BMJ open

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

| | |
|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID: | bmjopen-2013-003873 |
| Article Type: | Research |
| Date Submitted by the Author: | 23-Aug-2013 |
| Complete List of Authors: | Andersen, Hege; University Hospital of North Norway, CEO office; University of Tromsø, Department of sociology, political science and community planning. Faculty of humanities, social sciences and education<br>Røvik, Kjell Arne; University of Tromsø, Department of sociology, political science and community planning. Faculty of humanities, social sciences and education<br>Ingebrigtsen, Tor; University Hospital of North Norway, CEO office; University of New South Wales, Centre for clinical governance research. Australian institute of health innovation |
| Primary Subject Heading: | Health services research |
| Secondary Subject Heading: | Health policy |
| Keywords: | Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
| | |

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

**Corresponding author:**

Hege Andersen

University Hospital of North Norway

Box 100, 9038 Tromsø, Norway

Hege.andersen@unn.no Telephone no: +47 99530353 Fax: +47 77626041

**Authors:**

Hege Andersen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Kjell Arne Røvik

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Tor Ingebrigtsen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Clinical Medicine

Faculty of Health Sciences

University of Tromsø, Norway and
Centre for Clinical Governance research
Australian Institute of Health Innovation
University of New South Wales, Sydney Australia

**Key words:**

Lean thinking, quality improvement, health care, implementation, context

**Word-count:** 3926

## ABSTRACT

**Objective:** Lean interventions aim to improve quality of health care 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 theorizes the concept of context by establishing a two-dimensional conceptual framework acknowledging lean as complex social interventions, deployed during several stages, and in different organizational dimensions. The specific aim of the study was to identify factors facilitating intended outcomes from lean interventions, and to understand when and in which dimension 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 categorized according to the intervention phases and dimensions of capability provided by the framework.

**Results:** We provide a framework emphasizing context by relating facilitators to stages and dimensions of capability. 23 factors enabling successful lean in hospitals were identified in the systematic review, whereby management and a supportive culture, training, accurate data, physicians and team involvement 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 the organizations strategic and cultural capability, should be given further attention in health care quality improvement.

## ARTICLE SUMMARY

### Article focus

- There is conflicting evidence on the outcomes of lean thinking in health care.
- Reviewing the literature within the approach of a new contextual framework can deepen our understanding of lean as a quality improvement method.
- Identifying factors facilitating intended outcomes from lean interventions, contribute to new knowledge on when and how lean interventions works.

### Key messages

- 23 factors enabling successful lean in hospitals are identified, whereby management and a supportive culture, training, accurate data, physicians and team involvement most frequent.
- Characteristics of lean and local application, in addition to the organizations strategic and cultural capability, should be given further attention in health care quality improvement.
- In the absence of evidence, a framework incorporating the context may prove useful for future research on lean interventions.

### Strengths and limitations of this study

- This review of reviews sums up the mayor findings regarding facilitators for lean interventions in health care the latest decade.
- The immaturity of the research filed makes it hard to find solid evidence for effective lean interventions in health care.
- The fact that lean is social, complex and context-dependent interventions call for a shift from cause-effect to conditional attributions in research.

## INTRODUCTION

Lean thinking has been introduced in health care 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]. Lack of evidence may lead to resistance and hinder speed up and spread of quality initiatives in health care[1 8-10].

Lean interventions aim to improve quality by reducing waste, and facilitate flow in patient care work 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]. Focus on measurements and continuous improvement is expected to promote implementation and sustainability.

In a recent review, Mazzocato et al. (2010) concluded that lean has been applied successfully in health care institutions worldwide[13]. However, most studies have a narrow technical application with limited organizational reach. Many are single case studies, some quite anecdotal, while others are biased or characterized by a weak study design. Some reviews suggest that inappropriate analyses, a lack of alternative hypotheses, and other methodological limitations undermine validity[2 14]. This makes it difficult to rule out confounding explanatory factors, to measure outcomes and generalize results from lean interventions[6].

Advocates for experimental designs question results from qualitative studies, and argues that randomized controlled trials are necessary to isolate effects[15 16]. Most studies using an experimental design did not find any significant effect of lean interventions[2 5 9 10 14]. 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].

Is there a cure for this lack of evidence? On a paramount level, one must ask whether absence of evidence justifies inaction[17]. The *quality chasm* between the health care we have and the

health care we should have is well documented[1 18 19]. 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. (2007) emphasized 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 organizational and social context in which care is delivered[20]. Such integration of the intervention and its context seldom happens in quality improvement research[21].
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. Context are simply defined as all surrounding factors that are not part of the intervention itself[8 22]. However, the boundaries between the intervention and its surroundings may be relatively arbitrary, as lean interventions are social, complex and inherently context-dependent[23 24]. 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 standardize. Lean and other quality improvement methods are often adjusted, mixed, implemented and used simultaneously[5 10 25 26]. 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. We observe a growing consensus that characteristics like management, resources and culture matter, but the current knowledge base lacks specification on when and how the different facilitators work. This vagueness partly rest on insufficient methodological attention to the context in which lean interventions work. To understand and assess variation in lean interventions 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 contextual factors which help the progress of lean interventions[8 21 27], 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[28]. An enterprise-wide comprehensive program for

improvement of clinical pathways using lean methods was launched. The program aimed to accomplish a quality improvement effort in parallel with the organizational change to counteract the transitional setbacks in quality that large-scale change may entail[29]. A research program was established to evaluate the effects. We identified a need for a theoretical and methodological framework to analyse variation in adoption of lean interventions at the hospital. The proposed framework represents a theoretical tool to understand more of how and when lean interventions work. Our approach incorporates the complex social and organizational 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 organizations readiness for change[21]. The specific aim of the study was to identify factors influencing intended outcomes of lean interventions, and to understand when and in which dimension different factors contribute.

## METHODS

A systematic narrative review[30] of reviews of quality improvement in hospitals was conducted. One reviewer performed the systematic review, supervised by the two co-authors. Discrepancies were 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. Search words included hospital, health care, 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. 15 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 (supplementary file)[31].196 original articles were excluded. Exclusion criteria included absence of a hospital or organizational 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 or lean thinking were issued. Articles that mainly represented practical guidelines also were excluded. The final review included 18 articles[10 13 21 22 25 26 29 32-42].

### Data analysis

The 18 articles were systematized according to the number of studies included in each review. Eight articles reviewed a number of definite cases, varying from four 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 like *Productive ward* and process oriented redesign. Lean was extracted and treated separately as far as possible, though confined by the observed mix, similarity and simultaneously use of different quality improvement methods in hospitals[5 21 25 26]. Methods used in the original studies were qualitative, quantitative, or a mixed-method approach. Most studies were based on cases originated in the United States, Australia and Great Britain.

The next step was to search for facilitators, defined as contextual factors predicted to promote quality improvement, as opposed to barriers that hinder improvement[35]. The decision to concentrate on facilitators and not barriers to lean improvement were based on the fact that the research literature at this field chiefly pays attention to facilitators and not barriers[5 8 10 13 21 22 33 36]. 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 localization of similarities and differences among studies[30], the articles were systematically analyzed and recorded in a standardized format, according to the facilitators. The procedure were conducted by creating a worksheet categorizing every paper according to author, year of publishing, kind of review, supplementary quality improvement methods (in addition to lean), research method, labelling of facilitators, and facilitating factors. The complete worksheet is attached as a supplementary file.

All the identified facilitators were assigned to larger categories. This classification was done 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 like management support, commitment and ownership. Cultural issues were all categorized as *supportive culture*, including views, norms and beliefs supporting lean. 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 below. Finally, the frequency of each of the facilitators in the 18 reviews was accounted for.

**A theoretical and methodological framework**

Lean interventions consist of several different phases, from planning and preparation to implementation and sustainability, involving different organizational capabilities. The facilitators for improvement were analyzed and reorganized in a table combining Shortell's *dimensions of capability*[2 43], and Walshe's *domains of an intervention*[9]. Shortell categorized 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 organization. The *technical* dimension covers training and information system issues, while the *strategic* dimension emphasizes the conditions that offer the greatest opportunities to change. This dimension touch upon 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 relate to mechanisms that facilitate learning and disseminate best practices throughout the organization. The four dimensions are multiplicative, interrelated, 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[43].

Walshe's differentiated domains or phases in quality interventions are labelled as context, content, application and outcomes. The context involves the preparation phase before starting improvement work, highlighting aspects of the situation, setting or organization in which the intervention is deployed. This is a narrow view of context, and should not be confused with the broader understanding of context as all surrounding factors that are not part of the technical intervention itself[8]. In this article, we therefore renamed this phase as the organizational *setting*. The *content* describes the phase where lean is introduces as a tool, the nature or characteristics of the intervention itself. The content of lean may be standardized 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. O*utcomes* are the results of the intervention, including the maintenance phase after implementation. All of these phases may be characterized by low or high variance. High levels of variance in the settings, content and application may explain

interventions varying success. Variances also reduce the ability to generalize 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, both as emerging in different phases in a multistage process and by different organizational dimensions. The framework was used to describe and understand the organizational and contextual factors encountered in an organizational-wide quality improvement effort.

## RESULTS

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

*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**: Include patient and workforce value creation and improvements

**External support**: Expert change agents, networks and sponsorship triggers 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**: Multi-skilled 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 lean represent readiness

**Management:** Leadership support, ownership and commitment

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

*Figure 1: Frequency of different facilitators identified in 18 reviewed articles*

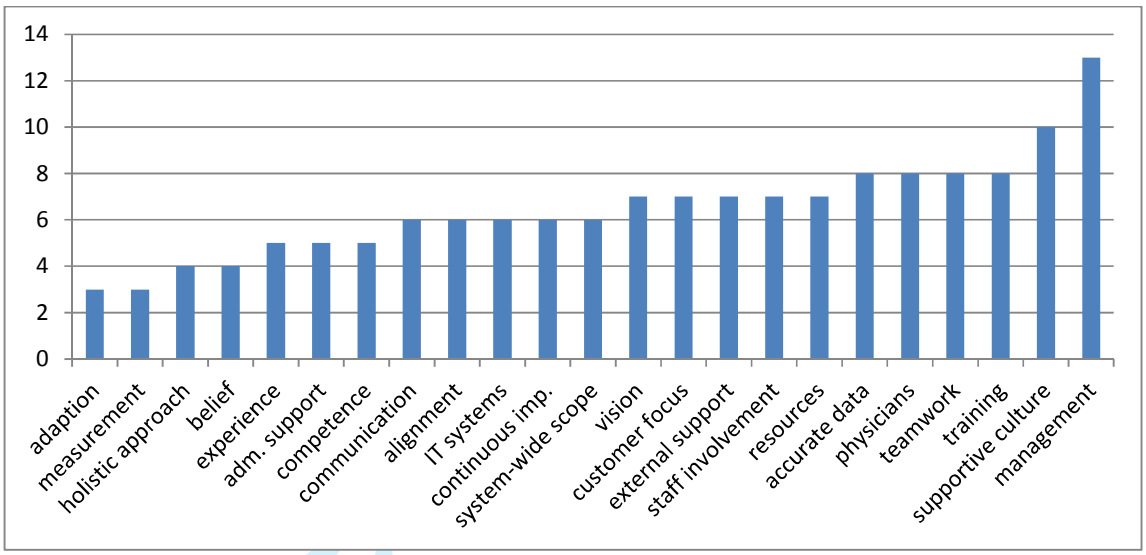



Table 1 show how the different facilitators were found relevant in the different intervention phases and affected organizational dimension.

*Table 1: Facilitators for change, literature reviews 2000–2012*

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

**Setting: Situation and organization.**

Initially, a well-proven, successful quality improvement method characterized by program maturity facilitates. Prior experience are enabling improvement[22 29 35]. Lean should be accompanied by success stories demonstrating benefits for patients and staff. This relates to the organization's cultural capability and the influence of the underlying beliefs, values, norms, and behaviours. Motivation influences the willingness to participate[13 33 35 36 38 39 42]. IT-systems infrastructure and competence[22 29 33-36], as well as external experts sponsoring, strengthen the technical and structural capability. Sponsorship triggers learning and may contribute to dissemination of best practices throughout the organization[29 32 33 36-38 42]. Competence in tools and methods support the assumptions of lean, and increase the potential for change[25 26 34 36]. Ambitious targets aligned with the hospital's overall goals and strategies strengthen the strategic capability[29 33 34 36 39 42]. The goals have to be of strategic importance, but at the same time realistic, based on simple and practical solutions[21 29 33 34 38 42].

**Content: Characteristics of the intervention**

Adaption and translation to local conditions are a precondition for success[25 32 35]. A methodology communicating a clear patient and workforce focus supports the cultural dimension. Emphasis on patient processes, value creation, and patient needs facilitate quality improvement in health care[10 13 22 32 35 40 42]. Access to, and accomplished substantial training in methods and tools strengthens the organizations technical capability[10 21 25 29 32-34 36 42], as sufficient and available resources affect the strategic dimension[10 21 22 29 32-34 36 42]. 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, which facilitates lean interventions[13 33-35 37 38 42]. Availability and sufficiency of training, data and other resources are among the most frequent facilitators in the reviewed articles, and thereby among the most important drivers for change.

**Application: Local delivery process**

Collaborating multidisciplinary and multi-skilled teams strongly facilitate local application of lean[22 29 32 34-36 40 41]. Strengthening the improvement culture presupposes workforce stability, team leadership, and decentralized decision making. Administrative project management and practical support secures backing, and contributes to the technical capability of the organization[21 29 34 42]. Strategically, involvement of physicians and management encourage change. Management engagement include both frontline and senior managers[10

13 21 22 29 32-34 36-40 42]. Physicians represent champions and clinical leadership, and their involvement, engagement, and collaboration are crucial at the strategic level[10 22 29 33 34 36 38 41]. Both management and physicians involvement are among the most frequent identified enablers of quality improvement in the literature. Key factors to disseminate best practices are staff participation, engagement, and empowerment. Staff commitment, responsibility and ownership, are required for achieving lasting outcomes of lean interventions[25 32 36-40 42].

**Outcomes: Results and maintenance**

To secure maintenance, a hospital depends strongly on a supportive culture characterized by norms and beliefs supporting quality improvement and readiness[10 21 22 32 34-36]. At the technical dimension, communication and feedback between patients and staff are facilitating[29 32 36 41 42]. Strategically, a holistic approach based on continuous improvement and sustained attention affect the ability to accomplish change. A holistic approach emphasizes that lean is a tool not only to promote everyday improvement but also a philosophy of ongoing quality improvement within the hospital's value system[13 26 32 33 39]. A long-term plan should be established to secure continuous improvement[10 13 25 26 33 35]. Local audits and measurements conducted on a regular basis relate to the organization's structural capability, which strengthen the evidence for lean interventions[34 35 37 38]. A system-wide multifaceted approach, across functional divides, allows best practices to be learned and disseminated.

In addition to a supportive culture, the most frequent facilitators are identified in the *content* and local *application* parts of the intervention. That is, the most reported success-factors for lean, touch upon characteristics of the intervention and its local delivery process. Most of the frequent facilitators concern the *strategic* or the *cultural* dimension of capability, interventions strategic importance to the hospitals overall goals and the organizations underlying beliefs, values, norms and behavior.

## DISCUSSION

Analysis based on the conceptual framework suggest that understanding which facilitators influence the intervention at different stages and dimensions of capability, probably is more important than a quantitative approach[8 33]. The emphasis on the interventions different

parts and the organizational dimensions represent a shift from cause-effect to conditional attributions[43]. Each part and dimension is influenced by the status of other dimensions. Our results summarized in table 1 show that a number of facilitators representing the four dimensions may interact during the four stages of change. The four dimensions and the associated facilitators are interrelated and equally necessary to achieve lasting results[2]. In the following, we elaborate our interpretation of these findings.

Rycroft-Malone et al (2002) concludes that there are three key elements of implementation: evidence, facilitation and context[44]. 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. However, it is evident that little is known about which facilitators that are most important[8 21]. Management and leadership engagement was 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 recent research in the field, and may indicate that these facilitators are vital to accomplish quality improvement[13 22 29 32]. Two recent reviews conclude that leadership, culture, maturity, and data infrastructure have a stronger evidence base than others[22 36]. Our results nevertheless suggest that successful interventions must utilise multiple facilitators from the four dimensions of capability, interplaying as the change processes go through its four stages. The observation that 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 health care[22 44 45] strengthen 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 are not a receipt 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 to Radnor et al (2012), that advocate that lean interventions must be contextualized, rather than transplanted like a recipe[26].

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 health care[46]. Finally, the local application of lean in hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-floor staff must be engaged and empowered. Womack and Jones (2003) that initially advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main advantage for hospitals, making lean suitable for health care[12].

The cultural and strategic dimensions of capability embrace most of the frequent facilitators. A supportive culture are fundamental to achieve quality improvements[36]. The organizational 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. This finding are supported by other recent hospital-based studies, like Rozenblum et al (2013)[46].

The main contribution of this review is a two-dimensional framework for identification and analysis of facilitators for lean interventions in health care. This framework incorporates the complex social and organizational context in which lean are applied. These findings coincide with recent research calling for more attention to the influence of organizational context when trying to understand variance in interventions in healthcare[22]. 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.

**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. Conducting feature maps and presenting all the identified facilitators in appendices promote transparency. Further on, 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.

And finally, including both qualitative and quantitative studies eliminates the possibility of quantifying the findings and predicting 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*[47]. 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 organizing that could improve patient care[48].

The facilitators identified and the two-dimensional framework proposed in the present work incorporates structure and process. Still, the facilitators are characterized by vagueness, as broad and comprehensive determinants, that needs further specification and practical content to guide future effective quality improvements to health care organizations[21]. 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 health care providers performance (adherence to recommended practice), patient outcome (as quality of life or mortality), surrogate outcomes (as readmission) and organizational outcomes (like resource use or sustainability)[34]. At the University Hospital of North Norway, more than five 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

We provide a framework, which emphasizes the importance of context by relating facilitators to four dimensions of organizational capability and four stages of change, and suggest that this represent a practical tool for understanding and assessing variation in lean adoption. The article can 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 organization-wide quality intervention. The review of reviews identified 23 interrelated 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 organizations cultural and strategic capability.

Acknowledgements: The authors would like to thank David Greenfield (PhD) and John Øvretveit (PhD) for their assistance in clarifying concepts in the discussion. We would also like to thank James Morrison for his language assistance.

Contributors:All the listed authors met the authorship requirements as defined by the ICJME. HA contributed to the conception and design, the acquisition, analysis and interpretation of the data, as well as drafting and revising the article. TI and KAR made a substantial contribution to the design and interpretation of the data, as well as to drafting and critical revising of the article. All the authors have provided final approval of the submitted manuscript.

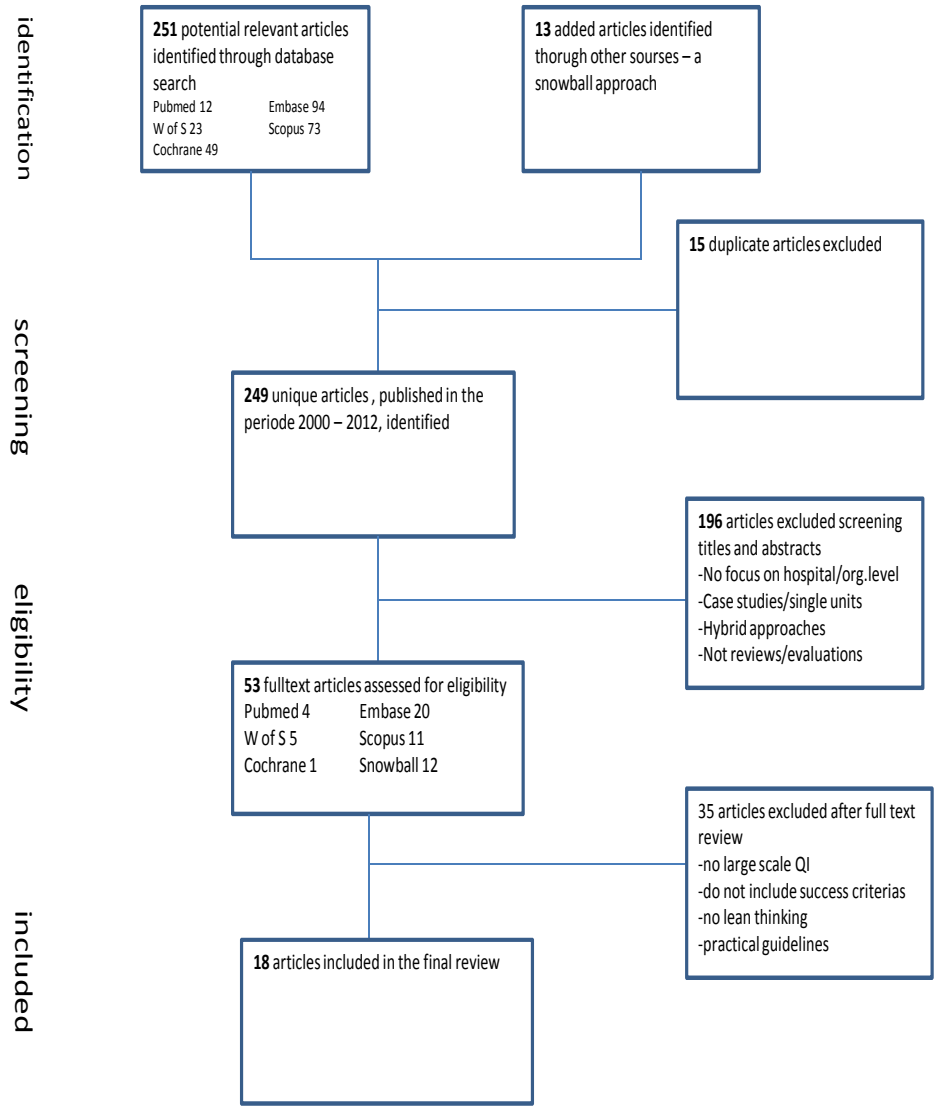
Funding: The PhD-study is founded by the regional health trust of North Norway, Helse Nord RHF

Competing interest: None

1. Joosten T, Bongers I, Janssen R. Application of lean thinking to health care: issues and observations. International Journal for Quality in Health Care 2009;**21**(5):341-47
2. Shortell SM. *Assessing the Implementation and Impact of Clinical Quality Improvement Efforts: Abstract, Executive Summary and Final Report*: Agency for Health Care Policy and Research, 1998.
3. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Affairs 2005;**24**(1):138-50
4. Rycroft-Malone J, Kitson A, Harvey G, et al. Ingredients for change: revisiting a conceptual framework. Quality and Safety in Health Care 2002;**11**(2):174-80 doi: 10.1136/qhc.11.2.174[published Online First: Epub Date]|.
5. Young T, McClean S. A critical look at Lean Thinking in healthcare. Quality and Safety in Health Care 2008;**17**(5):382-86
6. Alexander JA, Hearld LR. What Can We Learn From Quality Improvement Research? A Critical Review of Research Methods. Medical Care Research and Review 2009 doi: 10.1177/1077558708330424[published Online First: Epub Date]|.
7. de Souza LB. Trends and approaches in lean healthcare. Leadership in Health Services 2009;**22**(2):121-39
8. Øvretveit J. Understanding the conditions for improvement: research to discover which context influences affect improvement success. BMJ quality & safety 2011;**20**(Suppl 1):i18-i23
9. Walshe K. Understanding what works—and why—in quality improvement: the need for theory-driven evaluation. International Journal for Quality in Health Care 2007;**19**(2):57-59
10. Øvretveit J, Gustafson D. Evaluation of quality improvement programmes. Quality and Safety in Health Care 2002;**11**(3):270-75
11. Liker JK, Kaisha TJKK. *The Toyota way: 14 management principles from the world's greatest manufacturer*: McGraw-Hill New York, 2004.
12. Womack JP, Jones DT. *Lean thinking: banish waste and create wealth in your corporation, revised and updated*: Free Press, 2003.
13. Mazzocato P, Savage C, Brommels M, et al. Lean thinking in healthcare: a realist review of the literature. Quality and Safety in Health Care 2010;**19**(5):376-82
14. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and studergroup's hardwiring excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. Implement Sci 2009;**4**(35):1-9
15. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**(sep29_1):a1655-a55
16. Perneger T. Ten reasons to conduct a randomized study in quality improvement. International Journal for Quality in Health Care 2006;**18**(6):395-96
17. Altman DG, Bland JM. Statistics notes: Absence of evidence is not evidence of absence. BMJ 1995;**311**(7003):485 doi: 10.1136/bmj.311.7003.485[published Online First: Epub Date]|.
18. Corrigan JM. *Crossing the quality chasm*: Washington, DC, National Academy Press, 2001.
19. Kohn LT, Corrigan J, Donaldson MS. *To err is human: building a safer health system*: Joseph Henry Press, 2000.
20. Shortell SM, Rundall TG, Hsu J. Improving patient care by linking evidence-based medicine and evidence-based management. JAMA: the journal of the American Medical Association 2007;**298**(6):673-76
21. Walshe K, Freeman T. Effectiveness of quality improvement: learning from evaluations. Quality and Safety in Health Care 2002;**11**(1):85-87
22. KAPLAN HC, BRADY PW, DRITZ MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Quarterly 2010;**88**(4):500-59
23. Davidoff F. Systems of service: reflections on the moral foundations of improvement. BMJ quality & safety 2011;**20**(Suppl 1):i5-i10
24. Pawson R, Greenhalgh T, Harvey G, et al. Realist review–a new method of systematic review designed for complex policy interventions. Journal of health services research & policy 2005;**10**(suppl 1):21-34
25. Walshe K. Pseudoinnovation: the development and spread of healthcare quality improvement methodologies. International Journal for Quality in Health Care 2009;**21**(3):153-59
26. Radnor ZJ, Holweg M, Waring J. Lean in healthcare: The unfilled promise? Social Science & Medicine 2012;**74**(3):364-71
27. Shortell SM, Bennett CL, Byck GR. Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. Milbank Quarterly 2001;**76**(4):593-624
28. Ingebrigtsen T, Lind M, Krogh T, et al. Merging of three hospitals into one university hospital. Tidsskrift for den Norske lægeforening: tidsskrift for praktisk medicin, ny række 2012;**132**(7):813

29. Vos L, Chalmers SE, Dückers MLA, et al. Towards an organisation-wide process-oriented organisation of care: A literature review. Implementation Science 2011;**6**(1):8
30. Hart C. *Doing a literature review*. London: Sage Publications, 1998.
31. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS medicine 2009;**6**(7):e1000097
32. Poksinska B. The current state of Lean implementation in health care: literature review. Quality Management in Healthcare 2010;**19**(4):319
33. Powell A, Rushmer R, Davies H. A systematic narrative review of quality improvement models in health care. Social Dimensions of Health Institute at The Universities of Dundee and St Andrews 2008
34. Brennan S, McKenzie J, Whitty P, et al. Continuous quality improvement: effects on professional practice and healthcare outcomes. The Cochrane Library 2009
35. de Souza LB, Pidd M. Exploring the barriers to lean health care implementation. Public Money & Management 2011;**31**(1):59-66
36. Kaplan HC, Provost LP, Froehle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ quality & safety 2012;**21**(1):13-20
37. Kim CS, MBA DAS, Billi JE. Creating value in health care: the case for lean thinking. JCOM 2009;**16**(12)
38. Kim CS, Spahlinger DA, Kin JM, et al. Implementation of Lean Thinking: one health system's journey. Joint Commission Journal on Quality and Patient Safety 2009;**35**(8):406-13
39. Lukas CVD, Holmes SK, Cohen AB, et al. Transformational change in health care systems: an organizational model. Health care management review 2007;**32**(4):309-20
40. Kollberg B, Dahlgaard JJ, Brehmer PO. Measuring lean initiatives in health care services: Issues and findings. International Journal of Productivity and Performance Management 2007;**56**(1):7-24
41. Winch S, Henderson AJ. Making cars and making health care: a critical review. Medical Journal of Australia 2009;**191**(7):415
42. Morrow E, Robert G, Maben J, et al. Emerald Article: Implementing large-scale quality improvement: Lessons þÿfromTheProductiveWard: ReleasingTimetoCare! Quality Assurance 2012;**25**(4):237-53
43. O'Brien JL, Shortell SM, Hughes EF, et al. An integrative model for organization-wide quality improvement: lessons from the field. Quality Management in Healthcare 1995;**3**(4):19-30
44. Rycroft-Malone J, Kitson A, Harvey G, et al. Ingredients for change: revisiting a conceptual framework. Quality & Safety in Health Care 2002;**11**:174 - 80
45. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Quarterly 2004;**82**(4):581-629
46. Rozenblum R, Lisby M, Hockey PM, et al. The patient satisfaction chasm: the gap between hospital management and frontline clinicians. BMJ quality & safety 2013;**22**(3):242-50
47. Hearld LR, Alexander JA, Fraser I, et al. Review: how do hospital organizational structure and processes affect quality of care? A critical review of research methods. Medical Care Research and Review 2008;**65**(3):259-99
48. West E. Management matters: the link between hospital organisation and quality of patient care. Quality in Health Care 2001;**10**(1):40-48

Appendix 1. *Flow chart, detailed search strategy (Web only)*



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<br>Training and responsibility to staff (empowerment)<br>Consultants/trainers from health care<br>Management support, ownership and resources<br>Organization culture<br>An holistic approach - lean is not a toolbox<br>Improve the entire system, involve several units<br>Adaption, not adoption<br>Clear view of the customer<br>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<br>Quality as part of everyday life/every ones work<br>Long time approach<br>Active health professionals/doctors engagement<br>Belief that staff/patient will benefit<br>Strong leadership and clear vision<br>Sustained active participation from board and senior management<br>Multifaceted interventions sustained action at different levels<br>Substantial investment in training and development (including IT and training of staff)<br>Support from ”change agents” to provide skills<br>Robust and timely data<br>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<br>Clinical leadership and involvement<br>Team-based problem solving<br>Adequate information and communication technology support<br>Administrative support<br>Ambitious targets<br>External facilitators<br>Organizational readiness<br>Selection and execution of projects in order of urgency<br>Using a change strategy that already proved to be successful<br>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<br>Competency in QI methods and tools<br>Alignment of QI activities with the organizations priorities<br>Management structures and systems that support QI, including appropriate data and analysis systems.<br>Leadership support for QI at all levels.<br>Ability to work as a team (team performance), team member participation,<br>Presence of a champion<br>Physician support and participation,<br>team members technical competence,<br>training in theory, methods, and tools,<br>support to facilitate implementation and use,<br>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,<br>provide evidence that it works,<br>focus on patient processes,<br>translate it,<br>make a culture,<br>data – evidence based,<br>continuous improvement,<br>multidisciplinary teams across silos,<br>local performance measurement,<br>technical support,<br>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)<br>Project sponsorship (personnel, expertise, facilities from outside)<br>QI leadership (senior management board)<br>Senior leader project sponsor (to champion and support)<br>Culture support<br>Program maturity/sophistication of QI<br>Data infrastructure<br>Resource availability<br>Workforce QI focus/training/engaged<br>Micro system leadership (personally involved)<br>Culture support; teamwork, communication, freedom to improve<br>Capability (team ability to use QI methods)<br>Motivation/willingness<br>Team diversity<br>Physician involvement<br>Expert (subject matter) |

| | | | | |
|---|---|---|---|---|
| | | | | Team tenure (worked as a team before)<br>Prior QI experience<br>Team leadership<br>Team decision making processes<br>Team norms of behavior<br>Team QI skills<br>Trigger (a specific event stimulates a new emphasis)<br>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<br>Organizational culture<br>Organizational structure (clinical integration across departments)<br>Data infrastructure and information systems<br>Years involved in QI (experience)<br>Customer focus<br>Physician involvement<br>Micro system motivation to change<br>Resources for QI<br>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<br>Work across functional divides<br>Pursue value creation for patients<br>Nurture long term holistic culture of CQI<br>A need to improve<br>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<br>leadership - clinical champions and senior management support<br>frontline worker engagement in the QI processes<br>Use metrics to develop and track interventions<br>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<br>leadership commitment<br>Actively engage staff in meaningful problem solving<br>Alignment to achieve consistency of organization goals<br>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<br>active involvement and<br>multi-skilled teams |

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

| | | | | |
|---|---|---|---|---|
| | | | | Communication and feedback to staff and patients<br>Need for change, valuing the initiative<br>Simple, practical solutions to real problems<br>Accessibility of recourses and teaching modules<br>Self-nomination (units to take part)<br>Local ownership and empowerment<br>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.<br>Expert guidance for their initial projects.<br>A well-structured set of metrics, on a regular basis, readjusted<br>Aligning individual goals, projects, and metrics<br>Provide flexibility for frontline workers to experiment at the site and time they identify a problem.<br>Frontline management need to avail themselves to the area |

# PRISMA 2009 Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 3 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 1 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 3 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | 4 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | App1 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 3 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | App1 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | App1 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 4 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 3 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 12 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 4 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ for each meta-analysis. | 12 |

# PRISMA 2009 Checklist



| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 12 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 4 |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | App1, 2 |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | App2 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 12 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | - |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | - |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 12 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | - |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 12 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 12 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 13 |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 14 |

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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

| | |
|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID: | bmjopen-2013-003873.R1 |
| Article Type: | Research |
| Date Submitted by the Author: | 13-Dec-2013 |
| Complete List of Authors: | Andersen, Hege; University Hospital of North Norway, CEO office; University of Tromsø, Department of sociology, political science and community planning. Faculty of humanities, social sciences and education<br>Røvik, Kjell Arne; University of Tromsø, Department of sociology, political science and community planning. Faculty of humanities, social sciences and education<br>Ingebrigtsen, Tor; University Hospital of North Norway, CEO office; University of New South Wales, Centre for clinical governance research. Australian institute of health innovation |
| Primary Subject Heading: | Health services research |
| Secondary Subject Heading: | Health policy |
| Keywords: | Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
| | |

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

**Corresponding author:**

Hege Andersen

University Hospital of North Norway

Box 100, 9038 Tromsø, Norway

Hege.andersen@unn.no Telephone no: +47 99530353 Fax: +47 77626041

**Authors:**

Hege Andersen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Kjell Arne Røvik

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Tor Ingebrigtsen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Clinical Medicine

Faculty of Health Sciences

University of Tromsø, Norway and
Centre for Clinical Governance research
Australian Institute of Health Innovation
University of New South Wales, Sydney Australia

**Key words:**

Lean thinking, quality improvement, health care, implementation, context

**Word-count:** 3819

## ABSTRACT

**Objective:** Lean interventions aim to improve quality of health care 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 theorizes the concept of context by establishing a two-dimensional conceptual framework acknowledging lean as complex social interventions, deployed in different organizational 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 categorized according to the intervention domains and dimensions of capability provided by the framework.

**Results:** We provide a framework emphasizing context by relating facilitators to domains and dimensions of capability. 23 factors enabling successful lean in hospitals were identified in the systematic review, whereby 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 health care quality improvement.

## ARTICLE SUMMARY

### Article focus

- There is conflicting evidence on the outcomes of lean thinking in health care.
- Reviewing the literature within the approach of a new contextual framework can deepen our understanding of lean as a quality improvement method.
- Identifying factors facilitating intended outcomes from lean interventions, contribute to new knowledge on when and how lean interventions work.

### Key messages

- 23 factors enabling successful lean in hospitals are identified, whereby management and a supportive culture, training, accurate data, physicians and team involvement were most frequent.
- Characteristics of lean and local application, in addition to the organizations strategic and cultural capability, should be given further attention in health care quality improvement.
- In the absence of evidence, a framework incorporating the context may prove useful for future research on lean interventions.

### Strengths and limitations of this study

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

## INTRODUCTION

Lean thinking has been introduced in health care 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]. Lack of evidence may lead to resistance and hinder speed up and spread of quality initiatives in health care[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]. Focus on measurements and continuous improvement is expected to promote implementation and sustainability.

In a recent review, Mazzocato et al. (2010) concluded that lean has been applied successfully in health care institutions worldwide[13]. However, most studies have a narrow technical application with limited organizational reach. Many are single case studies, some quite anecdotal, while others are biased or characterized by a weak study design. Some reviews suggest that inappropriate analyses, a lack of alternative hypotheses, and other methodological limitations undermine validity[2 5 14]. This makes it difficult to rule out confounding explanatory factors, to measure outcomes and generalize results from lean interventions[6].

Advocates for experimental designs question results from qualitative studies, and argues that randomized 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

findings from one setting to another. Is there a cure for this lack of evidence? On a paramount level, one must ask whether absence of evidence justifies inaction[18]. The *quality chasm* between the health care we have and the health care 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. (2007) emphasized 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 organizational and social context in which care is delivered[21]. 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. Context are 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 standardize. 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, systematic reviews provide the best evidence on the effectiveness of quality improvement[28]. We observe a growing consensus that characteristics like management, resources and culture matter, but the current knowledge base lacks specification on when and how the different facilitators work. This vagueness partly rest 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 program for improvement was launched. The program aimed to accomplish quality improvement in parallel with the organizational change to counteract the transitional setbacks in quality that large-scale change may entail[31]. A research program 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 organizational 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 organizations' 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 co-authors. 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. Search words included hospital, health care, 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. 15 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 (supplementary file)[34].196 original articles were excluded. Exclusion criteria included absence of a hospital or organizational 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 or 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 systematized according to the number of studies included in each review. Eight articles reviewed a number of definite cases, varying from four 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 like *Productive ward* and process oriented redesign. Lean was extracted and treated separately as far as possible, though confined by the observed mix, similarity and simultaneously 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 United States, 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 barriers to lean improvement were based on the fact that the research literature at this field chiefly pays attention to facilitators and not 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 localization of similarities and differences among studies[33], the articles were systematically analyzed and recorded in a standardized format, according to the facilitators. The procedure were conducted by creating a worksheet categorizing every paper according to author, year of publishing, kind 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 a supplementary file.

All the identified facilitators were assigned to larger categories. This classification was done 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 like management support, commitment and ownership. Cultural issues were all categorized 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 below. Finally, the frequency of each of the facilitators in the 18 reviews was accounted for.

**A theoretical and methodological framework**

Lean interventions consist of several different phases, from planning and preparation to implementation and sustainability, involving different organizational capabilities. The facilitators for improvement were analyzed and reorganized in a table combining Shortell's *dimensions of capability*[2 45], and Walshe's *domains of an intervention*[9]. Shortell categorized 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 organization. The *technical* dimension covers training and information system issues, while the *strategic* dimension emphasizes the conditions that offer the greatest opportunities to change. This dimension touch upon 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 relate to mechanisms that facilitate learning and disseminate best practices throughout the organization. The four dimensions are multiplicative, interrelated, 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 organization in which the intervention is deployed. Context may vary widely, both within and between hospitals. The *content* describes the the nature or characteristics of the intervention itself. The content of lean may be standardized 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. O*utcomes* are the results of the intervention, including the maintenance phase after implementation. All of these domains may be characterized by low or high variance. High levels of variance in the settings, content and

application may explain interventions varying success. Variances also reduce the ability to generalize 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, both as emerging in different domains in a multistage process and by different organizational dimensions. The framework was used to describe and understand the contextual factors encountered in an organizational-wide quality improvement effort.

## RESULTS

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

*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**: Include patient and workforce value creation and improvements

**External support**: Expert change agents, networks and sponsorship triggers 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**: Multi-skilled and –disciplinary team collaboration including decision-making

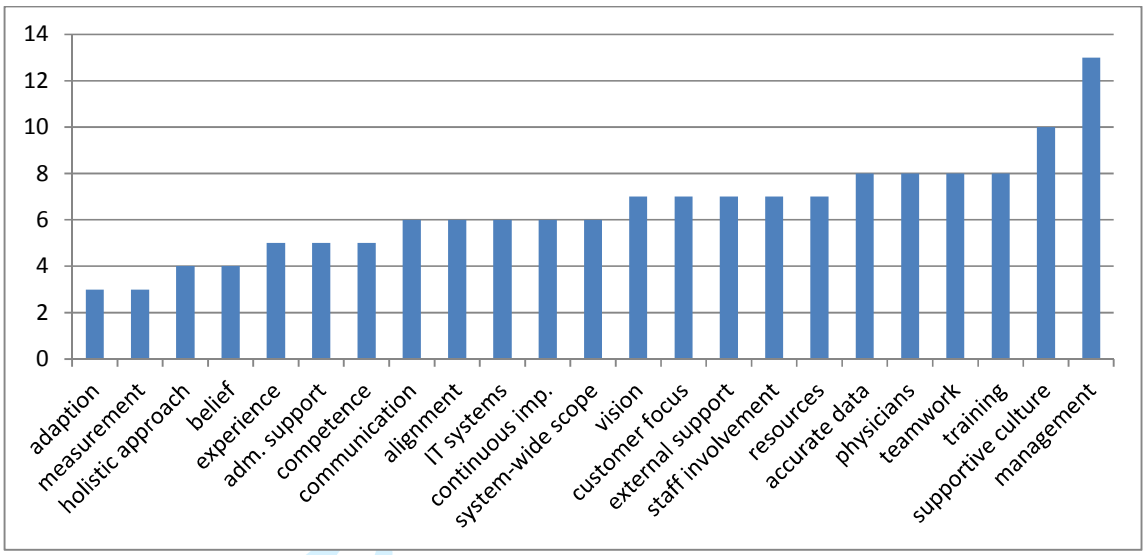
**Training**: Accessible, substantial, practical and relevant training for immediate use

**Supportive culture**: Views, norms and beliefs that support quality improvement

**Management:** Leadership support, ownership and commitment

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

*Figure 1: Frequency of different facilitators identified in 18 reviewed articles*




## DISCUSSION

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

*Table 1: Facilitators for change, literature reviews 2000–2012*

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

**Context: Situation and organization.**

Prior experience, accompanied by success stories demonstrating benefits for patients and staff, enables improvement[23 31 37]. This relates to the organization'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 practices throughout the organization[17 31 35 38-40 44]. Competence in tools and methods support the assumptions of lean, and increase 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 needs facilitate quality improvement in health care[10 13 23 35 37 42 44]. Access to, and accomplished substantial training in methods and tools strengthens the organizations 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 multi-skilled teams facilitate local application of lean[23 31 35-38 42 43]. Strengthening the improvement culture presupposes workforce stability, team leadership, and decentralized 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 include both 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]. Both management and physicians involvement are among the most frequent 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 lasting outcomes [26 35 38-42 44].

**Outcomes: Results and maintenance**

To secure maintenance, a hospital depends first and foremost on a supportive culture characterized 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 affect the ability to accomplish change. A holistic approach emphasizes that lean is a strategy not only 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 organization's structural capability, which strengthen 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 represent a shift from cause-effect to conditional attributions[45]. Each domain and dimension is influenced by the status of other ones. Our results summarized 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 interrelated and probably all necessary to achieve lasting 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. Unfortunally, little is known about which facilitators that are most important[8 22]. Management and leadership engagement was 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 touch upon the different domains. The observation that 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 health care[4 23 46] strengthen 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 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 to Radnor et al (2012), that advocate that lean interventions must be contextualized, rather than transplanted like a recipe[27].

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 health care[47]. Finally, the local application of lean in hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-floor staff must be engaged and empowered. Womack and Jones (2003) that initially advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main advantage for hospitals, making lean suitable for health care[12].

The cultural and strategic dimensions of capability embrace most of the frequent facilitators. A supportive culture are fundamental to achieve quality improvements[38]. The organizational 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 (2013)[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 are 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 both qualitative and quantitative studies eliminates the possibility of quantifying the findings and predicting 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 organizing that could improve patient care[49].

The facilitators identified and the two-dimensional framework proposed in the present work incorporates structure and process. Still, the facilitators are characterized by vagueness, as broad and comprehensive determinants, that needs further specification and practical content to guide future effective quality improvements to health care organizations[8 22 38 50]. In addition to contextual preconditions, success are dependent on how the organization utilize, combine and sequence organizational 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 health care providers performance (adherence to recommended practice), patient outcome (as quality of life or mortality), surrogate outcomes (as readmission) and organizational outcomes (like resource use or sustainability)[36]. At the University Hospital of North Norway, more than five 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 organization-wide quality intervention. The review of reviews identified 23 interrelated 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 organizations' 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 health care. This framework incorporates the complex social and organizational context in which lean are applied. These findings coincide with recent research calling for more attention to the influence of organizational 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.

Acknowledgements: The authors would like to thank David Greenfield (PhD) and John Øvretveit (PhD) for their assistance in clarifying concepts in the discussion. We would also like to thank James Morrison for his language assistance.

Contributors: All the listed authors met the authorship requirements as defined by the ICJME. HA contributed to the conception and design, the acquisition, analysis and interpretation of the data, as well as drafting and revising the article. TI and KAR made a substantial contribution to the design and interpretation of the data, as well as to drafting and critical revising of the article. All the authors have provided final approval of the submitted manuscript.

Funding: The PhD-study is founded by the regional health trust of North Norway, Helse Nord RHF

Competing interest: None

1. Joosten T, Bongers I, Janssen R. Application of lean thinking to health care: issues and observations. International Journal for Quality in Health Care 2009;**21**(5):341-47
2. Shortell SM. *Assessing the Implementation and Impact of Clinical Quality Improvement Efforts: Abstract, Executive Summary and Final Report*: Agency for Health Care Policy and Research, 1998.
3. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Affairs 2005;**24**(1):138-50
4. Rycroft-Malone J, Kitson A, Harvey G, et al. Ingredients for change: revisiting a conceptual framework. Quality & Safety in Health Care 2002;**11**:174 - 80
5. Young T, McClean S. A critical look at Lean Thinking in healthcare. Quality and Safety in Health Care 2008;**17**(5):382-86
6. Alexander JA, Hearld LR. What Can We Learn From Quality Improvement Research? A Critical Review of Research Methods. Medical Care Research and Review 2009 doi: 10.1177/1077558708330424[published Online First: Epub Date]|.
7. de Souza LB. Trends and approaches in lean healthcare. Leadership in Health Services 2009;**22**(2):121-39
8. Øvretveit J. Understanding the conditions for improvement: research to discover which context influences affect improvement success. BMJ quality & safety 2011;**20**(Suppl 1):i18-i23
9. Walshe K. Understanding what works—and why—in quality improvement: the need for theory-driven evaluation. International Journal for Quality in Health Care 2007;**19**(2):57-59
10. Øvretveit J, Gustafson D. Evaluation of quality improvement programmes. Quality and Safety in Health Care 2002;**11**(3):270-75
11. Liker JK, Kaisha TJKK. *The Toyota way: 14 management principles from the world's greatest manufacturer*: McGraw-Hill New York, 2004.
12. Womack JP, Jones DT. *Lean thinking: banish waste and create wealth in your corporation, revised and updated*: Free Press, 2003.
13. Mazzocato P, Savage C, Brommels M, et al. Lean thinking in healthcare: a realist review of the literature. Quality and Safety in Health Care 2010;**19**(5):376-82
14. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and studergroup's hardwiring excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. Implement Sci 2009;**4**(35):1-9
15. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**(sep29_1):a1655-a55
16. Perneger T. Ten reasons to conduct a randomized study in quality improvement. International Journal for Quality in Health Care 2006;**18**(6):395-96
17. Powell A, Rushmer R, Davies H. A systematic narrative review of quality improvement models in health care. Social Dimensions of Health Institute at The Universities of Dundee and St Andrews 2008
18. Altman DG, Bland JM. Statistics notes: Absence of evidence is not evidence of absence. BMJ 1995;**311**(7003):485 doi: 10.1136/bmj.311.7003.485[published Online First: Epub Date]|.
19. Corrigan JM. *Crossing the quality chasm*: Washington, DC, National Academy Press, 2001.
20. Kohn LT, Corrigan J, Donaldson MS. *To err is human: building a safer health system*: Joseph Henry Press, 2000.
21. Shortell SM, Rundall TG, Hsu J. Improving patient care by linking evidence-based medicine and evidence-based management. JAMA: the journal of the American Medical Association 2007;**298**(6):673-76
22. Walshe K, Freeman T. Effectiveness of quality improvement: learning from evaluations. Quality and Safety in Health Care 2002;**11**(1):85-87
23. KAPLAN HC, BRADY PW, DRITZ MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Quarterly 2010;**88**(4):500-59
24. Davidoff F. Systems of service: reflections on the moral foundations of improvement. BMJ quality & safety 2011;**20**(Suppl 1):i5-i10
25. Pawson R, Greenhalgh T, Harvey G, et al. Realist review–a new method of systematic review designed for complex policy interventions. Journal of health services research & policy 2005;**10**(suppl 1):21-34
26. Walshe K. Pseudoinnovation: the development and spread of healthcare quality improvement methodologies. International Journal for Quality in Health Care 2009;**21**(3):153-59
27. Radnor ZJ, Holweg M, Waring J. Lean in healthcare: The unfilled promise? Social Science & Medicine 2012;**74**(3):364-71
28. Grimshaw J, McAuley L, Bero L, et al. Systematic reviews of the effectiveness of quality improvement strategies and programmes. Quality and safety in health care 2003;**12**(4):298-303

29. Shortell SM, Bennett CL, Byck GR. Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. Milbank Quarterly 2001;**76**(4):593-624
30. Ingebrigtsen T, Lind M, Krogh T, et al. Merging of three hospitals into one university hospital. Tidsskrift for den Norske lægeforening: tidsskrift for praktisk medicin, ny række 2012;**132**(7):813
31. Vos L, Chalmers SE, Dückers MLA, et al. Towards an organisation-wide process-oriented organisation of care: A literature review. Implementation Science 2011;**6**(1):8
32. Weiner BJ. A theory of organizational readiness for change. Implement Sci 2009;**4**(1):67
33. Hart C. *Doing a literature review*. London: Sage Publications, 1998.
34. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS medicine 2009;**6**(7):e1000097
35. Poksinska B. The current state of Lean implementation in health care: literature review. Quality Management in Healthcare 2010;**19**(4):319
36. Brennan S, McKenzie J, Whitty P, et al. Continuous quality improvement: effects on professional practice and healthcare outcomes. The Cochrane Library 2009
37. de Souza LB, Pidd M. Exploring the barriers to lean health care implementation. Public Money & Management 2011;**31**(1):59-66
38. Kaplan HC, Provost LP, Froehle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ quality & safety 2012;**21**(1):13-20
39. Kim CS, MBA DAS, Billi JE. Creating value in health care: the case for lean thinking. JCOM 2009;**16**(12)
40. Kim CS, Spahlinger DA, Kin JM, et al. Implementation of Lean Thinking: one health system's journey. Joint Commission Journal on Quality and Patient Safety 2009;**35**(8):406-13
41. Lukas CVD, Holmes SK, Cohen AB, et al. Transformational change in health care systems: an organizational model. Health care management review 2007;**32**(4):309-20
42. Kollberg B, Dahlgaard JJ, Brehmer PO. Measuring lean initiatives in health care services: Issues and findings. International Journal of Productivity and Performance Management 2007;**56**(1):7-24
43. Winch S, Henderson AJ. Making cars and making health care: a critical review. Medical Journal of Australia 2009;**191**(7):415
44. Morrow E, Robert G, Maben J, et al. Emerald Article: Implementing large-scale quality improvement: Lessons þÿfromTheProductiveWard: ReleasingTimetoCare! Quality Assurance 2012;**25**(4):237-53
45. O'Brien JL, Shortell SM, Hughes EF, et al. An integrative model for organization-wide quality improvement: lessons from the field. Quality Management in Healthcare 1995;**3**(4):19-30
46. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Quarterly 2004;**82**(4):581-629
47. Rozenblum R, Lisby M, Hockey PM, et al. The patient satisfaction chasm: the gap between hospital management and frontline clinicians. BMJ quality & safety 2013;**22**(3):242-50
48. Hearld LR, Alexander JA, Fraser I, et al. Review: how do hospital organizational structure and processes affect quality of care? A critical review of research methods. Medical Care Research and Review 2008;**65**(3):259-99
49. West E. Management matters: the link between hospital organisation and quality of patient care. Quality in Health Care 2001;**10**(1):40-48
50. Bate P, Mendel P, Robert GB. *Organizing for quality: the improvement journeys of leading hospitals in Europe and the United States*: Radcliffe Publishing, 2008.

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

**Corresponding author:**

Hege Andersen

University Hospital of North Norway

Box 100, 9038 Tromsø, Norway

Hege.andersen@unn.no Telephone no: +47 99530353 Fax: +47 77626041

**Authors:**

Hege Andersen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Kjell Arne Røvik

Department of Sociology, Political Science, and Community Planning

Faculty of Humanities, Social Sciences, and Education

University of Tromsø, Norway.

Tor Ingebrigtsen

CEO office, University Hospital of North Norway, Tromsø Norway and

Department of Clinical Medicine

Faculty of Health Sciences

University of Tromsø, Norway and
Centre for Clinical Governance research
Australian Institute of Health Innovation
University of New South Wales, Sydney Australia

**Key words:**

Lean thinking, quality improvement, health care, implementation, context

**Word-count:** ~~3926~~ 3819

Field Code Changed

## ABSTRACT

**Objective:** Lean interventions aim to improve quality of health care 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 theorizes the concept of context by establishing a two-dimensional conceptual framework acknowledging lean as complex social interventions, deployed ~~during several stages, and~~ in different organizational dimensions and domains. The specific aim of the study was to identify factors facilitating intended outcomes from lean interventions, and to understand when and ~~in which dimension~~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 categorized according to the intervention ~~phases~~ domains and dimensions of capability provided by the framework.

**Results:** We provide a framework emphasizing context by relating facilitators to ~~stages~~ domains and dimensions of capability. 23 factors enabling successful lean in hospitals were identified in the systematic review, whereby 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 ~~the organizations~~ strategic and cultural capability, should be given further attention in health care quality improvement.

## ARTICLE SUMMARY

### Article focus

- There is conflicting evidence on the outcomes of lean thinking in health care.
- Reviewing the literature within the approach of a new contextual framework can deepen our understanding of lean as a quality improvement method.
- Identifying factors facilitating intended outcomes from lean interventions, contribute to new knowledge on when and how lean interventions works.

### Key messages

- 23 factors enabling successful lean in hospitals are identified, whereby management and a supportive culture, training, accurate data, physicians and team involvement were most frequent.
- Characteristics of lean and local application, in addition to the organizations strategic and cultural capability, should be given further attention in health care quality improvement.
- In the absence of evidence, a framework incorporating the context may prove useful for future research on lean interventions.

### Strengths and limitations of this study

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

## INTRODUCTION

Lean thinking has been introduced in health care 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]. Lack of evidence may lead to resistance and hinder speed up and spread of quality initiatives in health care[1 8-10].

Lean interventions aim to improve quality by reducing waste~~,~~ and facilitate flow in ~~patient~~ care ~~work~~ 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]. Focus on measurements and continuous improvement is expected to promote implementation and sustainability.

In a recent review, Mazzocato et al. (2010) concluded that lean has been applied successfully in health care institutions worldwide[13]. However, most studies have a narrow technical application with limited organizational reach. Many are single case studies, some quite anecdotal, while others are biased or characterized by a weak study design. Some reviews suggest that inappropriate analyses, a lack of alternative hypotheses, and other methodological limitations undermine validity[2 5 14]. This makes it difficult to rule out confounding explanatory factors, to measure outcomes and generalize results from lean interventions[6].

Advocates for experimental designs question results from qualitative studies, and argues that randomized controlled trials are necessary to isolate effects[15 16]. Many~~ost~~ studies using an experimental design did not find any significant effect of lean and other quality improvement interventions~~[2 5 9 10 14]~~[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

findings from one setting to another. Is there a cure for this lack of evidence? On a paramount level, one must ask whether absence of evidence justifies inaction[18]. The *quality chasm* between the health care we have and the health care 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. ~~[21]~~

## Lean as social, complex and context-dependent interventions

Shortell et al. (2007) emphasized 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 organizational and social context in which care is delivered[21]. 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. Context are 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 standardize. 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, systematic reviews provide the best evidence on the effectiveness of quality improvement[28]. We observe a growing consensus that characteristics like management, resources and culture matter, but the current knowledge base lacks specification on when and how the different facilitators work. This vagueness partly rest on insufficient methodological attention to the context in which lean interventions work. To understand and assess variation in lean intervention~~s~~ 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 ~~contextual~~ 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 ~~comprehensive~~ lean program for improvement ~~of clinical pathways using lean methods~~ was launched. The program aimed to accomplish ~~a~~ quality improvement ~~effort~~ in parallel with the organizational change to counteract the transitional setbacks in quality that large-scale change may entail[31]. A research program was established to evaluate the effects. ~~We identified a need for a theoretical and methodological framework to analyse variation in adoption of lean interventions at the hospital.~~ 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 organizational 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 organizations' 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 co-authors. ~~Discrepancies~~ Any confusion ~~were~~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. Search words included hospital, health care, 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. 15 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 (supplementary file)[34].196 original articles were excluded. Exclusion criteria included absence of a hospital or organizational 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 or lean thinking were issued. Articles that mainly represented practical guidelines were also ~~were~~ excluded. The final review included 18 articles[10 13 17 22 23 26 27 31 35-44].

**Data analysis**

The 18 articles were systematized according to the number of studies included in each review. Eight articles reviewed a number of definite cases, varying from four 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 like *Productive ward* and process oriented redesign. Lean was extracted and treated separately as far as possible, though confined by the observed mix, similarity and simultaneously use of different quality improvement methods in hospitals[5 22 26 27]. The m~~M~~ethods used in the original studies were qualitative, quantitative, or a mixed-method approach. Most studies were based on cases originated in the United States, Australia and Great Britain.

The next step was to search for facilitators, defined as ~~contextual~~ contingency factors predicted to promote quality improvement, as opposed to barriers that hinder improvement[37]. The decision to concentrate on facilitators and not barriers to lean improvement were based on the fact that the research literature at this field chiefly pays attention to facilitators and not 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 localization of similarities and differences among studies[33], the articles were systematically analyzed and recorded in a standardized format, according to the facilitators. The procedure were conducted by creating a worksheet categorizing every paper according to author, year of publishing, kind of review, ~~supplementary~~ other quality improvement methods comprised (in addition to lean), research method, labelling of facilitators, and facilitating factors. The complete worksheet is attached as a supplementary file.

All the identified facilitators were assigned to larger categories. This classification was done 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 like management support, commitment and ownership. Cultural issues were all categorized as *supportive culture*, including views, norms ~~and,~~ beliefs and behaviours supporting ~~lean~~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 below. Finally, the frequency of each of the facilitators in the 18 reviews was accounted for.

**A theoretical and methodological framework**

Lean interventions consist of several different phases, from planning and preparation to implementation and sustainability, involving different organizational capabilities. The facilitators for improvement were analyzed and reorganized in a table combining Shortell's *dimensions of capability*[2 45], and Walshe's *domains of an intervention*[9]. Shortell categorized 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 organization. The *technical* dimension covers training and information system issues, while the *strategic* dimension emphasizes the conditions that offer the greatest opportunities to change. This dimension touch upon 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 relate to mechanisms that facilitate learning and disseminate best practices throughout the organization. The four dimensions are multiplicative, interrelated, 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 ~~or phases~~ in quality interventions are labelled as context, content, application and outcomes. The context involves ~~the preparation phase before starting improvement work, highlighting aspects of~~ the situation, setting or organization in which the intervention is deployed. Context may vary widely, both within and between hospitals. ~~This is a narrow view of context, and should not be confused with the broader understanding of context as all surrounding factors that are not part of the technical intervention itself[8]. In~~

Field Code Changed

~~this article, we therefore renamed this phase as the organizational *setting*.~~ The *content* describes the ~~phase where lean is introduces as a tool,~~ the nature or characteristics of the intervention itself. The content of lean may be standardized 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. O*utcomes* are the results of the intervention, including the maintenance phase after implementation. All of these ~~phases~~ domains may be characterized by low or high variance. High levels of variance in the settings, content and application may explain interventions varying success. Variances also reduce the ability to generalize 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, both as emerging in different ~~phases~~ domains in a multistage process and by different organizational dimensions. The framework was used to describe and understand the ~~organizational and~~ contextual factors encountered in an organizational-wide quality improvement effort.

## RESULTS

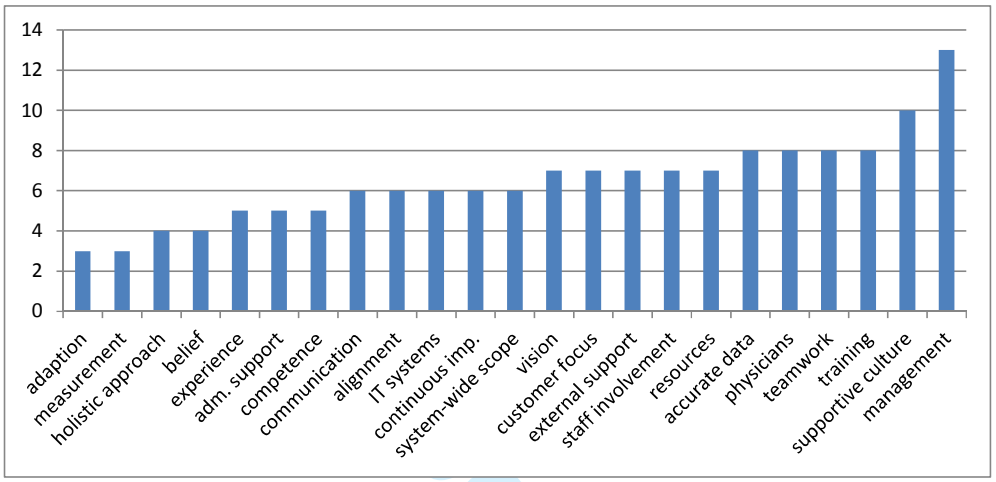
Among the 18 reviewed articles, 149 facilitators for lean interventions were found. The reviews identified ~~three~~ 3 to 16 (median seven) facilitators for improvement. All were identified in several reviews, varying from ~~three~~ 3 to 14 (median seven) times. The facilitators were categorized into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

*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**: Include patient and workforce value creation and improvements
**External support**: Expert change agents, networks and sponsorship triggers 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**: Multi-skilled 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 ~~lean represent readiness~~quality improvement
**Management:** Leadership support, ownership and commitment

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

*Figure 1: Frequency of different facilitators identified in 18 reviewed articles*




## DISCUSSION

Table 1 show how the different facilitators were found relevant in the different intervention ~~phases~~ domains and affected organizational dimensions.

*Table 1: Facilitators for change, literature reviews 2000–2012*

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

**~~Setting~~Context: Situation and organization.**

~~Initially, a well-proven, successful quality improvement method characterized by program maturity facilitates.~~ Prior experience, accompanied by success stories demonstrating benefits for patients and staff, ~~are enabling~~enables improvement[23 31 37]. ~~Lean should be accompanied by success stories demonstrating benefits for patients and staff.~~ This relates to the organization'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 ~~may~~ contribute to dissemination of best practices throughout the organization[17 31 35 38-40 44]. Competence in tools and methods support the assumptions of lean, and increase 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 needs facilitate quality improvement in health care[10 13 23 35 37 42 44]. Access to, and accomplished substantial training in methods and tools strengthens the organizations 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~~, which facilitates lean interventions~~[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 multi-skilled teams ~~strongly~~ facilitate local application of lean[23 31 35-38 42 43]. Strengthening the improvement culture presupposes workforce stability, team leadership, and decentralized decision making. Administrative project management and practical support secures backing, and contributes to the technical capability

of the organization[22 31 36 44]. Strategically, involvement of physicians and management encourage change. Management engagement include both 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 crucial important at the strategic level as role models and peers for others[10 17 23 31 36 38 40 43]. Both management and physicians involvement are among the most frequent identified enablers of quality improvement in the literature jointly with teamwork. Key factors to disseminate best practices are staff participation, engagement, and empowerment. Staff commitment, responsibility and ownership, are required for achieving lasting outcomes of lean interventions[26 35 38-42 44].

**Outcomes: Results and maintenance**

To secure maintenance, a hospital depends first and foremost strongly on a supportive culture characterized by norms, and beliefs and behaviours supporting the principles and practice of quality improvement and readiness[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 facilitatingenablers [31 35 38 43 44]. Strategically, a holistic approach based on continuous improvement and sustained attention affect the ability to accomplish change. A holistic approach emphasizes that lean is a toolstrategy not only 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 organization's structural capability, which strengthen 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.

In addition to a supportive culture, the most frequent facilitators are identified in the *content* and local *application* parts of the intervention. That is, the most reported success factors for lean, touch upon characteristics of the intervention and its local delivery process. Most of the frequent facilitators concern the *strategic* or the *cultural* dimension of capability, interventions strategic importance to the hospitals overall goals and the organizations underlying beliefs, values, norms and behavior.

## DISCUSSION

Analysis based on the conceptual framework suggest that understanding which facilitators influence the intervention at different stages domains and dimensions of capability, is probably is more important than a quantitative approach[8 17]. The emphasis on the interventions different parts and the organizational dimensionsThis represent a shift from cause-effect to conditional attributions[45]. Each part domain and dimension is influenced by the status of other dimensionsones. Our results summarized in table 1 show indicate that a number of facilitators representing the four dimensions may interact during thewithin and between the four stages domains and dimensionsof change. The four dimensions, domains and the associated facilitators are interrelated and equally probably all necessary to achieve lasting results[2]. In the followingFinally, we elaborate our interpretation of these findings.

Ryeroft Malone et al (2002) concludes that there are three key elements of implementation: evidence, facilitation and context[4]. 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. HoweverUnfortunally, it is evident that little is known about which facilitators that are most important[8 22]. Management and leadership engagement was 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 recent relevant research in the field, 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 go through its fourtouch upon the different stagesdomains. The observation that 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 health care[4 23 46] strengthen the findings.

Field Code Changed

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 are not a ~~receipt~~ 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 to Radnor et al (2012), that advocate that lean interventions must be contextualized, rather than transplanted like a recipe[27].

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 health care[47]. Finally, the local application of lean in hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-floor staff must be engaged and empowered. Womack and Jones (2003) that initially advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main advantage for hospitals, making lean suitable for health care[12].

The cultural and strategic dimensions of capability embrace most of the frequent facilitators. A supportive culture are fundamental to achieve quality improvements[38]. The organizational 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. ~~This finding~~These findings are supported by other recent hospital-based studies, like Rozenblum et al (2013)[47].

~~The main contribution of this review is a two-dimensional framework for identification and analysis of facilitators for lean interventions in health care. This framework incorporates the complex social and organizational context in which lean are applied. These findings coincide with recent research calling for more attention to the influence of organizational 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.~~

**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 are promoted by c~~C~~onducting feature maps and presenting all the identified facilitators in appendices ~~promote transparency~~.

~~Further on, i~~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.

~~And finally, i~~Including both qualitative and quantitative studies eliminates the possibility of quantifying the findings and predicting 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 organizing that could improve patient care[49].

The facilitators identified and the two-dimensional framework proposed in the present work incorporates structure and process. Still, the facilitators are characterized by vagueness, as broad and comprehensive determinants, that needs further specification and practical content to guide future effective quality improvements to health care organizations[8 22 38 50]. In addition to contextual preconditions, success are dependent on how the organization utilize, combine and sequence organizational 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 health care providers performance (adherence to recommended practice), patient outcome (as quality of life or mortality), surrogate outcomes (as readmission) and organizational outcomes (like resource use or sustainability)[36]. At the University Hospital of North Norway, more than five 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 ~~article can~~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 organization-wide quality intervention. The review of reviews identified 23 interrelated 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 organizations' 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 health care. This framework incorporates the complex social and organizational context in which lean are applied. These findings coincide with recent research calling for more attention to the influence of organizational 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.

~~We provide a framework, which emphasizes the importance of context by relating facilitators to four dimensions of organizational capability and four stages of change, and suggest that this represent a practical tool for understanding and assessing variation in lean adoption. The article can 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 organization-wide quality intervention. The review of reviews identified 23 interrelated 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 organizations cultural and strategic capability.~~

Acknowledgements: The authors would like to thank David Greenfield (PhD) and John Øvretveit (PhD) for their assistance in clarifying concepts in the discussion. We would also like to thank James Morrison for his language assistance.

Contributors: All the listed authors met the authorship requirements as defined by the ICJME. HA contributed to the conception and design, the acquisition, analysis and interpretation of the data, as well as drafting and revising the article. TI and KAR made a substantial

contribution to the design and interpretation of the data, as well as to drafting and critical revising of the article. All the authors have provided final approval of the submitted manuscript.

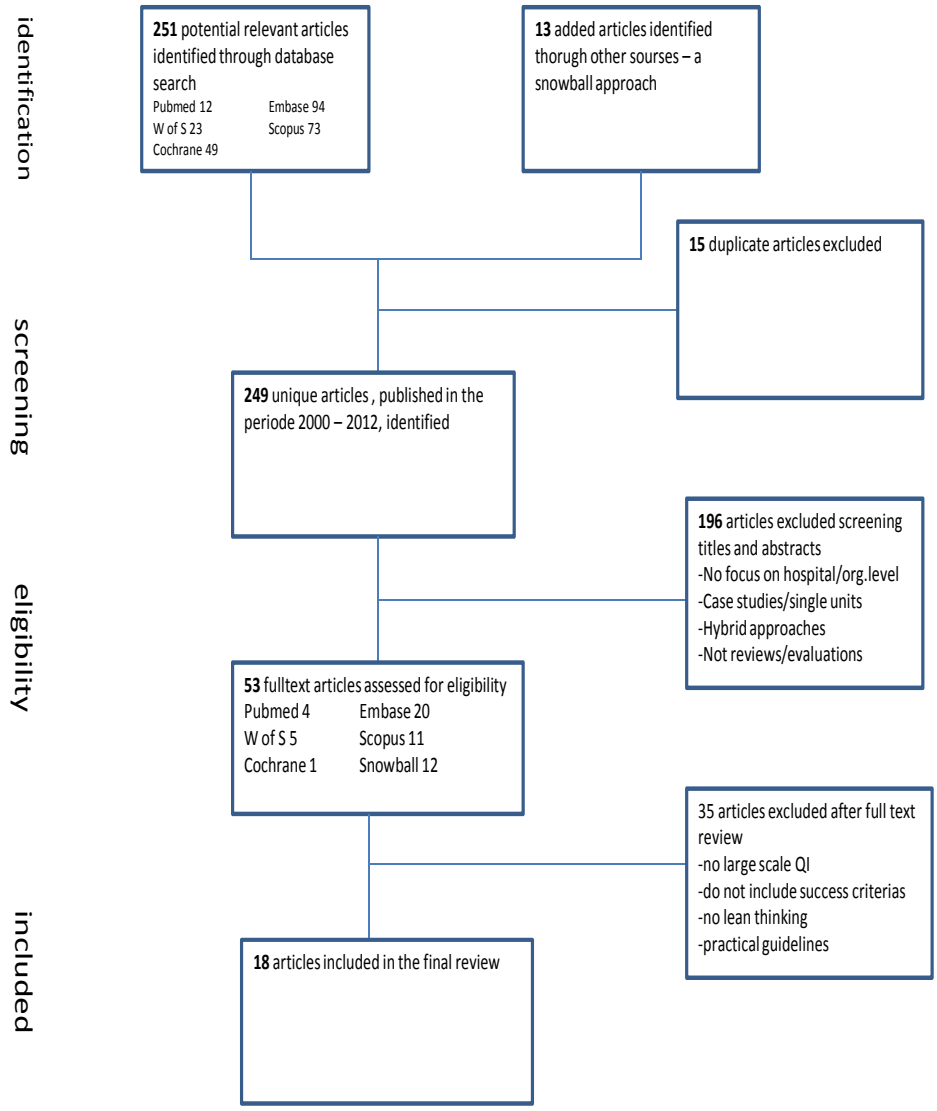
Funding: The PhD-study is founded by the regional health trust of North Norway, Helse Nord RHF

Competing interest: None

1. Joosten T, Bongers I, Janssen R. Application of lean thinking to health care: issues and observations. International Journal for Quality in Health Care 2009;**21**(5):341-47
2. Shortell SM. *Assessing the Implementation and Impact of Clinical Quality Improvement Efforts: Abstract, Executive Summary and Final Report*: Agency for Health Care Policy and Research, 1998.
3. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Affairs 2005;**24**(1):138-50
4. Rycroft-Malone J, Kitson A, Harvey G, et al. Ingredients for change: revisiting a conceptual framework. Quality & Safety in Health Care 2002;**11**:174 - 80
5. Young T, McClean S. A critical look at Lean Thinking in healthcare. Quality and Safety in Health Care 2008;**17**(5):382-86
6. Alexander JA, Hearld LR. What Can We Learn From Quality Improvement Research? A Critical Review of Research Methods. Medical Care Research and Review 2009 doi: 10.1177/1077558708330424[published Online First: Epub Date]|.
7. de Souza LB. Trends and approaches in lean healthcare. Leadership in Health Services 2009;**22**(2):121-39
8. Øvretveit J. Understanding the conditions for improvement: research to discover which context influences affect improvement success. BMJ quality & safety 2011;**20**(Suppl 1):i18-i23
9. Walshe K. Understanding what works—and why—in quality improvement: the need for theory-driven evaluation. International Journal for Quality in Health Care 2007;**19**(2):57-59
10. Øvretveit J, Gustafson D. Evaluation of quality improvement programmes. Quality and Safety in Health Care 2002;**11**(3):270-75
11. Liker JK, Kaisha TJKK. *The Toyota way: 14 management principles from the world's greatest manufacturer*: McGraw-Hill New York, 2004.
12. Womack JP, Jones DT. *Lean thinking: banish waste and create wealth in your corporation, revised and updated*: Free Press, 2003.
13. Mazzocato P, Savage C, Brommels M, et al. Lean thinking in healthcare: a realist review of the literature. Quality and Safety in Health Care 2010;**19**(5):376-82
14. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and studergroup's hardwiring excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. Implement Sci 2009;**4**(35):1-9
15. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**(sep29_1):a1655-a55
16. Perneger T. Ten reasons to conduct a randomized study in quality improvement. International Journal for Quality in Health Care 2006;**18**(6):395-96
17. Powell A, Rushmer R, Davies H. A systematic narrative review of quality improvement models in health care. Social Dimensions of Health Institute at The Universities of Dundee and St Andrews 2008
18. Altman DG, Bland JM. Statistics notes: Absence of evidence is not evidence of absence. BMJ 1995;**311**(7003):485 doi: 10.1136/bmj.311.7003.485[published Online First: Epub Date]|.
19. Corrigan JM. *Crossing the quality chasm*: Washington, DC, National Academy Press, 2001.
20. Kohn LT, Corrigan J, Donaldson MS. *To err is human: building a safer health system*: Joseph Henry Press, 2000.
21. Shortell SM, Rundall TG, Hsu J. Improving patient care by linking evidence-based medicine and evidence-based management. JAMA: the journal of the American Medical Association 2007;**298**(6):673-76
22. Walshe K, Freeman T. Effectiveness of quality improvement: learning from evaluations. Quality and Safety in Health Care 2002;**11**(1):85-87
23. KAPLAN HC, BRADY PW, DRITZ MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Quarterly 2010;**88**(4):500-59
24. Davidoff F. Systems of service: reflections on the moral foundations of improvement. BMJ quality & safety 2011;**20**(Suppl 1):i5-i10
25. Pawson R, Greenhalgh T, Harvey G, et al. Realist review–a new method of systematic review designed for complex policy interventions. Journal of health services research & policy 2005;**10**(suppl 1):21-34
26. Walshe K. Pseudoinnovation: the development and spread of healthcare quality improvement methodologies. International Journal for Quality in Health Care 2009;**21**(3):153-59
27. Radnor ZJ, Holweg M, Waring J. Lean in healthcare: The unfilled promise? Social Science & Medicine 2012;**74**(3):364-71
28. Grimshaw J, McAuley L, Bero L, et al. Systematic reviews of the effectiveness of quality improvement strategies and programmes. Quality and safety in health care 2003;**12**(4):298-303

29. Shortell SM, Bennett CL, Byck GR. Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. Milbank Quarterly 2001;**76**(4):593-624
30. Ingebrigtsen T, Lind M, Krogh T, et al. Merging of three hospitals into one university hospital. Tidsskrift for den Norske lægeforening: tidsskrift for praktisk medicin, ny række 2012;**132**(7):813
31. Vos L, Chalmers SE, Dückers MLA, et al. Towards an organisation-wide process-oriented organisation of care: A literature review. Implementation Science 2011;**6**(1):8
32. Weiner BJ. A theory of organizational readiness for change. Implement Sci 2009;**4**(1):67
33. Hart C. *Doing a literature review*. London: Sage Publications, 1998.
34. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS medicine 2009;**6**(7):e1000097
35. Poksinska B. The current state of Lean implementation in health care: literature review. Quality Management in Healthcare 2010;**19**(4):319
36. Brennan S, McKenzie J, Whitty P, et al. Continuous quality improvement: effects on professional practice and healthcare outcomes. The Cochrane Library 2009
37. de Souza LB, Pidd M. Exploring the barriers to lean health care implementation. Public Money & Management 2011;**31**(1):59-66
38. Kaplan HC, Provost LP, Froehle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ quality & safety 2012;**21**(1):13-20
39. Kim CS, MBA DAS, Billi JE. Creating value in health care: the case for lean thinking. JCOM 2009;**16**(12)
40. Kim CS, Spahlinger DA, Kin JM, et al. Implementation of Lean Thinking: one health system's journey. Joint Commission Journal on Quality and Patient Safety 2009;**35**(8):406-13
41. Lukas CVD, Holmes SK, Cohen AB, et al. Transformational change in health care systems: an organizational model. Health care management review 2007;**32**(4):309-20
42. Kollberg B, Dahlgaard JJ, Brehmer PO. Measuring lean initiatives in health care services: Issues and findings. International Journal of Productivity and Performance Management 2007;**56**(1):7-24
43. Winch S, Henderson AJ. Making cars and making health care: a critical review. Medical Journal of Australia 2009;**191**(7):415
44. Morrow E, Robert G, Maben J, et al. Emerald Article: Implementing large-scale quality improvement: Lessons þÿfromTheProductiveWard: ReleasingTimetoCare! Quality Assurance 2012;**25**(4):237-53
45. O'Brien JL, Shortell SM, Hughes EF, et al. An integrative model for organization-wide quality improvement: lessons from the field. Quality Management in Healthcare 1995;**3**(4):19-30
46. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Quarterly 2004;**82**(4):581-629
47. Rozenblum R, Lisby M, Hockey PM, et al. The patient satisfaction chasm: the gap between hospital management and frontline clinicians. BMJ quality & safety 2013;**22**(3):242-50
48. Hearld LR, Alexander JA, Fraser I, et al. Review: how do hospital organizational structure and processes affect quality of care? A critical review of research methods. Medical Care Research and Review 2008;**65**(3):259-99
49. West E. Management matters: the link between hospital organisation and quality of patient care. Quality in Health Care 2001;**10**(1):40-48
50. Bate P, Mendel P, Robert GB. *Organizing for quality: the improvement journeys of leading hospitals in Europe and the United States*: Radcliffe Publishing, 2008.

Appendix 1. *Flow chart, detailed search strategy (Web only)*



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<br>Training and responsibility to staff (empowerment)<br>Consultants/trainers from health care<br>Management support, ownership and resources<br>Organization culture<br>An holistic approach - lean is not a toolbox<br>Improve the entire system, involve several units<br>Adaption, not adoption<br>Clear view of the customer<br>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<br>Quality as part of everyday life/every ones work<br>Long time approach<br>Active health professionals/doctors engagement<br>Belief that staff/patient will benefit<br>Strong leadership and clear vision<br>Sustained active participation from board and senior management<br>Multifaceted interventions sustained action at different levels<br>Substantial investment in training and development (including IT and training of staff)<br>Support from ”change agents” to provide skills<br>Robust and timely data<br>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<br>Clinical leadership and involvement<br>Team-based problem solving<br>Adequate information and communication technology support<br>Administrative support<br>Ambitious targets<br>External facilitators<br>Organizational readiness<br>Selection and execution of projects in order of urgency<br>Using a change strategy that already proved to be successful<br>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<br>Competency in QI methods and tools<br>Alignment of QI activities with the organizations priorities<br>Management structures and systems that support QI, including appropriate data and analysis systems.<br>Leadership support for QI at all levels.<br>Ability to work as a team (team performance), team member participation,<br>Presence of a champion<br>Physician support and participation,<br>team members technical competence,<br>training in theory, methods, and tools,<br>support to facilitate implementation and use,<br>the nature and complexity of the targeted change |
| de Souza LB, Pidd M. 2011 | Review 90 articles | Lean.<br>Case studies. | Success factors | Clarify the nature of lean healthcare,<br>provide evidence that it works,<br>focus on patient processes,<br>translate it,<br>make a culture,<br>data – evidence based,<br>continuous improvement,<br>multidisciplinary teams across silos,<br>local performance measurement,<br>technical support,<br>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)<br>Project sponsorship (personnel, expertise, facilities from outside)<br>QI leadership (senior management board)<br>Senior leader project sponsor (to champion and support)<br>Culture support<br>Program maturity/sophistication of QI<br>Data infrastructure<br>Resource availability<br>Workforce QI focus/training/engaged<br>Micro system leadership (personally involved)<br>Culture support; teamwork, communication, freedom to improve<br>Capability (team ability to use QI methods)<br>Motivation/willingness<br>Team diversity<br>Physician involvement<br>Expert (subject matter) |

| | | | | |
|---|---|---|---|---|
| | | | | Team tenure (worked as a team before)<br>Prior QI experience<br>Team leadership<br>Team decision making processes<br>Team norms of behavior<br>Team QI skills<br>Trigger (a specific event stimulates a new emphasis)<br>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<br>Organizational culture<br>Organizational structure (clinical integration across departments)<br>Data infrastructure and information systems<br>Years involved in QI (experience)<br>Customer focus<br>Physician involvement<br>Micro system motivation to change<br>Resources for QI<br>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<br>Work across functional divides<br>Pursue value creation for patients<br>Nurture long term holistic culture of CQI<br>A need to improve<br>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<br>leadership - clinical champions and senior management support<br>frontline worker engagement in the QI processes<br>Use metrics to develop and track interventions<br>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<br>leadership commitment<br>Actively engage staff in meaningful problem solving<br>Alignment to achieve consistency of organization goals<br>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<br>active involvement and<br>multi-skilled teams |

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

| | | | | |
|---|---|---|---|---|
| | | | | Communication and feedback to staff and patients<br>Need for change, valuing the initiative<br>Simple, practical solutions to real problems<br>Accessibility of recourses and teaching modules<br>Self-nomination (units to take part)<br>Local ownership and empowerment<br>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.<br>Expert guidance for their initial projects.<br>A well-structured set of metrics, on a regular basis, readjusted<br>Aligning individual goals, projects, and metrics<br>Provide flexibility for frontline workers to experiment at the site and time they identify a problem.<br>Frontline management need to avail themselves to the area |

# PRISMA 2009 Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 3 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 1 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 3 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | 4 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | App1 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 3 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | App1 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | App1 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 4 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 3 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 12 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 4 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ for each meta-analysis. | 12 |

# PRISMA 2009 Checklist



| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 12 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 4 |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | App1, 2 |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | App2 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 12 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | - |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | - |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 12 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | - |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 12 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 12 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 13 |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 14 |

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.