

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Lean thinking in hospitals: Is there a cure for the absence of evidence? A systematic review of reviews
<b>AUTHORS</b>	Andersen, Hege; Røvik, Kjell Arne; Ingebrigtsen, Tor

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Prof Terry Young Brunel University, DISC
<b>REVIEW RETURNED</b>	04-Oct-2013

<b>GENERAL COMMENTS</b>	<p>This is a very interesting paper that attempts to illuminate the question of evidence and practice. I am pleased to see paper coming through for review, since we have tried to raise the issue before but the BMJ has not been interested.</p> <p>In a sense, the paper in its method encounters exactly the same problem that it attempts to analyse in Lean health – namely that it is looking at a very messy problem. Methodologically acceptable approaches, which tend to apply a reductionist approach in an attempt to sanitise the problem also tend to clean out any real insight into the problem, because such insight tends to come from messy, and therefore inadmissible, sources.</p> <p>This paradox manifests itself in the paper in two ways: firstly, some of the people who have worked hard to make Lean work in healthcare (and are probably closest to the original sensei in their operational approach) do not appear to have made the final evidential cut. I have not looked up all of the papers, but a quick skim seems to indicate gaps around Ben-Tovim at Flinders or Silvester in the UK, who spring immediately to mind. Secondly – and here I use my judgement – I am not sure I believe the long list. In other words, the method seems to have failed to unearth critical issues. I am sure the list came out of the analysis, but I am not sure it captures the key issues. Numeracy, for instance, underpins Lean in a very fundamental way and specially the thrust towards Lean-Six Sigma. Although Lean came out of practical people, they came from a highly numerate culture. One might argue that numeracy is hidden under several of the headings. However, one of the big criticisms of those seeking to push Lean in healthcare is a lamentable lack of numeracy at all levels that prevents the results from being adequately understood and inhibits the systematic drive for improvement. This is just one example. So we have a problem in that a acceptable methods excludes critical courses of insight, and it also ends up with findings that have clear gaps in their coverage. Thus, we have the paradox that methodologically sound approach has excluded good insight and produced a manifestly flawed lists of results.</p> <p>There are therefore two critical questions. Is the BMJ prepared to address the question of evidence and method in care delivery in a more satisfactory way or is it going to continue to pretend that the</p>
-------------------------	--

	<p>sort of evidence that drives evidence-based medicine is all there is? Our research indicates that people involved in improvement have many stakeholders to satisfy and that, in healthcare, these stakeholders have widely varying views of what constitutes acceptable evidence. If the hospital is going broke, for instance, the chief finance officer is unlikely to authorise new expenditure, notwithstanding persuasive clinical evidence – and there are many recent case studies that illustrate this tension of evidence – the bottom line against the guideline. I am not against EBM – I admire it hugely. And given what has been invested in building the evidence base, and the 60+ years since Doll and Hill, I am sure we could put the evidence of service delivery on a similar footing. We are just a long way behind.</p> <p>The second question is whether this paper should be published. My take is that we desperately need papers on this topic, and I very much like the struggle evident in this paper. Clearly, the word 'evidence' is the elephant in the room – it means different things in different places. I don't think there is space to address this in the paper without destroying it. My recommendation therefore is that there be a more rigorous discussion about the findings. Lean (and indeed, the other improvement philosophies) succeeded in industry because it presented a very small number – a prime number! – of critical steps or factors for people to work with. That is part of the elegance. The irony is that, as academics, we create very much longer lists – although this one is also prime – that serve neither to illuminate nor to guide.</p> <p>One quick piece of analysis would be to create a second sieve created by practical experts and then to put this list through their recommendations. Their outputs tend not to be in the highest graded journals, but they do tend to reflect a reality on the ground. I suspect the authors are familiar with that reality. This might help to focus, add to, and perhaps, seriously de-prioritise some of the factors identified.</p> <p>I would hope this could be done in less than a month and if the paper is sent directly to me, I will do my best to turn it around this time within 24 hours.</p> <p>My other comments are minor – some syntax errors, etc.</p>
--	---

<b>REVIEWER</b>	Dr Victoria Allgar University of York England
<b>REVIEW RETURNED</b>	09-Oct-2013

<b>GENERAL COMMENTS</b>	The review is mainly descriptive. There is no formal statistical analysis undertaken.
<b>REVIEWER</b>	Pamela Mazzocato Karolinska Institutet, Sweden No competing interests to declare
<b>REVIEW RETURNED</b>	0-Nov-2013

<b>GENERAL COMMENTS</b>	<p>General comments</p> <p>This study is a systematic review of lean review/evaluation articles and analyzes the literature based on a two-dimensional framework to identify contextual factors facilitating intended outcomes from lean interventions and to understand when and in which dimension different facilitators contribute. The topic addressed in this study is timely and relevant. While the framework developed could be useful</p>
-------------------------	---

to better understand variation in lean interventions, this study suffers from several conceptual and methodological limitations. Thus, major revisions are needed before this study can be considered for publication.

Introduction/Major revisions:

In the introduction, the authors present the scientific problem addressed, i.e. the inconclusive evidence about how lean works in healthcare; this is important and relevant but needs to be more clearly explained. From the introduction, it is however unclear whether the lack of evidence is due to:

- Conflicting evidence about the outcomes of lean thinking (this statement needs to be supported by references that clearly report “failed” lean changes; this is particularly important as the field of lean healthcare seems to be dominated by a positive publication bias);
- Lack of evidence (this statement seems not be supported by the current state of the knowledge);
- Conflicting evidence between qualitative and quantitative studies (this statement needs to be supported by references that clearly illustrate this conflict);
- Experimental designs that do not report significant effect of lean (do the references that support this statement – 2, 5, 9, 10, 14 – actually report the lack of significant effect of lean?)

To this reviewer, the key problem seems to be the adoption of study designs that do not allow drawing solid conclusions, particularly as they fail to take into account contingency factors that may influence what about lean works, how, and when. This knowledge is needed in order to better understand how findings from one setting can be generalized/translated to another setting.

Make sure that the references are cited correctly.

Pag 4, fourth paragraph: it is stated that most studies using an experimental design did not find any significant effect on lean interventions. Five references are reported to support this statement. Do these references actually refer to intervention studies on lean healthcare, or is still a general challenge for quality improvement studies?

Introduction/Minor revisions

Page 4, line 8: what do you mean by “patient care work processes”? Lean can be applied core (care process), support, and managerial processes. Which types of processes does this statement refer to?

The case of the University Hospital of North Norway is introduced in the background. Although this is interesting, the reference to this case may not be needed in this study.

Page 6: the concept of “organizational readiness for change” is introduced. This concept needs to be better explained. In the discussion, the authors could get back to this concept and discuss the findings of this study in relation to “readiness for change”.

Methods/major revisions

Line 3: “discrepancies were resolved by discussion involving all three authors”. Which kind of discrepancies?

Page 7, second paragraph: supplementary quality improvement

methods (in addition to lean) are mentioned. How are these different from “hybrid approaches” that, according to the exclusion criteria, were not included in the study?

Facilitators are defined as “contextual factors predicted to promote quality improvement”. The term “contextual factors” results confusing as as “context” is indeed one of the key dimensions in one of the frameworks used to analyze the studies (Walshe). Why not referring to “facilitating factors” or “contingency factors” and then keep “context” (rather than “setting”) as one dimension of the framework?

Page 7, last paragraph: what are the views, norms, and beliefs supporting lean? Can you bring some examples based on the literature?

Theoretical framework: the authors build on Shortell and Walshe. However, the way the domains described by Walshe are used in this article, seems to diverge from the original work. Walshe himself build, implicitly, on the work by Pawson and Tilley and their realistic evaluation approach. The four dimensions of QI (context, application, content, and outcomes) are not described as “phases” of QI interventions, but rather as four dimensions; their interaction can explain variation in results (outcomes). Thus, the context is not the “preparation phase”, but rather the “situation, setting or organization in which the intervention is deployed”. This original definition is not as “narrow” as stated by the authors and includes, in contrary to what stated by the authors, the “organizational setting”. In general, the authors should explain and motivate possible deviations from the original framework.

Page 8, second paragraph, lean is defined as a “tool”, this is in contrast to the literature, that defines lean as a management strategy.

Results/Major revisions

Page 10, box 1: views, norms, and beliefs that support lean represent readiness; which are the kind of views, norms, and beliefs support lean?

Setting: the first sentence is unclear. In what sense does a quality improvement method characterized by program maturity facilitates lean? What is does “a quality improvement method characterized by program maturity” imply?

Content: what type of resources is needed to support lean changes?

Application: how does physicians and management involvement facilitate lean changes? What is their role in lean transformations?

Outcomes: what is meant by “a supportive culture characterized by norms and beliefs supporting quality improvement and readiness”? How is “supportive culture” an outcome? How is this different from the beliefs and norms reported under “setting”? To this reviewer, it is hard to understand how the factors reported under the heading “outcomes” influence “results and maintenance” compared to other factors, such as leadership and management.

In general, the results section presents four major limitations:  
1. It is unclear to what extent the findings reported are based on empirical evidence, or rather on an interpretation done by the

authors? For instance, on page 12, first paragraph, do the studies reviewed actually report that lean should be accompanied by success stories demonstrating the benefits for patients and staff? Or, how does sponsorship trigger learning, based on the reviewed articles? Or, how does competence in tools and methods support the assumptions of lean?

2. In the description of the factors influencing lean interventions, the authors refer to the “strength” of the influence, using adverbs such as “strongly”. Are the authors able, based on the evidence collected, to rate the strengths of the relationship between facilitating factors and the success of lean interventions?

3. It is unclear, how the facilitators for change were organized within the theoretical framework. For instance, the targets of lean programs could likewise fit under “content”. External support, training, and measurement could be part of the application. Etc. As the categorization of the factors appears to be the result of an interpretation, it seems inappropriate to provide a quantitative analysis of the frequency with which these factors present in the literature (last paragraph of the results section).

4. The analysis of the facilitating factors does not help to understand how the four dimensions of change proposed by Walshe interact with one another.

Unless the authors are better able to empirically support how the facilitating factors relate to the different elements in the theoretical framework proposed, this reviewer recommends to first present the empirical evidence, and then an interpretation of the findings. In the description of the facilitating factors, the authors could focus on the most important factors, and explain more in detail how they seem to influence successful lean changes.

#### Discussion/Major revisions

This reviewer recommends expanding the discussion particularly by elaborating on facilitating factors that seem to be specific to lean programs. Are there any facilitating factors that seem to be specific to lean, compared to other quality improvement approaches? Particularly, the lean literature emphasizes specific management and leadership practices and behaviors. Is there any evidence of such lean practices and behaviors in the literature?

The authors suggest the findings of this study to be aligned with the work by Rycroft-Malone. This statement needs to be further developed; otherwise it does not seem to add much value to the discussion.

In its current status, the discussion presents many overlaps with the results section. This further corroborates this reviewers' impression that, the results section is characterized by a high degree of interpretation.

Limitations: the authors claim the impracticality to quantify and weighting the various factors. While this reviewer agrees on this point, the findings in this article do report quantitative measures as well as attempts to weight the impact of the factors (for instance by using adverbs such as “strongly”).

#### Other general comments

Language editing is needed.

## VERSION 1 – AUTHOR RESPONSE

Reviewer # 1 Terry Young

1. We are pleased to notice that the reviewer's positive comment on the papers attempt to illuminate the question of evidence and practice. The reviewer's comments on the list of facilitators are recognized by the authors, as in the literature. We fully agree with the reviewer on this point, and have now included a discussion of the limitations of these broad and often self-evident enablers in the Direction for future research. Research where the recommended second sieve is conducted, are now referred to in the Discussion.

Reviewer # 2 Pamela Mazzocato

1. Responses to Introduction/major revisions:

- We appreciate the reviewer's comments, and agree to the statement that the key problem seems to be the adoption of study designs that do not allow drawing solid conclusions, which limits spread of quality improvement. This clarification is now included in the Introduction as in the Abstract.
- The references that support our statement are controlled and corrected. Some reviews include other quality improvement interventions in addition to lean. This is indicated in the text and in the appendices.

2. Responses to Introduction/minor revisions:

- The term care processes has been clarified
- The paragraph concerning the local hospital are still included as part of the background, but shortened.
- the term organizational readiness for change has been removed, to secure consistency in the text.

3. Responses to Methods/major revisions:

- The term discrepancies are replaced by the term confusion to give a more correct description of how the review was conducted in cooperation and by consensus.
- The supplementary methods, that often are included in reviews in addition to lean, are distinguished from hybrid methods that combine lean and other methods in one single intervention. This is clarified both in Methods, and in the appendices.
- We revised the domain labeled setting, now using the original term context. This is in accordance to Walshe's work, and in accordance to the reviewer recommendation.
- The views, norms, and beliefs that support lean are specified in the Methods, and examples given in the Results and the Discussion.

4. Responses to Theoretical framework:

- We agree that our translation of Walshe's domains of an intervention deviated from the original framework in our first submission, though in an unintended matter. We therefore revised this part of the article in accordance to the original work, as the reviewer recommended. This revision clarifies that facilitators in different domains interact.
- Lean as a tool is revised to lean as a strategy, as recommended.

5. Responses to Results/major revisions:

- Examples of the kind of views, norms and beliefs that support lean are challenging to detect in the included reviews that stress the right culture and organizational culture without specification. Some tentative examples are cited in the Discussion.
- The reviewer points out that the meaning of program maturity is unclear. We found that this sentence does not add any substance to the text, and it has now been deleted from the manuscript.
- examples of what kind of resources that are needed to support lean are now clarified in Discussion.
- The physicians and managements role in lean has now been clarified in the Discussion.
- The reviewer enquires how supportive culture can be an outcome. We apologize if the manuscript has not been clear enough on this point, elucidating that a supportive culture is a facilitator, affecting the outcomes, that is, the results and maintenance over time.

- As the reviewer recommended, we decided to make a clear distinction between the identified facilitators and how they are organized in the framework by moving the latter to the Discussion part of the paper. This is to oblige the reviewer's indication of unclear division of empirical evidence and the authors' interpretation of the findings.
- Words indicating the strength of facilitators' influence are removed from the text.

#### 6. Responses to Discussion/major revisions:

- The reviewer recommends expanding the discussion by elaborating on lean specific facilitators. That is a very interesting suggestion, but unfortunately outside the scope of this paper. Potentially lean specific findings are limited, because most of the reviews include other quality improvement methods in addition to lean.
- The reference to Rycroft-Malone has been removed to make clarity to the argumentation.
- The indicated overlaps between the Results and Discussion section have been corrected by the previously described revisions.
- Minor revisions and language editing are conducted consecutive as suggested by the reviewer.