interventions pursuing quality improvement in patient pathways, laboratories and administrative processes. All interventions implemented from 2008 to 2012, having at least one year in operation, were included.

Data was collected from internal quality registries based on recommendations from the SQUIRE guidelines.[22]

Comparisons of Lean interventions require a distinct definition of success. If an improved work process is not embedded in routines, which obtain durable, sustainable outcomes, the intervention cannot be called a success. Similarly, if the improved work process has a very limited range and a slight impact on outcome, we may question whether or not the change was an improvement. Therefore, this study included three aspects of success: Impact on outcome (range), sustainability of the improved work processes (durability), and effectiveness (goal achievement). The underlying assumption is that these aspects are related, so that successful interventions are characterised by high impact, effectiveness and sustainable outcomes. These three aspects of success represent the dependent variables of this study.

A research model, including the dependent variables and 11 independent variables divided in four categories, was developed. The data collected covered the initiative phase, the project phase, and implementation and one to two years after implementation (see Figure 1).

The method for grading interventions was based on Raab *et al*.[23,24] By using a five-part Likert scale, it was possible to rank the different interventions' impact on outcome, sustainability and success-criteria fulfilment, despite differences in size and subject for improvement. Table 2 shows the scales for ranking the interventions.

Due to the social, complex nature of Lean, a nominal group technique-based panel was chosen to rank the interventions.[25] Trained internal lean consultants, in addition to experienced project managers and mentors for more than two projects were invited to attend the panel. The selection criteria secured that the potential participants had both theoretical and practical knowledge of Lean. This yielded a list of 12 consultants, from which 11 participated in the panel.

The panel was separated into two groups to reduce the risk of bias, such as the bandwagon effect. The participants were assembled for a six hour meeting in September 2014. They received the data set by mail in advance. In addition, the panel collectively reviewed the data at the meeting. Based on the data, the panel ranked each of the 17 interventions regarding impact on outcome, effectiveness and sustainability. The ranking was independently and anonymously conducted in writing. Finally, the two groups collectively ranked the interventions to examine if consensus could be obtained.

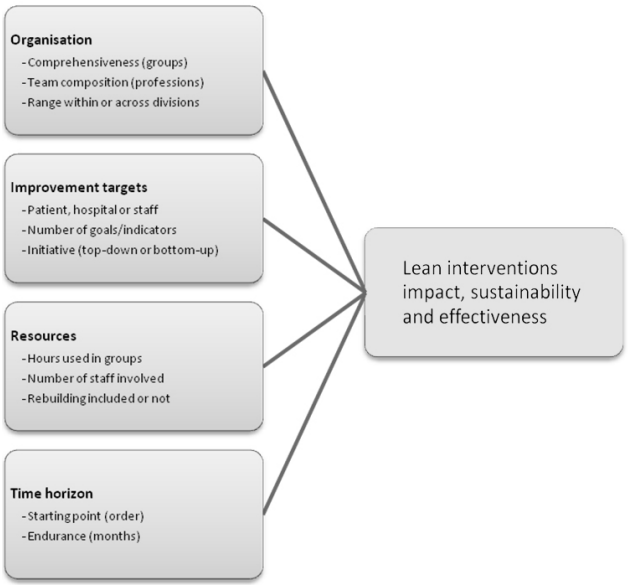

Figure 1. Research model

Before the results from the two groups were merged into one data set, the results were cross-checked for possible bias. Inter-rater reliability shows the degree to which different panel members gave consistent scores regarding each intervention's impact, sustainability and effectiveness. A relative standard deviation (*RSD*) lower than 15 percent is characterised as a high degree of inter-rater agreement. In this study, *RSD* varied from 10 percent to 36 percent (see Table 3). The interventions showing the highest variation in rank concerned administrative processes, rather than patient pathways. Correlation coefficients were applied to calculate the covariance between the panels' judgment of effectiveness, impact on outcome and sustainability, respectively.

Table 2. Scales for ranking Lean interventions

Ranking	No (1)	Minimal (2)	Moderate (3)	Significant (4)	High (5)
Impact on outcome scale	No impact on work processes	Minimal impact	Moderate impact	Substantial impact	Comprehensive wide-ranging impact
Sustainability scale	No sustainable improvement	Minimal sustainable improvement	Moderate sustainable improvement	Significant sustainable improvement	Robust sustainable improvement
Effectiveness scale	No significant goal achievement according to success criteria	Minimal achievement	Moderate achievement	Significant achievement	Outstanding achievement

A univariable and a stepwise backward multivariable linear mixed-model regression were applied to analyse associations between the interventions' different organisations, targets, resources and time horizons, and their impact, sustainability and effectiveness. Independent variables with a p-value < .20 from the univariate analysis were used in the multivariable analysis. Beta estimates (β) with 95 percent confidence intervals (CI) were calculated. p-value < .05 were considered statistically significant. The Statistical Package for the Social Science (SPSS) software version 22 (IBM Software, NY, USA) was applied for all analyses.

3. Results

Table 3 shows how the panel ranked the 17 Lean interventions and the inter-rater reliability (relative standard deviation).

Table 3. Ranking of 17 Lean interventions (median, based on a five-part Likert-scale [Table 2]) and relative standard deviation

Lean intervention	Impact	Sustainability	Effectiveness	*RSD*
Lung cancer	5	5	5	.17
Blood test unit	4	5	5	.20
Hip and knee	4	4	4	.10
Health research	4	4	4	.30
Child psychiatry	4	4	4	.10
Acute stroke	4	4	3	.14
Sepsis	4	2	3	.20
Triage ED	4	3	3	.30
Geriatric psychiatry	3	3	3	.20
Drug addiction (referrals)	3	3	3	.20
Drug addiction no-shows	3	3	3	.17
Internal medicine ward	4	3	3	.14
Coronary angiography	3	3	3	.22
Multiple sclerosis	4	3	3	.26
Acute psychiatry ward	3	2	3	.28
HR internal service	2	2	2	.36
Laboratory unit	3	2	2	.26

Five interventions were considered highly or significantly successful, ten were considered moderately successful and two were minimally so. The latter had low scores in all three aspects: Minimal or moderate impact, minimal sustainability and minimal effectiveness. The most successful interventions had high scores on both impact and sustainability, with one exception. Acute stroke was rated high on sustainability, but moderate on effectiveness. Five interventions had a high or significant impact on outcome, but only moderate effectiveness. In general, more than half of the interventions had a high or significant impact on outcome.

There was a relatively strong correlation between the panels' judgement of sustainability and effectiveness (Pearson's r = .83), while the correlation between effectiveness and impact (Pearson's r = .52) and impact and sustainability (Pearson's r = .47) were weaker.

Table 4 shows that employee and safety-staff representation (β 0.22 [CI 0.07–0.37]), top-management attendance (β 0.14 [CI 0.10–0.18]), patient-related goals (β 0.13 [CI 0.06–0.20]) and hours in work groups (β 0.01 [CI 0.00–0.01]) were related to higher-ranked impact on outcome.

Interventions that ranged across divisions (β -0.45 [CI -0.75– -0.19]), employee and safety-staff representation (β 0.44 [CI 0.29–0.60]), comprehensive project organisation (β 0.22 [CI 0.08–0.36]) and patient-related goals (β 0.18 [CI 0.11–0.26]) were related to higher-ranked sustainability.

Interventions that ranged across divisions (β -1.39 [CI -1.96– -0.81]), comprehensive project organisation (β 0.30 [CI 0.18–0.43]), employee and safety-staff representation (β 0.25 [CI 0.89–0.41]), limited top-management attendance (β -0.18 [CI -0.28– -0.08]), a multi-disciplinary team composed of several professions (β 0.16 [CI 0.08–0.24]) and patient-related goals (β 0.15 [CI 0.04–0.19]) were related to higher-ranked effectiveness.

4. Discussion

The main finding of this study is that 30 percent of the interventions were assessed as successful, 60 percent were assessed moderately successful, and 10 percent were assessed minimally successful. Interventions that ranged across divisions, comprehensive project organisation, employee and safety-staff representation, limited top-management attendance, a multi-disciplinary team composed of several professions, and patient-related goals were the statistically significant variables that predicted effectiveness. Investment in time, patient-related goals, employee and safety-staff, and top-management attendance were related to impact, as interventions across divisions, comprehensive organisation, patient-related goals, employee and safety-staff were related to sustainability.

4.1 Organisation – features of the project organisation

A comprehensive project design utilising steering-, project-, focus- and implementation-groups was related to both sustainability and effectiveness in this study, even though this do not correspond to recommendations of Lean handbooks.[26] An even more interesting finding is that improvements across divisions were related to sustainable effective interventions. This finding correspond to previous research that recommends improvements across the entire organisation and functional divides.[7,27] However, the literature's main emphases are that involving multiple units is associated with poor outcomes and that complexity complicates improvement

work.[18,23,28–30] A reason for this discontinuity may be that improvement across divisions is demanding. However, when it is successful, the gains are considerable.

A broad, multi-disciplinary team related to both comprehensive design and improvement across divisions, as it related to intervention effectiveness. However, there was no statistically significant relationship between success and physician participation, as is often argued.[31–33] Broad representation of all concerned professions seems more important than just physician representation.

Table 4. Linear mixed model

Parameter	Impact on outcome		Sustainability		Effectiveness	
	Univariable	Multivariable	Univariable	Multivariable	Univariable	Multivariable
Degree comprehensive organisation	0.23 (-0.1–0.5)**		0.31 (-0.1–0.8)**	0.22 (0.08–0.36)*	0.40 (0.0–0.8)**	0.30 (0.18–0.43)*
Team composition by professions	0.16 (0.0–0.3)**		0.21 (0.0–0.5)**		0.22 (0.0–0.4)**	0.16 (0.08–0.24)*
Top management attendance	0.14 (0.1–0.2)**	0.14 (0.10–0.18)*	0.07 (-0.1–0.2)		0.10 (-0.1–0.3)**	-0.18 (-0.28– -0.08)*
Employee and safety representatives	0.39 (0.1–0.7)**	0.22 (0.07–0.37)*	0.58 (0.1–1.0)**	0.44 (0.29–0.60)*	0.55 (0.1–1.0)**	0.25 (0.89–0.41)*
Range, across or within divisions	-0.77 (-1.2– -0.3)**		-0.75 (-1.6–0.1)**	-0.45 (-0.75– -0.19)*	-0.81 (-1.6–0.0)**	-1.39 (-1.96– -0.81)*
Number of goals	0.02 (-0.1–0.2)		0.03 (-0.2–0.3)		0.02 (-0.2–0.2)	
Share of patient-centered goals	0.14 (0.0–0.3)**	0.13 (0.06–0.20)*	0.22 (0.0–0.5)**	0.18 (0.11–0.26)*	0.19 (-0.1–0.4)**	0.15 (0.04–0.19)*
Share of hospital-centered goals	-0.17 (-0.4–0.1)**		-0.10 (-0.5–0.3)		-0.16 (-0.5–0.2)	
Share of staff-centered goals	-0.03 (-0.3–0.2)		-0.17 (-0.5–0.2)		-0.1 (-0.4–0.2)	
Share of patient-centered indicators	0.19 (0.0–0.3)**		0.20 (-0.1–0.5)**		0.20 (0.0–0.4)**	
Number of indicators	0.04 (-0.1–0.2)		0.12 (-0.1–0.4)		0.07 (-0.2–0.3)	
Share of hospital-centered indicators	-0.10 (-0.03–0.1)		-0.02 (-0.3–0.2)		-0.07 (-0.3–0.2)	
Share of staff-centered indicators	-0.08 (-0.6–0.4)		-0.20 (-0.9–0.5)		-0.08 (-0.8–0.6)	
Number of participants	0.03 (0.0–0.1)**		0.03 (0.0–0.1)		0.04 (0.0–0.1)**	
Hours used in improvement groups	0.01 (0.0–0.0)**	0.01 (0.00–0.01)*	0.01 (0.0–0.0)		0.01 (0.0–0.0)**	
Physicians attendance	-0.06 (0.0–0.1)**		0.02 (-0.1–0.1)		0.03 (-0.1–0.1)	
Rebuilding (yes/no)	-0.10 (-0.8–0.6)		-0.02 (-1.0–1.0)		-0.08 (-1.0–0.9)	
Starting point (experience)	-0.01 (-0.1–0.1)		0.01 (-0.1–0.1)		0.00 (-0.1–0.1)	
Initiative from top or bottom	0.71 (0.1–1.3)		0.25 (-0.8–1.3)		0.44 (-0.5–1.4)	
Endurance (months)	0.01 (-0.1–0.1)		-0.04 (-0.2–0.1)		-0.03 (-0.2–0.1)	

Note. Beta estimate (β) for impact, sustainability and effectiveness; 95% confidence interval in brackets; $^{*}p < .05$; $^{**}p < .20$

Projects with considerable participation of employee and safety-staff representatives were related to high impact, sustainability and effectiveness. This was also the case for top-management representation concerning impact. Regarding effectiveness, there was a negative effect; the more top-management, the lower the interventions were ranked. This is surprising, and should be given further attention in future research, especially because leadership is among the most attributed facilitating factors for Lean in the literature and that top-level organisational commitment is viewed as necessary for true improvement.[7,23,34]

4.2 Improvement targets – characteristics of the chosen goals for improvement

Interventions dominated by improvements for patients were the only statistically significant independent variable concerning improvement targets. The advice to pursue value creation for patients is well-known in the literature.[7] At the same time, Lean's "work smarter, not harder"–slogan suggests that Lean should result in efficient work processes and improved workplace environment.[5] It may be that patient improvements trigger willingness and motivates change among health care workers more than effectiveness and better work environments.

Two of three interventions were management-initiated, in contrast to the Lean philosophy that recommends improvement initiatives grounded at the work-floor level. There was no statistically significant relationship between top-down or bottom-up initiatives and success. Likewise, there were no relationships between the number of goals or the number of indicators and an intervention's success, even if Lean management suggests that a few palpable goals enable success.[3,4,12]

4.3 Resources – investment in time, people and rebuilding

There was a statistically significant relationship between the impact on interventions outcomes and hours spent in work

groups. This was not the case regarding the two other independent variables: Number of participants and resources used in rebuilding. The literature commonly states that successful Lean requires a considerable investment in resources, time and effort.[35] Nevertheless, having sufficient accessible resources is not synonymous with maximizing resources. This finding implies that work group composition, including multiple professions, is more important than the number of participants.

4.4 Time horizon – experience and duration

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 further experience, practice and learning should lead to better results over time.[7,36,37] The first interventions were successful. Those in the middle showed moderate success. The later ones attained more success. One explanation for this observation may be that the first interventions were guided by external consultants. When these experts left, the hospital needed to build up internal competence and experience to resume similar success. When it comes to duration, Lean thinking typically recommends limited, quick-fix projects such as Blitz. On the other hand, one might anticipate long-lasting projects to secure more sustainable results.[35] However, among the 17 cases studied, project duration was not related to intervention sustainability.

4.5 Strengths and weaknesses of the study

The theoretical point of view underlying this study is the possibility to generalise from a systematic comparison across multiple complex interventions, within limits.[38] Comparative analysis can help us understand why the outcomes vary and, consequently, which attributes of an intervention enhance continuous improvement.

The study is limited to one hospital, which may reduce generalisability of the results. Still, it seemed like a golden opportunity to explore this hospital, given the considerable number of interventions and the years of experience. The strong interaction between Lean interventions and the context threatens the external validity, which may be confined by the number of cases included. There will always be a trade-off between sample size and time and resources in research. However, the study include all Lean interventions implemented at the case hospital in five years, which is a considerable time range representing a unique base of longitudinal data.

This work rely upon the COREQ checklist[39] to secure explicit, comprehensive reporting of methods, findings, analysis and interpretation. By using the scaling tool, and drawing on solid documentation, the panel could rank interventions with quite different applications. This offers more nuance than a simple success- or failure-classification, and pursues qualified judgments rather than intuition. Replicating of the scoring by two panels strengthens consistency of individual judgments and makes the results more reliable, even if the influence of single panel members cannot be completely ruled out.

The linear mixed model estimates relationships, and draws conclusions based upon an arbitrary cut-off at five percent, indicating statistical significance, which should not be confused with the size or importance of an effect. Regression analysis rests on some classical assumptions, such as the sample being representative of the population and that the independent variables are measured with no error and are linearly independent of each other. By the indication of relationships and interdependencies of variables, there is always a risk of spurious effects.[40] This study indicates that some organisational features relate to success, but the conclusions are limited since it is impossible to rule out the possibility that a third, unknown variable intervene. The research model is based on theory, *i.e.* assumptions of causal relationships, and evidence quoted in systematic literature reviews and reputable international guidelines, which should reduce this risk.

5. Implications and future research

The lack of evidence for Lean interventions is surprising with regard to its popularity in health care. There are three kinds of evidence that should be examined: Theoretical underpinning, explaining how and why it should work; empirical, stating under which settings it works best; and experimental, providing practical lessons based on experience.[41] This requires more research and greater scepticism regarding Lean thinking.[42,43] In addition, more work should be done on developing methods for testing implementation of Lean interventions across organisations and utilising longitudinal data. This study constitutes a possible methodological framework for future research.

Lean interventions vary in organisation, content, local application, and outcomes. For this study, the analysis and interpretation were confined to potential relationships between successful interventions and how they were designed. To attain sustainable improvement, policymakers should tailor Lean interventions toward patient improvement across functional divides, involve a comprehensive project organisation, and use a consciously compound multi-disciplinary team and employee and safety-staff representatives. Solid knowledge of what promotes quality improvement success may contribute to more accurate choices, implementation and operation of improved work processes in health care

and advice on how to better invest in organisational change management.

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