ORIGINAL ARTICLE

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

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ABSTRACT

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

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

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

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

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

1. INTRODUCTION

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

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

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

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

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

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

Table 1. Independent variables – dimensions and descriptions

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

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

2. METHODS

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

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

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

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

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

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

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

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

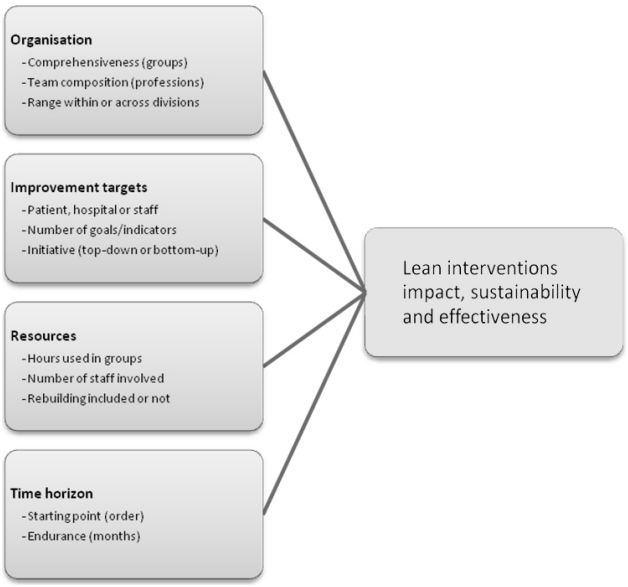

Figure 1. Research model

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

Table 2. Scales for ranking Lean interventions

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

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

3. Results

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

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

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

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

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

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

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

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

4. Discussion

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

4.1 Organisation – features of the project organisation

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

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

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

Table 4. Linear mixed model

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

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

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

4.2 Improvement targets – characteristics of the chosen goals for improvement

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

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

4.3 Resources – investment in time, people and rebuilding

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

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

4.4 Time horizon – experience and duration

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

4.5 Strengths and weaknesses of the study

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

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

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

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

5. Implications and future research

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

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

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

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