



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

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

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50
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54 **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

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3 health care we should have is well documented[1 18 19]. In other words, the call for action is
4 still there, and, these obstacles to quality improvement must be crossed.

6 **Lean as social, complex and context-dependent interventions**

8 Shortell et al. (2007) emphasized the need to link evidence-based medicine and what they
9 refer to as evidence-based management, arguing that medicine must take into account the
10 complex organizational and social context in which care is delivered[20]. Such integration of
11 the intervention and its context seldom happens in quality improvement research[21].

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13 Lean interventions operate differently from the clinical interventions affecting biological
14 systems, in which a linear cause-effect relationship controlling the influence of context is
15 assumed. Context are simply defined as all surrounding factors that are not part of the
16 intervention itself[8 22]. However, the boundaries between the intervention and its
17 surroundings may be relatively arbitrary, as lean interventions are social, complex and
18 inherently context-dependent[23 24]. Lean interventions consist of multiple, reciprocally
19 interacting elements. They evolve over time in response to continuous feedback as situation
20 dependent cumulative processes, and are therefore intrinsically unstable and difficult to
21 standardize. Lean and other quality improvement methods are often adjusted, mixed,
22 implemented and used simultaneously[5 10 25 26]. This fact challenges the strict distinction
23 between lean and other quality improvement methods. Finally, lean interventions are open
24 systems that feed back on themselves, so that with learning, they may change the conditions
25 that made them work in the first place.
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38 There is a growing literature on lean facilitators. We observe a growing consensus that
39 characteristics like management, resources and culture matter, but the current knowledge base
40 lacks specification on when and how the different facilitators work. This vagueness partly rest
41 on insufficient methodological attention to the context in which lean interventions work. To
42 understand and assess variation in lean interventions success there is a need for a conceptual
43 framework defining facilitators for change at the stages and levels where they are activated.
44 These facilitators, also named enablers, determinants for effectiveness and so on, may be
45 defined as contextual factors which help the progress of lean interventions[8 21 27], and shift
46 the focus from cause-effect to conditional attributions.
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54 The University Hospital of North Norway underwent a complex merger and restructuring
55 process between 2007 and 2010[28]. An enterprise-wide comprehensive program for
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3 improvement of clinical pathways using lean methods was launched. The program aimed to
4 accomplish a quality improvement effort in parallel with the organizational change to
5 counteract the transitional setbacks in quality that large-scale change may entail[29]. A
6 research program was established to evaluate the effects. We identified a need for a
7 theoretical and methodological framework to analyse variation in adoption of lean
8 interventions at the hospital. The proposed framework represents a theoretical tool to
9 understand more of how and when lean interventions work. Our approach incorporates the
10 complex social and organizational context in which the interventions are applied and the
11 different stages of adoption. We suggest that the emerging knowledge could guide decision
12 makers considering lean interventions, assessing the organizations readiness for change[21].
13 The specific aim of the study was to identify factors influencing intended outcomes of lean
14 interventions, and to understand when and in which dimension different factors contribute.
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24 **METHODS**

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26 A systematic narrative review[30] of reviews of quality improvement in hospitals was
27 conducted. One reviewer performed the systematic review, supervised by the two co-authors.
28 Discrepancies were resolved by discussion involving all three authors. The initial inclusion
29 criteria were English language articles published in a peer-reviewed journal in the period
30 2000-2012. Search words included hospital, health care, quality improvement, lean thinking,
31 lean management, and review/evaluation. By searching Pubmed, Web of Science, Embase,
32 Cochrane and Scopus, 251 articles were identified. A snowball approach was used to search
33 for supplementary articles, adding 13 articles. 15 duplicate articles were removed. The titles
34 and abstracts of these 249 articles were screened according to the *Prisma guidelines* for
35 reporting reviews and meta analysis (supplementary file)[31]. 196 original articles were
36 excluded. Exclusion criteria included absence of a hospital or organizational focus, single-unit
37 case studies, and hybrid quality improvement approaches. As a result, 53 articles were
38 assessed for eligibility. After a full-text review, another 35 articles were excluded by the
39 criteria that neither large-scale quality improvement, success criteria or lean thinking were
40 issued. Articles that mainly represented practical guidelines also were excluded. The final
41 review included 18 articles[10 13 21 22 25 26 29 32-42].
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54 **Data analysis**

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3 The 18 articles were systematized according to the number of studies included in each review.
4 Eight articles reviewed a number of definite cases, varying from four to 90 (median 33). The
5 remaining articles were expert evaluations, narrative or unsystematic reviews, all covering
6 lean interventions in hospitals. Half of the articles review only lean interventions, while the
7 others include lean and corresponding methods like *Productive ward* and process oriented
8 redesign. Lean was extracted and treated separately as far as possible, though confined by the
9 observed mix, similarity and simultaneously use of different quality improvement methods in
10 hospitals[5 21 25 26]. Methods used in the original studies were qualitative, quantitative, or a
11 mixed-method approach. Most studies were based on cases originated in the United States,
12 Australia and Great Britain.
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21 The next step was to search for facilitators, defined as contextual factors predicted to promote
22 quality improvement, as opposed to barriers that hinder improvement[35]. The decision to
23 concentrate on facilitators and not barriers to lean improvement were based on the fact that
24 the research literature at this field chiefly pays attention to facilitators and not barriers[5 8 10
25 13 21 22 33 36]. In most cases, the facilitators were quite easy to identify in the texts despite
26 different annotations used, including *enablers, conditions, factors* and *key facilitators, critical*
27 *elements, determinants of effectiveness, and contextual characteristics*. Using the method of
28 feature maps, which enable localization of similarities and differences among studies[30], the
29 articles were systematically analyzed and recorded in a standardized format, according to the
30 facilitators. The procedure were conducted by creating a worksheet categorizing every paper
31 according to author, year of publishing, kind of review, supplementary quality improvement
32 methods (in addition to lean), research method, labelling of facilitators, and facilitating
33 factors. The complete worksheet is attached as a supplementary file.
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45 All the identified facilitators were assigned to larger categories. This classification was done
46 to develop a more specific and practically focused state of knowledge concerning facilitators
47 for lean thinking, as the need for an overview necessitated reducing the information to
48 manageable amounts. All the identified facilitators concerning management and leadership
49 were placed in the category *management*, covering subjects like management support,
50 commitment and ownership. Cultural issues were all categorized as *supportive culture*,
51 including views, norms and beliefs supporting lean. All facilitators concerning local
52 translation were put in the category *adaption*, as all facilitators dealing with prior involvement
53 in quality improvement work were grouped under the heading *experience*, and so on. After
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3 examining all the 149 facilitators, grouping them with similar ones, we ended up with a list
4 comprising 23 facilitators. The different facets of these facilitators are all listed in box 1
5 below. Finally, the frequency of each of the facilitators in the 18 reviews was accounted for.
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9 10 **A theoretical and methodological framework**

11 Lean interventions consist of several different phases, from planning and preparation to
12 implementation and sustainability, involving different organizational capabilities. The
13 facilitators for improvement were analyzed and reorganized in a table combining Shortell's
14 *dimensions of capability*[243], and Walshe's *domains of an intervention*[9]. Shortell
15 categorized improvement factors according to cultural, technical, strategic, and structural
16 dimensions of an intervention. The *cultural* dimension refers to the underlying beliefs, values,
17 norms and behaviours of the organization. The *technical* dimension covers training and
18 information system issues, while the *strategic* dimension emphasizes the conditions that offer
19 the greatest opportunities to change. This dimension touch upon the degree of integration of
20 quality improvement in the hospital's strategic plans, and to which extent improvement efforts
21 are devoted to processes central to strategic priorities. The *structural* dimension relate to
22 mechanisms that facilitate learning and disseminate best practices throughout the
23 organization. The four dimensions are multiplicative, interrelated, and equally necessary for
24 lasting quality improvement according to Shortell. Varying lean success can be understood as
25 a result of the interplay of dynamic processes related to the four dimensions[43].
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38 Walshe's differentiated domains or phases in quality interventions are labelled as context,
39 content, application and outcomes. The context involves the preparation phase before starting
40 improvement work, highlighting aspects of the situation, setting or organization in which the
41 intervention is deployed. This is a narrow view of context, and should not be confused with
42 the broader understanding of context as all surrounding factors that are not part of the
43 technical intervention itself[8]. In this article, we therefore renamed this phase as the
44 organizational *setting*. The *content* describes the phase where lean is introduced as a tool, the
45 nature or characteristics of the intervention itself. The content of lean may be standardized
46 and repeatable or modified and easy to redesign. The *application* covers the process through
47 which the intervention is delivered. This process may be protocol-driven or widely varying
48 depending on local actors. *Outcomes* are the results of the intervention, including the
49 maintenance phase after implementation. All of these phases may be characterized by low or
50 high variance. High levels of variance in the settings, content and application may explain
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3 interventions varying success. Variances also reduce the ability to generalize empirically, and
4 to draw conclusions about effects from one specific context to another. The complex
5 relationship between context, content, application and outcomes must be unpicked to develop
6 a situational understanding of effectiveness[9].
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11 By combining Shortell's dimensions and Walshe's domains, this two-dimensional framework
12 made it possible to classify identified facilitators for quality improvement, both as emerging
13 in different phases in a multistage process and by different organizational dimensions. The
14 framework was used to describe and understand the organizational and contextual factors
15 encountered in an organizational-wide quality improvement effort.
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20 21 **RESULTS**

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

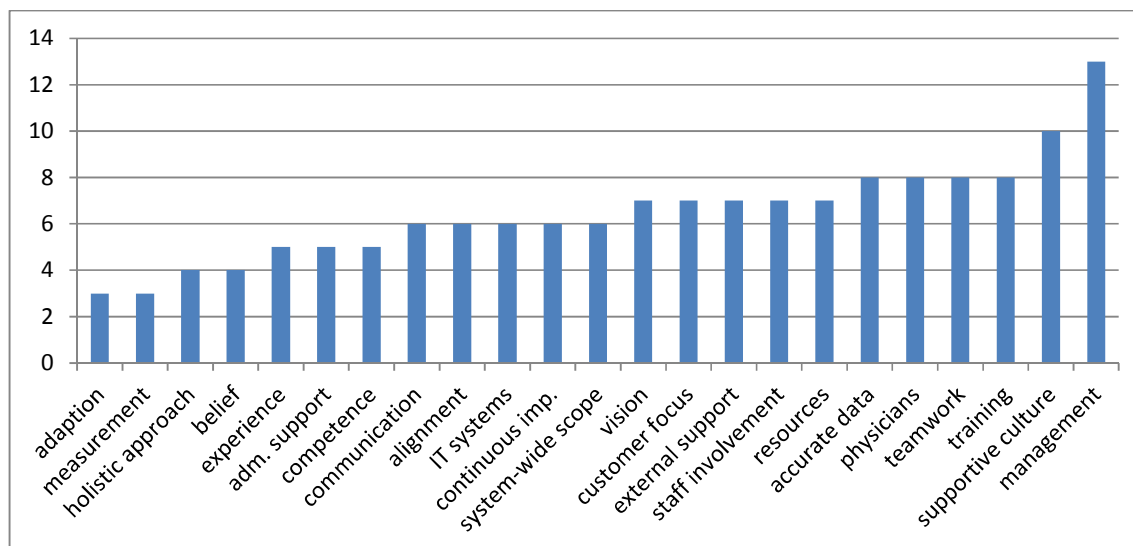


Table 1 show how the different facilitators were found relevant in the different intervention phases and affected organizational dimension.

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
<i>Cultural</i> Underlying beliefs, values, norms and behavior	Experience Belief	Adaption Customer focus	Teamwork	Supportive culture
<i>Technical</i> Training and info support systems	IT systems Competence	Training	Administrative support	Communication
<i>Strategic</i> Strategic importance and opportunity to change	Alignment Vision	Resources	Physicians Management	Holistic approach Continuous improvement
<i>Structural</i> Mechanisms to facilitate learning and disseminate best practices	External support	Accurate data	Staff involvement	Measurement System-wide scope

Setting: Situation and organization.

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3 Initially, a well-proven, successful quality improvement method characterized by program
4 maturity facilitates. Prior experience are enabling improvement[22 29 35]. Lean should be
5 accompanied by success stories demonstrating benefits for patients and staff. This relates to
6 the organization's cultural capability and the influence of the underlying beliefs, values,
7 norms, and behaviours. Motivation influences the willingness to participate[13 33 35 36 38 39
8 42]. IT-systems infrastructure and competence[22 29 33-36], as well as external experts
9 sponsoring, strengthen the technical and structural capability. Sponsorship triggers learning
10 and may contribute to dissemination of best practices throughout the organization[29 32 33
11 36-38 42]. Competence in tools and methods support the assumptions of lean, and increase
12 the potential for change[25 26 34 36]. Ambitious targets aligned with the hospital's overall
13 goals and strategies strengthen the strategic capability[29 33 34 36 39 42]. The goals have to
14 be of strategic importance, but at the same time realistic, based on simple and practical
15 solutions[21 29 33 34 38 42].
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26 **Content: Characteristics of the intervention**

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28 Adaption and translation to local conditions are a precondition for success[25 32 35]. A
29 methodology communicating a clear patient and workforce focus supports the cultural
30 dimension. Emphasis on patient processes, value creation, and patient needs facilitate quality
31 improvement in health care[10 13 22 32 35 40 42]. Access to, and accomplished substantial
32 training in methods and tools strengthens the organizations technical capability[10 21 25 29
33 32-34 36 42], as sufficient and available resources affect the strategic dimension[10 21 22 29
34 32-34 36 42]. On the structural dimension, accurate and robust data represent an impetus to
35 learning and spread of best practices. Timely data contribute to an evidence-based quality
36 improvement initiative, which facilitates lean interventions[13 33-35 37 38 42]. Availability
37 and sufficiency of training, data and other resources are among the most frequent facilitators
38 in the reviewed articles, and thereby among the most important drivers for change.
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48 **Application: Local delivery process**

49 Collaborating multidisciplinary and multi-skilled teams strongly facilitate local application of
50 lean[22 29 32 34-36 40 41]. Strengthening the improvement culture presupposes workforce
51 stability, team leadership, and decentralized decision making. Administrative project
52 management and practical support secures backing, and contributes to the technical capability
53 of the organization[21 29 34 42]. Strategically, involvement of physicians and management
54 encourage change. Management engagement include both frontline and senior managers[10
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3 13 21 22 29 32-34 36-40 42]. Physicians represent champions and clinical leadership, and
4 their involvement, engagement, and collaboration are crucial at the strategic level[10 22 29 33
5 34 36 38 41]. Both management and physicians involvement are among the most frequent
6 identified enablers of quality improvement in the literature. Key factors to disseminate best
7 practices are staff participation, engagement, and empowerment. Staff commitment,
8 responsibility and ownership, are required for achieving lasting outcomes of lean
9 interventions[25 32 36-40 42].
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14 15 16 **Outcomes: Results and maintenance**

17 To secure maintenance, a hospital depends strongly on a supportive culture characterized by
18 norms and beliefs supporting quality improvement and readiness[10 21 22 32 34-36]. At the
19 technical dimension, communication and feedback between patients and staff are
20 facilitating[29 32 36 41 42]. Strategically, a holistic approach based on continuous
21 improvement and sustained attention affect the ability to accomplish change. A holistic
22 approach emphasizes that lean is a tool not only to promote everyday improvement but also a
23 philosophy of ongoing quality improvement within the hospital's value system[13 26 32 33
24 39]. A long-term plan should be established to secure continuous improvement[10 13 25 26
25 33 35]. Local audits and measurements conducted on a regular basis relate to the
26 organization's structural capability, which strengthen the evidence for lean interventions[34
27 35 37 38]. A system-wide multifaceted approach, across functional divides, allows best
28 practices to be learned and disseminated.
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39 In addition to a supportive culture, the most frequent facilitators are identified in the *content*
40 and local *application* parts of the intervention. That is, the most reported success-factors for
41 lean, touch upon characteristics of the intervention and its local delivery process. Most of the
42 frequent facilitators concern the *strategic* or the *cultural* dimension of capability,
43 interventions strategic importance to the hospitals overall goals and the organizations
44 underlying beliefs, values, norms and behavior.
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51 **DISCUSSION**

52 Analysis based on the conceptual framework suggest that understanding which facilitators
53 influence the intervention at different stages and dimensions of capability, probably is more
54 important than a quantitative approach[8 33]. The emphasis on the interventions different
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3 parts and the organizational dimensions represent a shift from cause-effect to conditional
4 attributions[43]. Each part and dimension is influenced by the status of other dimensions. Our
5 results summarized in table 1 show that a number of facilitators representing the four
6 dimensions may interact during the four stages of change. The four dimensions and the
7 associated facilitators are interrelated and equally necessary to achieve lasting results[2]. In
8 the following, we elaborate our interpretation of these findings.
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14 Rycroft-Malone et al (2002) concludes that there are three key elements of implementation:
15 evidence, facilitation and context[44]. Our analyses of data from previous review articles
16 within this new framework show that successful lean interventions share some common
17 features. We identified 23 facilitators associated with successful interventions. However, it is
18 evident that little is known about which facilitators that are most important[8 21].
19 Management and leadership engagement was identified as important by 13 of the 18 reviewed
20 reviews. The other facilitators most frequently identified were a supportive culture, accurate
21 data and training, along with physician and team involvement. This is in accordance with the
22 conclusions from recent research in the field, and may indicate that these facilitators are vital
23 to accomplish quality improvement[13 22 29 32]. Two recent reviews conclude that
24 leadership, culture, maturity, and data infrastructure have a stronger evidence base than
25 others[22 36]. Our results nevertheless suggest that successful interventions must utilise
26 multiple facilitators from the four dimensions of capability, interplaying as the change
27 processes go through its four stages. The observation that the facilitators identified in this
28 study were in accordance with those promoted in other, broader theories of implementation
29 concerning uptake of evidence and innovations in health care[22 44 45] strengthen the
30 findings.
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44 The most frequent facilitators belong to the *content* or *application* part of the intervention.
45 This may indicate that policymakers should pay special attention to the content of lean and the
46 local delivery process. Sufficient resources, accurate data and training are crucial for lean
47 interventions to succeed. Lean are not a receipt that can be implemented locally if the training
48 or available resources are inadequate. The need for local resource allocation should not be
49 underestimated. This is in accordance to Radnor et al (2012), that advocate that lean
50 interventions must be contextualized, rather than transplanted like a recipe[26].
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3 This assertion is supported by the frequently identified facilitators labelled physicians and
4 management. Leadership and clinical leadership are keys to understand why, or why not, lean
5 interventions make contributions to health care[46]. Finally, the local application of lean in
6 hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-
7 floor staff must be engaged and empowered. Womack and Jones (2003) that initially
8 advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main
9 advantage for hospitals, making lean suitable for health care[12].
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16 The cultural and strategic dimensions of capability embrace most of the frequent facilitators.
17 A supportive culture are fundamental to achieve quality improvements[36]. The
18 organizational culture and the strategic importance of the patient path exposed to the
19 improvement initiative are essential to understand variation in outcomes of lean interventions.
20 Available resources, physicians and managements involvement, indicate and affect the
21 strategic importance and thereby the opportunity to change. This finding are supported by
22 other recent hospital-based studies, like Rozenblum et al (2013)[46].
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30 The main contribution of this review is a two-dimensional framework for identification and
31 analysis of facilitators for lean interventions in health care. This framework incorporates the
32 complex social and organizational context in which lean are applied. These findings coincide
33 with recent research calling for more attention to the influence of organizational context when
34 trying to understand variance in interventions in healthcare[22]. We suggest that it will prove
35 useful in future research aiming for a better understanding of how the likelihood to
36 accomplish success in lean interventions can be increased[14]. The framework will also be
37 used in future research locally at the hospital, as a practical tool to assess variation in adoption
38 of lean.
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46 **Limitations**

47 Making these interpretations from a systematic review of reviews must take the methods
48 limitations into consideration. The facilitators were grouped with similar ones, and sometimes
49 renamed, risking that the original meaning could be misread and mistranslated. Conducting
50 feature maps and presenting all the identified facilitators in appendices promote transparency.
51 Further on, it could be argued that facilitators identified in large reviews should be given more
52 weight than those identified in smaller ones. However, our analysis identified the same
53 facilitators across small and large reviews. Therefore, weighting was not conducted.
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3 And finally, including both qualitative and quantitative studies eliminates the possibility of
4 quantifying the findings and predicting effects of the various facilitators by meta-analysis.
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6 The inclusion of both types of studies broadens the scope, increase the ability to identify an
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8 ampler spectre of facilitators, and contribute to understanding the role of context in lean
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10 interventions.

11 12 13 **Directions for future research**

14 A critical review concluded that most of the research on hospital quality is dominated by
15 questions of *what* and does not go further to investigate the *how*, *when*, and *why*[47]. They
16 called for approaches that incorporate structure, process, and outcomes. The fact that we
17 know so little about the relationship between these, makes it difficult to recommend ways of
18 organizing that could improve patient care[48].
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24 The facilitators identified and the two-dimensional framework proposed in the present work
25 incorporates structure and process. Still, the facilitators are characterized by vagueness, as
26 broad and comprehensive determinants, that needs further specification and practical content
27 to guide future effective quality improvements to health care organizations[21]. A logical next
28 step will be to measure and analyse outcomes in the context of this framework, with the
29 identified facilitators as explanatory variables. Possible measures of outcomes could be
30 related to the health care providers performance (adherence to recommended practice), patient
31 outcome (as quality of life or mortality), surrogate outcomes (as readmission) and
32 organizational outcomes (like resource use or sustainability)[34]. At the University Hospital
33 of North Norway, more than five years of lean experience and more than 20 implemented lean
34 interventions leave us with a sufficient amount of empirically based cases to assess due to
35 varying success.
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46 **CONCLUSION**

47 We provide a framework, which emphasizes the importance of context by relating facilitators
48 to four dimensions of organizational capability and four stages of change, and suggest that
49 this represent a practical tool for understanding and assessing variation in lean adoption. The
50 article can contribute to reduce the gap between theory and practice, by a shift in focus from
51 cause-effect to conditional attributes or characteristics of an effective organization-wide
52 quality intervention. The review of reviews identified 23 interrelated facilitators for lean in
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3 hospitals, where management engagement, cultural support, accurate data and training, along
4 with teamwork, physician and staff involvement were most frequent. The findings suggest
5 that characteristics of lean and the local application should be given attention, in addition to
6 the organizations cultural and strategic capability.
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10
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20 revising of the article. All the authors have provided final approval of the submitted
21 manuscript.
22
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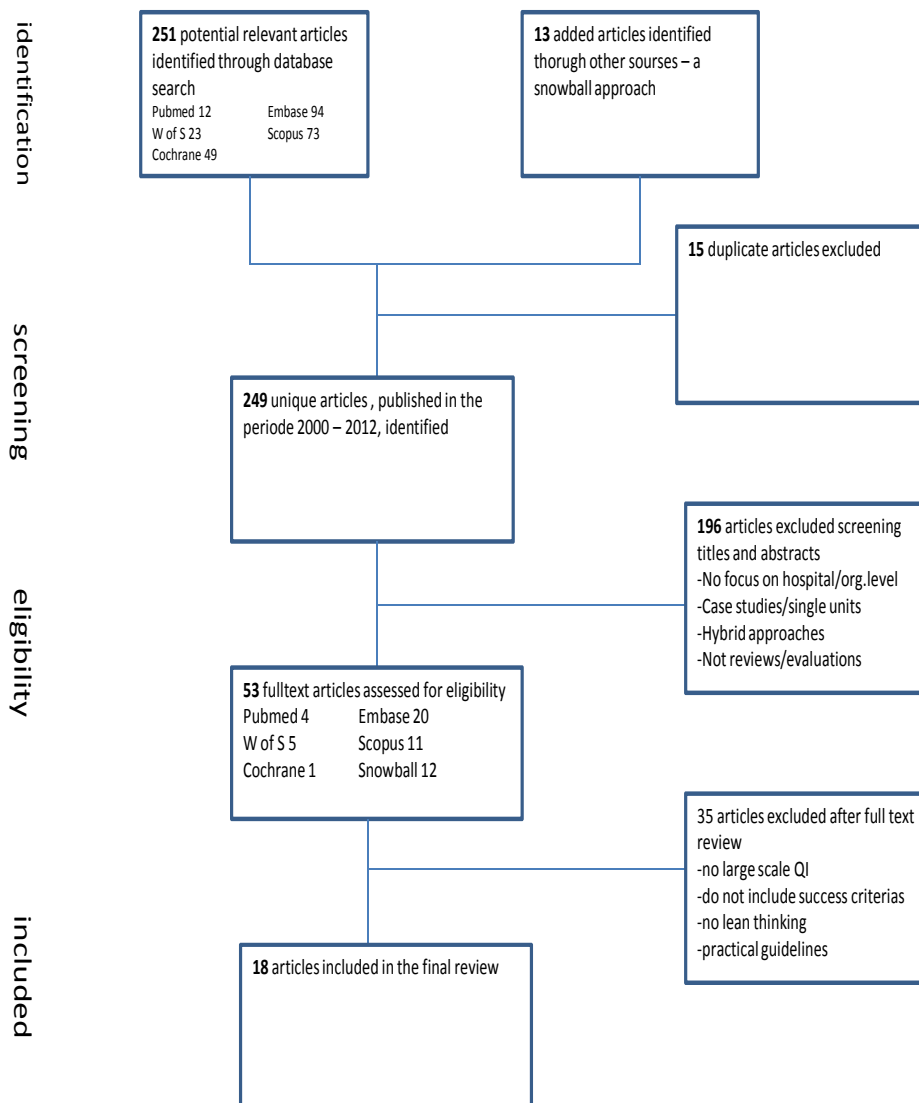
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Appendix 1. Flow chart, detailed search strategy (Web only)



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

Author/ year	Review/ size	QI/ research method	Labels	Factors
Poksinska B. 2010	Review 30 articles	Lean. Theoretical/ case studies.	Enablers	<ul style="list-style-type: none"> Commitment/participation from staff that owns and drives it Training and responsibility to staff (empowerment) Consultants/trainers from health care Management support, ownership and resources Organization culture An holistic approach - lean is not a toolbox Improve the entire system, involve several units Adaption, not adoption Clear view of the customer Teamwork, collaboration and communication
Powell A, Rushmer R, Davies H. 2008.	Review 59 articles	QI, including Lean. Observation, interviews, action research.	Necessary but not sufficient conditions for successful implementation	<ul style="list-style-type: none"> Alignment with strategic objectives Quality as part of everyday life/every ones work Long time approach Active health professionals/doctors engagement Belief that staff/patient will benefit Strong leadership and clear vision Sustained active participation from board and senior management Multifaceted interventions sustained action at different levels Substantial investment in training and development (including IT and training of staff) Support from "change agents" to provide skills Robust and timely data Resources
Vos L, Chalmers SE, Dückers MLA et al. 2011	Review 10 articles	Process oriented redesign including Lean. Uncontrolled before-after evaluations.	Factors for success	<ul style="list-style-type: none"> Senior management support Clinical leadership and involvement Team-based problem solving Adequate information and communication technology support Administrative support Ambitious targets External facilitators Organizational readiness Selection and execution of projects in order of urgency Using a change strategy that already proved to be successful Good communication and training in QI techniques

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

				<ul style="list-style-type: none"> Team tenure (worked as a team before) Prior QI experience Team leadership Team decision making processes Team norms of behavior Team QI skills Trigger (a specific event stimulates a new emphasis) Tasks strategic importance to the organization
Kaplan HC, Brady PW, Dritz MC, et al 2010	Review 47 articles	QI including Lean. Observation, controlled design, meta-analysis.	Factors important for QI success	<ul style="list-style-type: none"> Leadership from top management/board Organizational culture Organizational structure (clinical integration across departments) Data infrastructure and information systems Years involved in QI (experience) Customer focus Physician involvement Micro system motivation to change Resources for QI QI team leadership
Mazzocato P, Savage C, Brommels M et al. 2010	review 33 articles	Lean. Qualitative and quantitative.	Contextual characteristics of relevance	<ul style="list-style-type: none"> Senior management involvement Work across functional divides Pursue value creation for patients Nurture long term holistic culture of CQI A need to improve A willingness to improve
Kim CS, Spahlinger DA, Kin JM et al. 2009	UMHS-USA evaluasjon	Lean. Qualitative and quantitative.	Key factors	<ul style="list-style-type: none"> Expert guidance for initial efforts leadership - clinical champions and senior management support frontline worker engagement in the QI processes Use metrics to develop and track interventions Define a realistic project scope
Lukas CVD, Holmes SK, Cohen AB et al. 2007	12 healthcare system doc. review	QI including Lean Longitudinal case-studies, mixed method evaluation.	Interactive elements that appear critical to successful transformation of patient care	<ul style="list-style-type: none"> Impetus to transform leadership commitment Actively engage staff in meaningful problem solving Alignment to achieve consistency of organization goals Integration to bridge traditional intra-organizational boundaries among individual components.
Kollberg B, Dahlgaard JJ, Brehmer PO. 2007	Unsystematic review	QI including Lean. Qualitative and quantitative.	Critical success factors	<ul style="list-style-type: none"> patient focus active involvement and multi-skilled teams

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

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				<ul style="list-style-type: none"> Communication and feedback to staff and patients Need for change, valuing the initiative Simple, practical solutions to real problems Accessibility of recourses and teaching modules Self-nomination (units to take part) Local ownership and empowerment Sufficient resources, support and time (staff cover)
Kim CS, MBA, DAS, Billi JE. 2009	Unsystematic review	Lean. Qualitative and quantitative.	Critical Elements	<ul style="list-style-type: none"> Senior management support. Expert guidance for their initial projects. A well-structured set of metrics, on a regular basis, readjusted Aligning individual goals, projects, and metrics Provide flexibility for frontline workers to experiment at the site and time they identify a problem. Frontline management need to avail themselves to the area



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

Page 1 of 2

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.

Page 2 of 2
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**Lean thinking in hospitals: Is there a cure for the absence of evidence?
A systematic review of reviews**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003873.R1
Article Type:	Research
Date Submitted by the Author:	13-Dec-2013
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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

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

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47 Australian Institute of Health Innovation

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49 University of New South Wales, Sydney Australia

50 **Key words:**

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

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54 **Word-count:** 3819
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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

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3 findings from one setting to another. Is there a cure for this lack of evidence? On a paramount
4 level, one must ask whether absence of evidence justifies inaction[18]. The *quality chasm*
5 between the health care we have and the health care we should have is well documented[19
6 20]. In other words, the call for action is still there, and, these obstacles to quality
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8 improvement must be crossed.
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10 11 **Lean as social, complex and context-dependent interventions**

12 Shortell et al. (2007) emphasized the need to link evidence-based medicine and what they
13 refer to as evidence-based management, arguing that medicine must take into account the
14 complex organizational and social context in which care is delivered[21]. Such integration of
15 the intervention and its context seldom happens in quality improvement research[22].
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18 Lean interventions operate differently from the clinical interventions affecting biological
19 systems, in which a linear cause-effect relationship controlling the influence of context is
20 assumed. Context are simply defined as all surrounding factors that are not part of the
21 intervention itself[8 23]. However, the boundaries between the intervention and its
22 surroundings may be relatively arbitrary, as lean interventions are social, complex and
23 inherently context-dependent[24 25]. Lean interventions consist of multiple, reciprocally
24 interacting elements. They evolve over time in response to continuous feedback as situation
25 dependent cumulative processes, and are therefore intrinsically unstable and difficult to
26 standardize. Lean and other quality improvement methods are often adjusted, mixed,
27 implemented and used simultaneously[5 10 26 27]. This fact challenges the strict distinction
28 between lean and other quality improvement methods. Finally, lean interventions are open
29 systems that feed back on themselves, so that with learning, they may change the conditions
30 that made them work in the first place.
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43 There is a growing literature on lean facilitators. According to Grimshaw et al, systematic
44 reviews provide the best evidence on the effectiveness of quality improvement[28]. We
45 observe a growing consensus that characteristics like management, resources and culture
46 matter, but the current knowledge base lacks specification on when and how the different
47 facilitators work. This vagueness partly rest on insufficient methodological attention to the
48 context in which lean interventions work. To understand and assess variation in lean
49 intervention success, there is a need for a conceptual framework defining facilitators for
50 change at the stages and levels where they are activated. These facilitators, also named
51 enablers, determinants for effectiveness and so on, may be defined as contingency factors
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3 which help the progress of lean interventions[8 22 29], and shift the focus from cause-effect
4 to conditional attributions.
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8 The University Hospital of North Norway underwent a complex merger and restructuring
9 process between 2007 and 2010[30]. An enterprise-wide lean program for improvement was
10 launched. The program aimed to accomplish quality improvement in parallel with the
11 organizational change to counteract the transitional setbacks in quality that large-scale change
12 may entail[31]. A research program was established to evaluate the effects. The proposed
13 framework represents a theoretical tool to understand more of how and when lean
14 interventions work at the hospital. Our approach incorporates the complex social and
15 organizational context in which the interventions are applied and the different stages of
16 adoption. We suggest that the emerging knowledge could guide decision makers considering
17 lean interventions, assessing the organizations' readiness for change[22 32]. The specific aim
18 of the study was to identify contingency factors influencing intended outcomes of lean
19 interventions, and to understand when and in which dimension different factors contribute.
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29 30 **METHODS**

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32 A systematic narrative review[33] of reviews of quality improvement in hospitals was
33 conducted. One reviewer performed the systematic review, supervised by the two co-authors.
34 Any confusion was resolved by discussion involving all three authors. The initial inclusion
35 criteria were English language articles published in a peer-reviewed journal in the period
36 2000-2012. Search words included hospital, health care, quality improvement, lean thinking,
37 lean management, and review/evaluation. By searching Pubmed, Web of Science, Embase,
38 Cochrane and Scopus, 251 articles were identified. A snowball approach was used to search
39 for supplementary articles, adding 13 articles. 15 duplicate articles were removed. The titles
40 and abstracts of these 249 articles were screened according to the *Prisma guidelines* for
41 reporting reviews and meta analysis (supplementary file)[34]. 196 original articles were
42 excluded. Exclusion criteria included absence of a hospital or organizational focus, single-unit
43 case studies, and hybrid quality improvement approaches. As a result, 53 articles were
44 assessed for eligibility. After a full-text review, another 35 articles were excluded by the
45 criteria that neither large-scale quality improvement, success criteria or lean thinking were
46 issued. Articles that mainly represented practical guidelines were also excluded. The final
47 review included 18 articles[10 13 17 22 23 26 27 31 35-44].
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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*,

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3 including views, norms, beliefs and behaviours supporting the principles and practice of
4 quality improvement. All facilitators concerning local translation were put in the category
5 *adaptation*, as all facilitators dealing with prior involvement in quality improvement work were
6 grouped under the heading *experience*, and so on. After examining all the 149 facilitators,
7 grouping them with similar ones, we ended up with a list comprising 23 facilitators. The
8 different facets of these facilitators are all listed in box 1 below. Finally, the frequency of each
9 of the facilitators in the 18 reviews was accounted for.
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15 16 **A theoretical and methodological framework**

17 Lean interventions consist of several different phases, from planning and preparation to
18 implementation and sustainability, involving different organizational capabilities. The
19 facilitators for improvement were analyzed and reorganized in a table combining Shortell's
20 *dimensions of capability*[245], and Walshe's *domains of an intervention*[9]. Shortell
21 categorized improvement factors according to cultural, technical, strategic, and structural
22 dimensions of an intervention. The *cultural* dimension refers to the underlying beliefs, values,
23 norms and behaviours of the organization. The *technical* dimension covers training and
24 information system issues, while the *strategic* dimension emphasizes the conditions that offer
25 the greatest opportunities to change. This dimension touch upon the degree of integration of
26 quality improvement in the hospital's strategic plans, and to which extent improvement efforts
27 are devoted to processes central to strategic priorities. The *structural* dimension relate to
28 mechanisms that facilitate learning and disseminate best practices throughout the
29 organization. The four dimensions are multiplicative, interrelated, and equally necessary for
30 lasting quality improvement according to Shortell. Varying lean success can be understood as
31 a result of the interplay of dynamic processes related to the four dimensions[45].
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44 Walshe's differentiated domains in quality interventions are labelled as context, content,
45 application and outcomes. The context involves the situation, setting or organization in which
46 the intervention is deployed. Context may vary widely, both within and between hospitals.
47 The *content* describes the the nature or characteristics of the intervention itself. The content of
48 lean may be standardized and repeatable or modified and easy to redesign. The *application*
49 covers the process through which the intervention is delivered. This process may be protocol-
50 driven or widely varying depending on local actors. *Outcomes* are the results of the
51 intervention, including the maintenance phase after implementation. All of these domains may
52 be characterized by low or high variance. High levels of variance in the settings, content and
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3 application may explain interventions varying success. Variances also reduce the ability to
4 generalize empirically, and to draw conclusions about effects from one specific context to
5 another. The complex relationship between context, content, application and outcomes must
6 be unpicked to develop a situational understanding of effectiveness[9].
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11 By combining Shortell's dimensions and Walshe's domains, this two-dimensional framework
12 made it possible to classify identified facilitators for quality improvement, both as emerging
13 in different domains in a multistage process and by different organizational dimensions. The
14 framework was used to describe and understand the contextual factors encountered in an
15 organizational-wide quality improvement effort.
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20 21 **RESULTS**

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

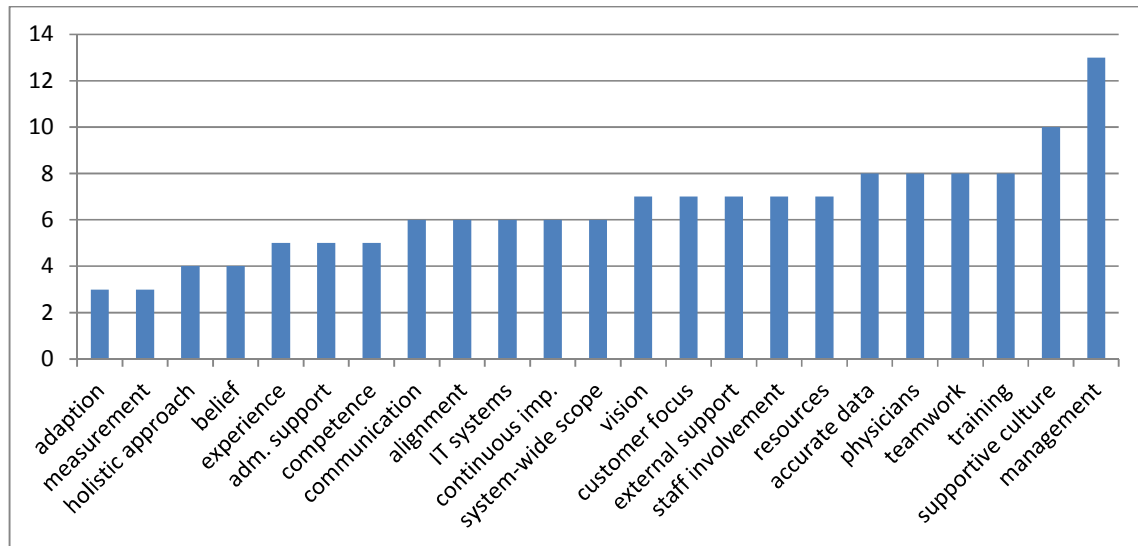
Training: Accessible, substantial, practical and relevant training for immediate use

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

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

Context: Situation and organization.

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3 Prior experience, accompanied by success stories demonstrating benefits for patients and
4 staff, enables improvement[23 31 37]. This relates to the organization's cultural capability
5 and the influence of the underlying beliefs, values, norms, and behaviours. Motivation
6 influences the willingness to participate[13 17 37 38 40 41 44]. IT-systems infrastructure and
7 competence[17 23 31 36-38], as well as external experts sponsoring, strengthen the technical
8 and structural capability. Sponsorship triggers learning and contribute to dissemination of best
9 practices throughout the organization[17 31 35 38-40 44]. Competence in tools and methods
10 support the assumptions of lean, and increase the potential for change[26 27 36 38].

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16 Ambitious targets aligned with the hospital's overall goals and strategies strengthen the
17 strategic capability[17 31 36 38 41 44]. The goals have to be of strategic importance, but at
18 the same time realistic, based on simple and practical solutions[17 22 31 36 40 44].
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22 23 **Content: Characteristics of the intervention**

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25 Adaption and translation to local conditions are a precondition for success[26 35 37]. A
26 methodology communicating a clear patient and workforce focus supports the cultural
27 dimension. Emphasis on patient processes, value creation, and patient needs facilitate quality
28 improvement in health care[10 13 23 35 37 42 44]. Access to, and accomplished substantial
29 training in methods and tools strengthens the organizations technical capability[10 17 22 26
30 31 35 36 38 44], as sufficient and available resources, financial as well as staff time, affect the
31 strategic dimension[10 17 22 23 31 35 36 38 44]. On the structural dimension, accurate and
32 robust data represent an impetus to learning and spread of best practices. Timely data
33 contribute to an evidence-based quality improvement initiative[13 17 36 37 39 40 44].
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3 44]. Physicians represent champions and clinical leadership, and their involvement,
4 engagement, and collaboration are important at the strategic level as role models and peers for
5 others[10 17 23 31 36 38 40 43]. Both management and physicians involvement are among
6 the most frequent identified enablers jointly with teamwork. Key factors to disseminate best
7 practices are staff participation, engagement, and empowerment. Staff commitment,
8 responsibility and ownership, are required for achieving lasting outcomes [26 35 38-42 44].
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13 **Outcomes: Results and maintenance**

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15 To secure maintenance, a hospital depends first and foremost on a supportive culture
16 characterized by norms, beliefs and behaviours supporting the principles and practice of
17 quality improvement [10 22 23 35-38]. In a supportive culture, employees feel that they can
18 make use of their skills and creativity, take initiative, and cause things to happen [35]. At the
19 technical dimension, communication and feedback between patients and staff are enablers [31
20 35 38 43 44]. Strategically, a holistic approach based on continuous improvement and
21 sustained attention affect the ability to accomplish change. A holistic approach emphasizes
22 that lean is a strategy not only to promote everyday improvement but also a philosophy of
23 ongoing quality improvement within the hospital's value system[13 17 27 35 41]. A long-
24 term plan should be established to secure continuous improvement[10 13 17 26 27 37]. Local
25 audits and measurements conducted on a regular basis relate to the organization's structural
26 capability, which strengthen the evidence for lean interventions[36 37 39 40]. A system-wide
27 multifaceted approach, across functional divides, allows best practices to be learned and
28 disseminated.
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41 Analysis based on the conceptual framework suggest that understanding which facilitators
42 influence the intervention at different domains and dimensions of capability, is probably more
43 important than a quantitative approach[8 17]. This represent a shift from cause-effect to
44 conditional attributions[45]. Each domain and dimension is influenced by the status of other
45 ones. Our results summarized in table 1 indicate that a number of facilitators may interact
46 within and between the domains and dimensions. The four dimensions, domains and the
47 associated facilitators are interrelated and probably all necessary to achieve lasting results[2].
48 Finally, we elaborate our interpretation of these findings.
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56 Our analyses of data from previous review articles within this new framework show that
57 successful lean interventions share some common features. We identified 23 facilitators
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3 associated with successful interventions. Unfortunately, little is known about which facilitators
4 that are most important[8 22]. Management and leadership engagement was identified as
5 important by 13 of the 18 reviewed reviews. The other facilitators most frequently identified
6 were a supportive culture, accurate data and training, along with physician and team
7 involvement. This is in accordance with the conclusions from relevant research, and may
8 indicate that these facilitators are vital to accomplish quality improvement[13 23 31 35]. Two
9 recent reviews conclude that leadership, culture, maturity, and data infrastructure have a
10 stronger evidence base than other factors[23 38]. Our results nevertheless suggest that
11 successful interventions must utilise multiple facilitators from the four dimensions of
12 capability, interplaying as the change processes touch upon the different domains. The
13 observation that the facilitators identified in this study were in accordance with those
14 promoted in other, broader theories of implementation concerning uptake of evidence and
15 innovations in health care[4 23 46] strengthen the findings.

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26 The most frequent facilitators belong to the *content* or *application* part of the intervention.
27 This may indicate that policymakers should pay special attention to the content of lean and the
28 local delivery process. Sufficient resources, accurate data and training are crucial for lean
29 interventions to succeed. Lean are not a recipe that can be implemented locally if the training
30 or available resources are inadequate. The need for local resource allocation should not be
31 underestimated. This is in accordance to Radnor et al (2012), that advocate that lean
32 interventions must be contextualized, rather than transplanted like a recipe[27].

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39 This assertion is supported by the frequently identified facilitators labelled physicians and
40 management. Leadership and clinical leadership are keys to understand why, or why not, lean
41 interventions make contributions to health care[47]. Finally, the local application of lean in
42 hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-
43 floor staff must be engaged and empowered. Womack and Jones (2003) that initially
44 advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main
45 advantage for hospitals, making lean suitable for health care[12].

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53 The cultural and strategic dimensions of capability embrace most of the frequent facilitators.
54 A supportive culture are fundamental to achieve quality improvements[38]. The
55 organizational culture and the strategic importance of the patient path exposed to the
56 improvement initiative are essential to understand variation in outcomes of lean interventions.
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3 Available resources, physicians and managements involvement, indicate and affect the
4 strategic importance and thereby the opportunity to change. These findings are supported by
5 other recent hospital-based studies, like Rozenblum et al (2013)[47].
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10 11 **Limitations**

12 Making these interpretations from a systematic review of reviews must take the methods'
13 limitations into consideration. The facilitators were grouped with similar ones, and sometimes
14 renamed, risking that the original meaning could be misread and mistranslated by our
15 interpretation. Transparency are promoted by conducting feature maps and presenting all the
16 identified facilitators in appendices.
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18 It could be argued that facilitators identified in large reviews should be given more weight
19 than those identified in smaller ones. However, our analysis identified the same facilitators
20 across small and large reviews. Therefore, weighting was not conducted, even though we
21 suggest that facilitators identified in many studies are significant.
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23 Including both qualitative and quantitative studies eliminates the possibility of quantifying the
24 findings and predicting effects of the various facilitators by meta-analysis. The inclusion of
25 both types of studies broadens the scope, increase the ability to identify an ampler spectre of
26 facilitators, and contribute to understanding the role of context in lean interventions.
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28 29 30 31 32 33 34 35 36 **Directions for future research**

37 A critical review concluded that most of the research on hospital quality is dominated by
38 questions of *what* and does not go further to investigate the *how*, *when*, and *why*[48]. They
39 called for approaches that incorporate structure, process, and outcomes. The fact that we
40 know so little about the relationship between these, makes it difficult to recommend ways of
41 organizing that could improve patient care[49].
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47 The facilitators identified and the two-dimensional framework proposed in the present work
48 incorporates structure and process. Still, the facilitators are characterized by vagueness, as
49 broad and comprehensive determinants, that needs further specification and practical content
50 to guide future effective quality improvements to health care organizations[8 22 38 50]. In
51 addition to contextual preconditions, success are dependent on how the organization utilize,
52 combine and sequence organizational resources and routines[32]. A logical next step will be
53 to measure and analyse outcomes in the context of this framework, with the identified
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3 facilitators as explanatory variables. Possible measures of outcomes could be related to the
4 health care providers performance (adherence to recommended practice), patient outcome (as
5 quality of life or mortality), surrogate outcomes (as readmission) and organizational outcomes
6 (like resource use or sustainability)[36]. At the University Hospital of North Norway, more
7 than five years of lean experience and more than 20 implemented lean interventions leave us
8 with a sufficient amount of empirically based cases to assess due to varying success.
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13 14 15 **CONCLUSION**

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17 The findings contribute to reduce the gap between theory and practice, by a shift in focus
18 from cause-effect to conditional attributes or characteristics of an effective organization-wide
19 quality intervention. The review of reviews identified 23 interrelated facilitators for lean in
20 hospitals, where management engagement, cultural support, accurate data and training, along
21 with teamwork, physician and staff involvement were most frequent. The findings suggest
22 that characteristics of lean and the local application should be given attention, in addition to
23 the organizations' cultural and strategic capability.
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28 The main contribution of this review is a two-dimensional framework for identification and
29 analysis of facilitators for lean interventions in health care. This framework incorporates the
30 complex social and organizational context in which lean are applied. These findings coincide
31 with recent research calling for more attention to the influence of organizational context when
32 trying to understand variance in interventions in healthcare[23]. We suggest that it will prove
33 useful in future research aiming for a better understanding of how the likelihood to
34 accomplish success in lean interventions can be increased[14]. The framework will also be
35 used in future research locally at the hospital, as a practical tool to assess variation in adoption
36 of lean.
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7 **Lean thinking in hospitals: Is there a cure for the absence of evidence?**
8 **A systematic review of reviews**

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47 **Key words:**

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

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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]. Manyest 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

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7 | [findings from one setting to another](#). Is there a cure for this lack of evidence? On a paramount
8 level, one must ask whether absence of evidence justifies inaction[18]. The *quality chasm*
9 between the health care we have and the health care we should have is well documented[19
10 20]. In other words, the call for action is still there, and, these obstacles to quality
11 improvement must be crossed. ~~[21]~~

14 **Lean as social, complex and context-dependent interventions**

15 Shortell et al. (2007) emphasized the need to link evidence-based medicine and what they
16 refer to as evidence-based management, arguing that medicine must take into account the
17 complex organizational and social context in which care is delivered[21]. Such integration of
18 the intervention and its context seldom happens in quality improvement research[22].
19 Lean interventions operate differently from the clinical interventions affecting biological
20 systems, in which a linear cause-effect relationship controlling the influence of context is
21 assumed. Context are simply defined as all surrounding factors that are not part of the
22 intervention itself[23]. However, the boundaries between the intervention and its
23 surroundings may be relatively arbitrary, as lean interventions are social, complex and
24 inherently context-dependent[24 25]. Lean interventions consist of multiple, reciprocally
25 interacting elements. They evolve over time in response to continuous feedback as situation
26 dependent cumulative processes, and are therefore intrinsically unstable and difficult to
27 standardize. Lean and other quality improvement methods are often adjusted, mixed,
28 implemented and used simultaneously[26 27]. This fact challenges the strict distinction
29 between lean and other quality improvement methods. Finally, lean interventions are open
30 systems that feed back on themselves, so that with learning, they may change the conditions
31 that made them work in the first place.

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41 | There is a growing literature on lean facilitators. [According to Grimshaw et al, systematic](#)
42 [reviews provide the best evidence on the effectiveness of quality improvement](#)[28]. We
43 observe a growing consensus that characteristics like management, resources and culture
44 matter, but the current knowledge base lacks specification on when and how the different
45 facilitators work. This vagueness partly rest on insufficient methodological attention to the
46 context in which lean interventions work. To understand and assess variation in lean
47 interventions success, there is a need for a conceptual framework defining facilitators for
48 change at the stages and levels where they are activated. These facilitators, also named
49 enablers, determinants for effectiveness and so on, may be defined as [contextual-contingency](#)

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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

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7 criteria that neither large-scale quality improvement, success criteria or lean thinking were
8 issued. Articles that mainly represented practical guidelines were also ~~were~~-excluded. The
9 final review included 18 articles[10 13 17 22 23 26 27 31 35-44].
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11 **Data analysis**

12 The 18 articles were systematized according to the number of studies included in each review.
13 Eight articles reviewed a number of definite cases, varying from four to 90 (median 33). The
14 remaining articles were expert evaluations, narrative or unsystematic reviews, all covering
15 lean interventions in hospitals-- Half of the articles review only lean interventions, while the
16 others include lean and corresponding methods like *Productive ward* and process oriented
17 redesign. Lean was extracted and treated separately as far as possible, though confined by the
18 observed mix, similarity and simultaneously use of different quality improvement methods in
19 hospitals[5 22 26 27]. The mMethods used in the original studies were qualitative,
20 quantitative, or a mixed-method approach. Most studies were based on cases originated in the
21 United States, Australia and Great Britain.
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30 The next step was to search for facilitators, defined as contextual-contingency factors
31 predicted to promote quality improvement, as opposed to barriers that hinder
32 improvement[37]. The decision to concentrate on facilitators and not barriers to lean
33 improvement were based on the fact that the research literature at this field chiefly pays
34 attention to facilitators and not barriers[5 8 10 13 17 22 23 38]. In most cases, the facilitators
35 were quite easy to identify in the texts despite different annotations used, including *enablers*,
36 *conditions*, *factors* and *key facilitators*, *critical elements*, *determinants of effectiveness*, and
37 *contextual characteristics*. Using the method of feature maps, which enable localization of
38 similarities and differences among studies[33], the articles were systematically analyzed and
39 recorded in a standardized format, according to the facilitators. The procedure were conducted
40 by creating a worksheet categorizing every paper according to author, year of publishing, kind
41 of review, supplementary-other quality improvement methods comprised (in addition to lean),
42 research method, labelling of facilitators, and facilitating factors. The complete worksheet is
43 attached as a supplementary file.
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51 All the identified facilitators were assigned to larger categories. This classification was done
52 to develop a more specific and practically focused state of knowledge concerning facilitators
53 for lean thinking, as the need for an overview necessitated reducing the information to
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7 manageable amounts. All the identified facilitators concerning management and leadership
8 were placed in the category *management*, covering subjects like management support,
9 commitment and ownership. Cultural issues were all categorized as *supportive culture*,
10 including views, norms ~~and~~ beliefs and behaviours supporting ~~lean~~ the principles and practice
11 of quality improvement. All facilitators concerning local translation were put in the category
12 *adaption*, as all facilitators dealing with prior involvement in quality improvement work were
13 grouped under the heading *experience*, and so on. After examining all the 149 facilitators,
14 grouping them with similar ones, we ended up with a list comprising 23 facilitators. The
15 different facets of these facilitators are all listed in box 1 below. Finally, the frequency of each
16 of the facilitators in the 18 reviews was accounted for.
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21 22 **A theoretical and methodological framework**

23 Lean interventions consist of several different phases, from planning and preparation to
24 implementation and sustainability, involving different organizational capabilities. The
25 facilitators for improvement were analyzed and reorganized in a table combining Shortell's
26 *dimensions of capability*[2 45], and Walshe's *domains of an intervention*[9]. Shortell
27 categorized improvement factors according to cultural, technical, strategic, and structural
28 dimensions of an intervention. The *cultural* dimension refers to the underlying beliefs, values,
29 norms and behaviours of the organization. The *technical* dimension covers training and
30 information system issues, while the *strategic* dimension emphasizes the conditions that offer
31 the greatest opportunities to change. This dimension touch upon the degree of integration of
32 quality improvement in the hospital's strategic plans, and to which extent improvement efforts
33 are devoted to processes central to strategic priorities. The *structural* dimension relate to
34 mechanisms that facilitate learning and disseminate best practices throughout the
35 organization. The four dimensions are multiplicative, interrelated, and equally necessary for
36 lasting quality improvement according to Shortell. Varying lean success can be understood as
37 a result of the interplay of dynamic processes related to the four dimensions[45].
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47 Walshe's differentiated domains ~~or phases~~ in quality interventions are labelled as context,
48 content, application and outcomes. The context involves ~~the preparation phase before starting~~
49 ~~improvement work, highlighting aspects of~~ the situation, setting or organization in which the
50 intervention is deployed. Context may vary widely, both within and between hospitals. This is
51 a narrow view of context, and should not be confused with the broader understanding of
52 context as all surrounding factors that are not part of the technical intervention itself[8]. In
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Field Code Changed

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7 ~~this article, we therefore renamed this phase as the organizational setting.~~ The *content*
8 describes the ~~phase where lean is introduced as a tool,~~ the nature or characteristics of the
9 intervention itself. The content of lean may be standardized and repeatable or modified and
10 easy to redesign. The *application* covers the process through which the intervention is
11 delivered. This process may be protocol-driven or widely varying depending on local actors.
12 *Outcomes* are the results of the intervention, including the maintenance phase after
13 implementation. All of these ~~phases-domains~~ may be characterized by low or high variance.
14 High levels of variance in the settings, content and application may explain interventions
15 varying success. Variances also reduce the ability to generalize empirically, and to draw
16 conclusions about effects from one specific context to another. The complex relationship
17 between context, content, application and outcomes must be unpicked to develop a situational
18 understanding of effectiveness[9].
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25 By combining Shortell's dimensions and Walshe's domains, this two-dimensional framework
26 made it possible to classify identified facilitators for quality improvement, both as emerging
27 in different ~~phases-domains~~ in a multistage process and by different organizational
28 dimensions. The framework was used to describe and understand the ~~organizational and~~
29 contextual factors encountered in an organizational-wide quality improvement effort.
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34 RESULTS

35 Among the 18 reviewed articles, 149 facilitators for lean interventions were found. The
36 reviews identified ~~three-3~~ to 16 (median seven) facilitators for improvement. All were
37 identified in several reviews, varying from ~~three-3~~ to 14 (median seven) times. The facilitators
38 were categorized into 23 extensive classes, covering the range of all the identified facilitators.
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60*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

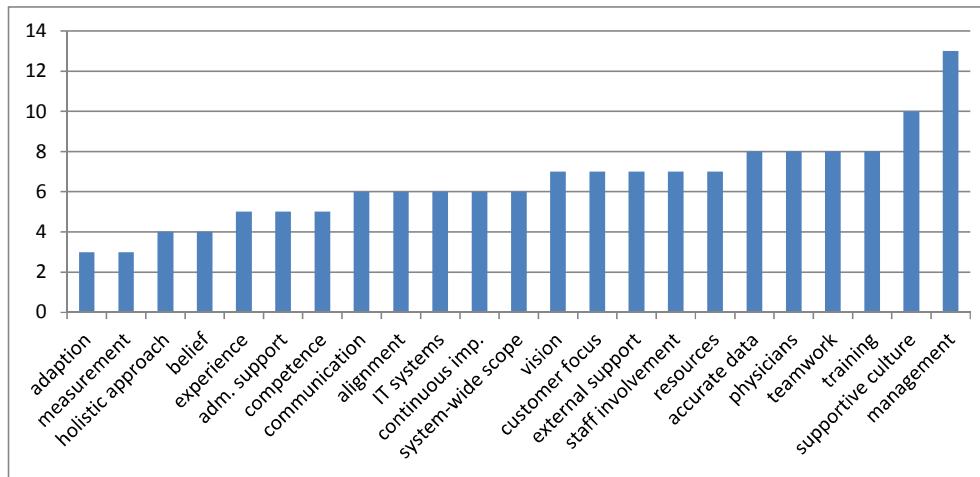
Training: Accessible, substantial, practical and relevant training for immediate use

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

SettingContext: Situation and organization.

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~~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 enablers~~ 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

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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 facilitating 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 total 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.

~~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 dimensions~~This 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 the~~within and between the four stages-domains and dimensions of change. The four dimensions, ~~domains~~ and the associated facilitators are interrelated and ~~equally-probably all~~ necessary to achieve lasting results[2]. ~~In the following~~Finally, 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~~[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.

~~However~~Unfortunately, ~~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 four~~touch 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.

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

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7 interventions to succeed. Lean are not a ~~reecipt~~recipe that can be implemented locally if the
8 training or available resources are inadequate. The need for local resource allocation should
9 not be underestimated. This is in accordance to Radnor et al (2012), that advocate that lean
10 interventions must be contextualized, rather than transplanted like a recipe[27].
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14 This assertion is supported by the frequently identified facilitators labelled physicians and
15 management. Leadership and clinical leadership are keys to understand why, or why not, lean
16 interventions make contributions to health care[47]. Finally, the local application of lean in
17 hospitals depends heavily on teamwork by multi-skilled and multidisciplinary teams. Work-
18 floor staff must be engaged and empowered. Womack and Jones (2003) that initially
19 advocated lean thinking in healthcare, emphasized the multi-skilled teams as a main
20 advantage for hospitals, making lean suitable for health care[12].
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25 The cultural and strategic dimensions of capability embrace most of the frequent facilitators.
26 A supportive culture are fundamental to achieve quality improvements[38]. The
27 organizational culture and the strategic importance of the patient path exposed to the
28 improvement initiative are essential to understand variation in outcomes of lean interventions.
29 Available resources, physicians and managements involvement, indicate and affect the
30 strategic importance and thereby the opportunity to change. ~~This finding~~These findings are
31 supported by other recent hospital-based studies, like Rozenblum et al (2013)[47].
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37 ~~The main contribution of this review is a two-dimensional framework for identification and~~
38 ~~analysis of facilitators for lean interventions in health care. This framework incorporates the~~
39 ~~complex social and organizational context in which lean are applied. These findings coincide~~
40 ~~with recent research calling for more attention to the influence of organizational context when~~
41 ~~trying to understand variance in interventions in healthcare[23]. We suggest that it will prove~~
42 ~~useful in future research aiming for a better understanding of how the likelihood to~~
43 ~~accomplish success in lean interventions can be increased[14]. The framework will also be~~
44 ~~used in future research locally at the hospital, as a practical tool to assess variation in adoption~~
45 ~~of lean.~~
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50 51 **Limitations**

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

~~Further on, i~~t 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~~ncluding 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.~~

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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.

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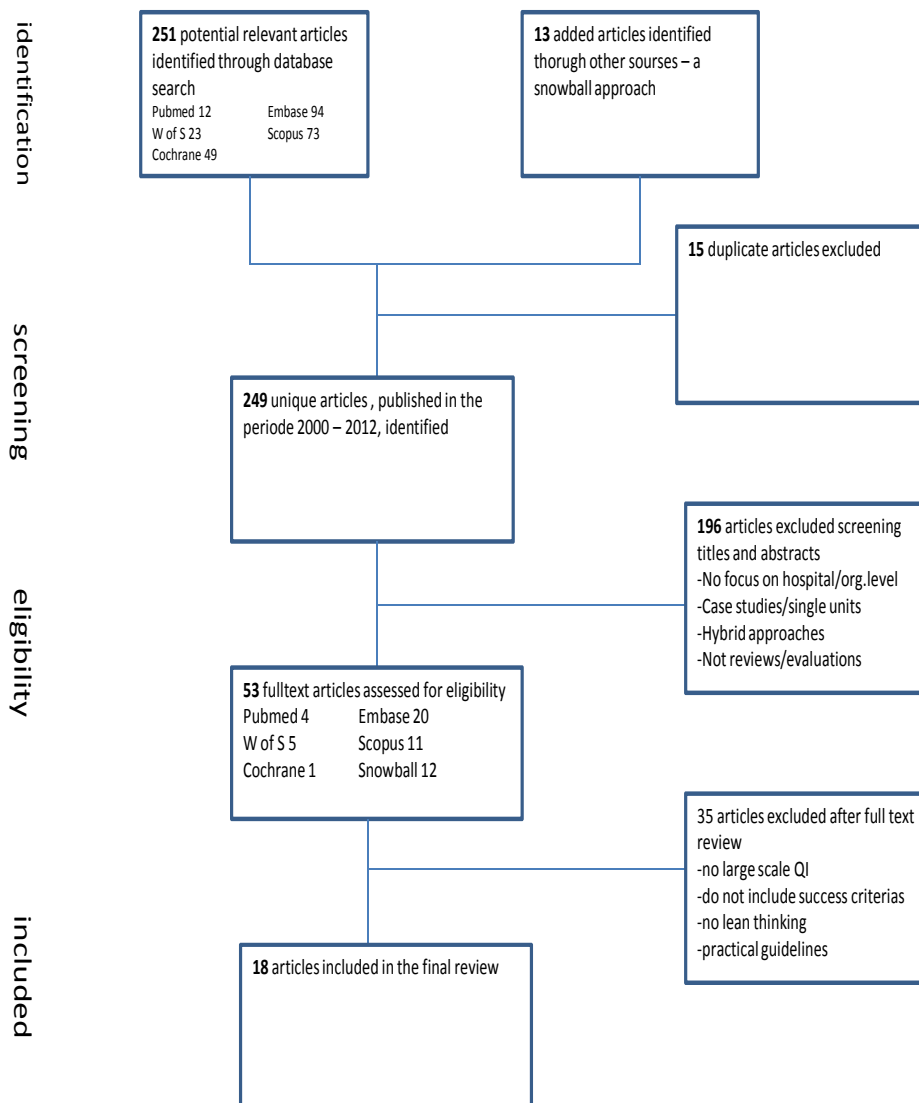
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Appendix 1. Flow chart, detailed search strategy (Web only)



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

Author/ year	Review/ size	QI/ research method	Labels	Factors
Poksinska B. 2010	Review 30 articles	Lean. Theoretical/ case studies.	Enablers	<ul style="list-style-type: none"> Commitment/participation from staff that owns and drives it Training and responsibility to staff (empowerment) Consultants/trainers from health care Management support, ownership and resources Organization culture An holistic approach - lean is not a toolbox Improve the entire system, involve several units Adaption, not adoption Clear view of the customer Teamwork, collaboration and communication
Powell A, Rushmer R, Davies H. 2008.	Review 59 articles	QI, including Lean. Observation, interviews, action research.	Necessary but not sufficient conditions for successful implementation	<ul style="list-style-type: none"> Alignment with strategic objectives Quality as part of everyday life/every ones work Long time approach Active health professionals/doctors engagement Belief that staff/patient will benefit Strong leadership and clear vision Sustained active participation from board and senior management Multifaceted interventions sustained action at different levels Substantial investment in training and development (including IT and training of staff) Support from "change agents" to provide skills Robust and timely data Resources
Vos L, Chalmers SE, Dückers MLA et al. 2011	Review 10 articles	Process oriented redesign including Lean. Uncontrolled before-after evaluations.	Factors for success	<ul style="list-style-type: none"> Senior management support Clinical leadership and involvement Team-based problem solving Adequate information and communication technology support Administrative support Ambitious targets External facilitators Organizational readiness Selection and execution of projects in order of urgency Using a change strategy that already proved to be successful Good communication and training in QI techniques

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

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				<ul style="list-style-type: none"> Team tenure (worked as a team before) Prior QI experience Team leadership Team decision making processes Team norms of behavior Team QI skills Trigger (a specific event stimulates a new emphasis) Tasks strategic importance to the organization
Kaplan HC, Brady PW, Dritz MC, et al 2010	Review 47 articles	QI including Lean. Observation, controlled design, meta-analysis.	Factors important for QI success	<ul style="list-style-type: none"> Leadership from top management/board Organizational culture Organizational structure (clinical integration across departments) Data infrastructure and information systems Years involved in QI (experience) Customer focus Physician involvement Micro system motivation to change Resources for QI QI team leadership
Mazzocato P, Savage C, Brommels M et al. 2010	review 33 articles	Lean. Qualitative and quantitative.	Contextual characteristics of relevance	<ul style="list-style-type: none"> Senior management involvement Work across functional divides Pursue value creation for patients Nurture long term holistic culture of CQI A need to improve A willingness to improve
Kim CS, Spahlinger DA, Kin JM et al. 2009	UMHS-USA evaluasjon	Lean. Qualitative and quantitative.	Key factors	<ul style="list-style-type: none"> Expert guidance for initial efforts leadership - clinical champions and senior management support frontline worker engagement in the QI processes Use metrics to develop and track interventions Define a realistic project scope
Lukas CVD, Holmes SK, Cohen AB et al. 2007	12 healthcare system doc. review	QI including Lean Longitudinal case-studies, mixed method evaluation.	Interactive elements that appear critical to successful transformation of patient care	<ul style="list-style-type: none"> Impetus to transform leadership commitment Actively engage staff in meaningful problem solving Alignment to achieve consistency of organization goals Integration to bridge traditional intra-organizational boundaries among individual components.
Kollberg B, Dahlgaard JJ, Brehmer PO. 2007	Unsystematic review	QI including Lean. Qualitative and quantitative.	Critical success factors	<ul style="list-style-type: none"> patient focus active involvement and multi-skilled teams

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

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				<ul style="list-style-type: none"> Communication and feedback to staff and patients Need for change, valuing the initiative Simple, practical solutions to real problems Accessibility of recourses and teaching modules Self-nomination (units to take part) Local ownership and empowerment Sufficient resources, support and time (staff cover)
Kim CS, MBA, DAS, Billi JE. 2009	Unsystematic review	Lean. Qualitative and quantitative.	Critical Elements	<ul style="list-style-type: none"> Senior management support. Expert guidance for their initial projects. A well-structured set of metrics, on a regular basis, readjusted Aligning individual goals, projects, and metrics Provide flexibility for frontline workers to experiment at the site and time they identify a problem. Frontline management need to avail themselves to the area



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

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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

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