Lean Management and Breakthrough Performance Improvement in Health Care

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Background and Objectives: Lean management in health care organizations attempts to empower staff to generate continuous improvement through incremental but regular improvements in work processes. However, because of the increasing pressure on health care organizations to substantially improve quality of care and patient outcomes while containing costs in the relatively short term, many health care leaders are looking for ways to achieve large breakthrough improvements in their organization's performance. The objective of this research is to understand whether and how Lean management can be used to achieve breakthrough improvements in performance. **Methods:** This study used grounded theory and content analysis of in-depth, semistructured interviews with 10 nationally recognized experts in the use of Lean management in health care organizations. The 10 participants constitute a purposive sample of experts with in-depth understanding of the strengths and limitations of Lean management in health care organizations. **Results:** Two out of 10 participants defined breakthrough improvement as a major change in a performance metric; 2 participants defined it as a fundamental redesign in a process or service; the remaining 6 participants defined breakthrough improvement as having both these characteristics. The extent to which participants believed Lean was an effective means for achieving breakthrough improvement in performance was related to how they defined breakthrough improvement. The 2 participants who defined breakthrough improvement as a significant change in a performance metric believed Lean methods alone were sufficient. The 2 participants who defined breakthrough improvement to be a fundamental redesign tended not to view Lean alone as an effective approach. Rather, they, and the 6 participants who defined breakthrough improvement as having both change-in-metric and process redesign characteristics, viewed human-centered design thinking as the primary or important complementary approach to achieving breakthrough improvement. Participants identified resources, culture change, and leadership commitment beyond what would be required to achieve incremental improvement as the main facilitators and barriers to achieving breakthrough improvements. **Conclusion:** This research reveals some differences in experts' definitions of breakthrough improvement, and illuminates the value of human-centered design thinking, alone or as a complement to Lean management, in achieving breakthrough improvement in health care organizations. Most of our expert participants agreed that supplementing Lean management methods with the contributions of innovation design and investing significant resources, strengthening the organizational culture to support the necessary changes, and providing stronger leadership commitment to the effort are important facilitators for achieving breakthroughs in organizational performance.

Key words: breakthrough improvement, health care innovation, Lean leadership, Lean management, performance improvement

Health care organizations throughout the United States face increasing pressure from payers to become more efficient and to improve quality of care and patient outcomes.[1] In response, many US hospitals are adopting transformational performance improvement approaches. One such approach is the Lean management system originally developed at Toyota,[2,3] adopted by many US manufacturers[4] and, more recently, by many service-based organizations.[5,6] We define Lean in health care as an overall management/operating system that uses a continuous improvement culture that empowers frontline workers to solve problems and eliminate waste by standardizing work to improve the value of care delivered to patients. Related approaches are Lean plus Six Sigma, which adds a focus on variance reduction, and Robust Process Improvement, which further adds a structured change management component.[1] Building on discussions in publications from the Institute for Healthcare Improvement,[7] Graban,[8] and Mann,[9] Table 1 identifies some of the important concepts and practices associated with Lean, which attempt to empower staff to generate continuous improvement through what are often incremental but regular improvements in their work

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Table 1. Examples of Lean Concepts and Activities

Concept/Activity	Description
A3 problem-solving	A structured problem-solving and continuous-improvement approach that provides a simple and organized procedure that guides problem-solving by workers. The approach typically uses a single sheet of ISO A3-size paper, which is the source of its name.
Flow	The progressive achievement of tasks along the value stream so that a product or service proceeds from design to launch, order to delivery, and into the hands of the customer with no stoppages, scrap, or backflows.
Gemba	A Japanese term meaning the "actual place." In the Lean management context, it refers to the place where work is done. Lean managers regularly take gemba walks to learn about the work that is being done, the challenges encountered by the workers, and to motivate and coach workers to help them overcome challenges.
Huddles	Periodic (often daily) stand-up meetings of collaborating employees to discuss the status of operations, plan for the day, and status of problem-solving efforts to address issues.
Kaizen event	A structured workshop lasting several days carried out by a work team assembled to improve a particular work process. The event is led by a team member and typically includes training, data collection and analysis, brainstorming, and implementation planning.
Plan-do-study-act cycles	A method for testing for performance improvement by developing a plan to test the selected change in work process (plan), carrying out the test (do), observing and learning from the consequences (study), and determining which modifications should be made to the test (act), typically performed repeatedly until performance targets are achieved.
Standard work	A precise description of each work activity specifying the sequence for specific tasks as appropriate for the employee's position.
Value	A capability provided to the customer at the right time at an appropriate price, as defined in each case by the customer.
Value stream	The specific people, equipment, and activities required to design, order, and provide a specific product or service for a customer.
Value stream mapping	Identification of all the specific activities occurring along a value stream for a product or service.
Visual controls	Approaches that make the status of a work process visible at a glance, including tracking charts that show actual versus expected performance.

processes.[8,10-13] Graban has compiled numerous published and unpublished reports of the use of Lean methods in hospitals to positively affect hospital safety and quality, waiting times, length of stay, patient flow, patient satisfaction, and financial performance.[8] However, systematic reviews of published studies show a mixed pattern of statistically significant and insignificant associations.[14-17] Case study research has documented some of the challenges of successfully implementing Lean in health care organizations, including the lack of resources, highly complex work processes, cultural resistance to the required changes, lack of leadership support, implementation focused on only one or a small number of units, and failure to understand the organizational context in which Lean is implemented.[18-24] In spite of these challenges, many hospitals have adopted Lean practices. Using data from a 2017 national survey, Shortell and colleagues[25] estimate that approximately 61% of US hospitals use Lean in some form.

Because of the increasing pressure hospitals face to substantially improve quality of care and patient outcomes while containing costs in the relatively short term,[26] many health care leaders are looking for ways to achieve large *breakthrough* improvement in their organization's performance.[7] We have found no discussion in the literature of the potential of Lean practices to achieve breakthrough performance results. To begin to fill this gap, we address the following 4 questions:

1. How is "breakthrough improvement" defined among leaders in health care applications of Lean management?
2. Is Lean management perceived as a useful approach for achieving breakthrough improvement?
3. What are examples of the use of Lean management for breakthrough improvement?
4. What are the major facilitators and barriers to achieving breakthrough improvement in health care organizations?

METHODS

We conducted semistructured interviews of senior health care leaders and managers about the use of Lean management to achieve breakthrough improvement. We used concepts from Lean management and breakthrough performance improvement to guide the development of interview questions and related probes.[6-8,10,12,20,27] We used grounded theory methodology[28] to analyze the participants' responses and develop answers to the research questions identified earlier.

Sample selection

A purposive sample was selected to obtain expert opinions from organizational leaders with significant experience implementing Lean in health care organizations. We started with a sample of 10 study participants and assessed whether saturation of concepts and themes occurred by the time the 10 interviews were completed. The participants' responses to the questions did, indeed, achieve saturation, becoming repetitive by the tenth interview. Examples of the titles held by the participants include chief executive officer, health system vice president, director of performance improvement, and consulting firm partner, which indicate the senior roles played by these participants. Each

of them is a nationally recognized expert in the use of Lean management in health care. The organizations in which they work are widely recognized for their use of Lean management to improve hospital performance: Fairview Health, Indiana University Health, Legacy Health, Palo Alto Medical Foundation/Sutter Health, Stanford Health, University of California San Francisco Health, Virginia Mason Health System, Catalysis, MossAdams Rona Consulting Group, and CauseEffect Consulting.

Data collection

The interviews were conducted by telephone between February and April 2018. Participants were interviewed for 30 to 45 minutes using the semistructured interview format. All interviewees gave their consent to be interviewed and for the interview to be recorded. Each interview was facilitated by a set of questions, listed in Table 2, that addressed (1) years of experience in Lean management, (2) definition of breakthrough improvement, (3) how Lean has been utilized for achievement of breakthrough improvements, (4) examples of utilization of Lean for breakthrough improvements in care delivery processes, (5) key learnings from experiences, (6) barriers and facilitators to achieving breakthrough improvement, and (7) examples of ineffective initiatives. Follow-up questions were prepared in advance to probe further on certain topics during the interviews. An additional topic emerged during the first 3 interviews that we had not anticipated: the role of human-centered design thinking in achieving breakthrough performance. These initial respondents identified this approach as important to achieving substantial improvements in performance. Human-centered design thinking is a "systematic innovation process that prioritizes deep empathy for end-user desires, needs, and challenges to fully understand a problem in hopes of developing more comprehensive and effective solutions."[29] What distinguishes human-centered design from other problem-solving approaches is its obsessive focus on understanding the perspective of the person who experiences the problem, their needs, and whether the solution that has been designed for them truly meets their needs. Typically, human-centered design initiatives involve the intended users of the new product or process in the design work. With its emphasis on qualitatively understanding the perspective of the person performing a given task, the human-centered design approach differs from the scientific approach to improvement represented by Lean's emphasis on the plan-do-study-act (PDSA) cycle of organization improvement. Although the approaches to product and process design differ in some ways, Lean and human-centered design thinking also share some features, such as rapid prototyping and listening to the voice of the customer. For the remaining interviews, we added a probe that asked about the role of human-centered design, independently or in concert with Lean management, to achieve breakthrough performance.

Three definitions of breakthrough improvement emerged after the first 2 interviews: breakthrough improvements as a significant outcome change, as a fundamental redesign, or both. The first 5 participants were asked to define breakthrough improvement with an open-ended question. The last 5 participants were asked the open-ended question but were also asked about the 3 emerging definitions of breakthrough improvement. A member of the research team took detailed notes of the participant's responses during the interviews. The recordings were then used to clarify and extend the interview notes.

Table 2. Interview Guide

Interview Question	Probe Questions
Could you tell me about your current role and how your experience in Lean management has led you to where you are now?	How long have you been working in Lean management?
Some people might define breakthrough improvements as major outcome improvements (like a 50% reduction in ED throughput time), and others might consider breakthrough improvements to be fundamentally different care design changes. How would you define a "breakthrough improvement" in care delivery?	How does a breakthrough improvement differ from other process/quality improvements?
In your experience, how has utilization of Lean intersected with achievement of these types of breakthrough improvements?	N/A
For what types of care delivery processes have you/your organization(s) used Lean to achieve breakthrough improvements?	What were key learnings from your experience?
	Major barriers to success? Major facilitators?
In your experiences with other organizations, why might they not be using Lean to achieve breakthrough improvements in care delivery?	Do you see Lean as a methodology that can help achieve breakthroughs? Why?
What features of your efforts have been sustained over time? Why do you think that is?	N/A
In your experience, could you tell me about any strategies that were intentionally dropped because they were not effective (or for any other reasons)? What are some failures you could tell me about?	What else?

Abbreviations: ED, emergency department; N/A, not available.

The Office for the Protection of Human Subjects at the University of California, Berkeley determined that the study did not constitute research on human subjects and, thus, did not require review.

Data analysis

Content analysis was performed on the 10 interviews using grounded theory,[30] which identified recurring statements regarding the respondents' definition of breakthrough improvement, and in their responses to the related questions. As the analysis proceeded, responses were coded and similar responses to each question were grouped together to create themes that reflected common beliefs and understandings with regard to the questions being asked. Since we asked a relatively small number of focused questions, we were able to code and group the responses using simple tables. A single member of the research team did the initial content analyses. Three members of the team then reviewed the initial analysis of the coding with differences discussed and resolved.

RESULTS

Breakthrough improvement definition

Findings from the interviews are summarized in Table 3. Two out of 10 participants defined a breakthrough improvement as a major change in an outcome metric. Two out of 10 participants defined it as a fundamental redesign in a process or service. Six out of 10 participants defined breakthrough improvement as including both elements.

Lean as a method of achieving breakthrough improvement

The 2 participants who defined breakthrough improvement as a significant change in a performance metric believed Lean methods alone were sufficient. The 2 participants who defined breakthrough improvement as a fundamental redesign tended not to view Lean alone as an effective approach. For those who perceived breakthroughs to be a fundamental redesign, a true breakthrough is more than just continuous incremental improvement; it also incorporates new ideas that are innovative, unconventional, or "outside-of-the-box." Those participants and the 6 participants who defined breakthrough improvement as having both change-in-metric and process redesign characteristics viewed human-centered design thinking as the primary, or important complementary, approach to achieving breakthrough improvement.

Examples of breakthrough improvement

Examples linked to hoshin kanri

Interview participants also discussed ways in which Lean can be deployed to achieve breakthrough improvement through the process of selecting or initiating projects. Two organizational leaders specifically identified formal use of the hoshin kanri method from Lean management for this selection process. Hoshin kanri roughly translates to "management control of a company's direction"[31] and is also commonly referred to as strategy or policy deployment. One respondent described their organization's use of hoshin kanri to plan various strategic priorities, identify market opportunities, and deploy corresponding improvement initiatives. At this participant's organization, one of the strategic priorities identified by hoshin kanri was primary care transformation. The goal was to redefine and reinvent primary care to deliver care in new ways that broke away from the "classic 1 patient, 1 physician, 1 visit" structure of the fee-for-service model. The participant noted that these types of breakthrough improvements cannot be achieved incrementally but require new designs and ways of thinking that break from historical solutions. In brief, with hoshin kanri, breakthrough improvement projects are considered in relation to an organization's strategic priorities rather than waiting

Table 3. Perceptions of Breakthrough Improvement and Lean

Participant	Breakthroughs as % Change	Breakthroughs as Redesign	Both	Lean as Approach for BI	Redesign/Innovation Design as a Complement
A			√√	√√	√√
B			√√	√√	√√
C		√√	√		√√
D		√√			√√
E	√√			√√	
F			√√	√	√√
G			√√	√√	√√
H			√√	√√	√√
I	√√			√√	
J			√√	√√	√√

Abbreviations: BI, breakthrough improvement; √, acknowledgment, but not full support; √√, full support.

for problems to surface from the frontline or middle management.

Examples linked to critical, immediate need

In contrast to the formal, top-down approach of hoshin kanri, all interview participants described examples of other breakthrough improvement projects that were selected as a result of high-pressure situations in which the organization decided to use Lean as a methodology to mitigate risks to productivity, financial investments, and patient care. High-pressure situations might be anticipated, such as an electronic health record implementation. However, they also may be unanticipated, such as when an inefficient process has slowly compounded into a larger issue and become a crisis event. In one example provided by a participant, breakthrough improvements were achieved after major workflow inefficiencies in accounts payable led to a month-long backlog that negatively impacted the organization's financial operations and prompted a Lean improvement project. Another common high-pressure scenario that often initiates breakthrough improvement efforts is extremely long patient throughput time in an emergency department or a clinic. For example, an endoscopy unit within one participant's hospital had long throughput times that were leading to significant financial losses and patient dissatisfaction. The workflow was redesigned through value stream mapping and subsequent improvement activities, resulting in a 75% improvement in throughput time.

Facilitators and barriers

Table 4 lists the identified facilitators and barriers to breakthrough improvement.

Facilitators

Resources. One key facilitator that participants highlighted for achieving breakthrough improvement is the provision of appropriate resources, as evidenced by dedicated staff, money, concentrated time, and space. These types of resources create an environment in which breakthroughs can be achieved. If one or more of them are missing, a breakthrough improvement initiative may not be successful or sustainable. As discussed at the beginning of this article, similar resources are also needed for organizations to be successful in achieving incremental improvement. However, an important distinction between Lean application for daily management and incremental change versus use of Lean for breakthrough improvement is the amount and intensity of resources required. Breakthrough improvements require concentrated staff time to achieve changes beyond minor workflow adjustments or waste reduction. Some organizations have dedicated performance improvement staff and/or innovation teams that work on breakthrough improvement, while others assign staff part-time to these efforts. According to one interview participant, having a project manager dedicating, for example, 20% of their weekly time to breakthrough improvement projects would not be enough time for successful achievement. Dedicating resources such as full-time staff, dollars, concentrated work time, and a physical space in which to assess performance problems, visualize ideas, and develop prototypes can facilitate breakthrough improvements.

Culture. Participants identified attention to culture as another key facilitator. Participants noted the importance of developing mission-driven and principles-driven personnel, rather than being overly tools-focused or finance-focused. This generates a cultural shift and orientation toward a unified mission, which can resonate deeply both internally among providers and staff, and externally to the patients. The greater the cultural shift, the more likely it is that people will actively engage in opportunities for breakthrough improvements. Lean thinking and practices that are embedded within the organization's culture and processes also help to ensure that the culture of

Table 4. Participant-Identified Facilitators and Barriers to Breakthrough Improvement

Category	Facilitators	Barriers
Resources	Staff	Absence of staff, dollars/budget, concentrated time, and space
	Dollars/budget	Partial allocation of resources
	Concentrated time	
	Space	
Culture	Mission-driven	Finance-focused
	Principles-focused	Tools-focused
Leadership	Clear strategic prioritization	Lack of prioritization, dedicated time, and communication
	Dedicated time	
	Communication of priorities	
Other	Including all stakeholders	Not engaging key stakeholders
	Obtaining the voice of the customer	Not obtaining the "voice of the customer"
		Making trade-offs too quickly

improvement survives leadership turnover and that Lean improvements are sustained over time.

Leadership. Leadership commitment expressed through not just executive sponsorship, but clear strategic prioritization and dedicated time, is another facilitator important for success. Having too many priorities and improvement projects that do not clearly align with the organization's strategic direction can scatter its efforts. On the other hand, having a leader who clearly prioritizes specific initiatives that are time-bound and properly resourced demonstrates commitment in their own schedule, and communicates the importance of a breakthrough initiative at all levels of the organization increases the chances of success for that project.

Barriers. Barriers to achieving breakthrough improvement that were described by participants included the absence of the aforementioned facilitators. Additional barriers included not engaging key stakeholders, not actually obtaining the "voice of the customer," and compromising on a vision by making too many trade-offs too quickly. It is important to secure the buy-in of key stakeholders like executive leadership, early adopters, physician champions, and other champions from among the frontlines. Because breakthrough improvement requires more time, resource dedication, and significant disruptions of work processes compared with an incremental improvement project, engaging stakeholders early and sustaining engagement throughout the project are of critical importance. Finally, it is important to hold to a clear vision when working to achieve a breakthrough improvement. One participant summarized their observations from various improvement projects by saying that compromising on a vision and making trade-offs too quickly can easily lead a project back to its original starting point.

DISCUSSION

Leaders in the health care sector consider breakthrough improvements to involve both significant outcome changes and fundamental process redesigns, and that Lean, in concert with human-centered design thinking, is an effective management system for achieving breakthrough improvement. Furthermore, senior leaders and executives overwhelmingly emphasized that resources, culture, and leadership are key challenges that must be addressed to facilitate success. These challenges are similar to those identified by case studies of the use of Lean to achieve incremental performance improvement. But our respondents emphasized that the amount of staff time and other resources dedicated to the effort, the extent to which cultural values and beliefs must change, and the degree of leadership commitment must all be substantially greater to achieve successful breakthrough improvement.

Our results also reveal the importance of developing mission- and principles-driven personnel. This enables a cultural shift in the organization toward a unified mission, which can resonate deeply with providers, staff, and patients. To avoid passive or active resistance to improvement efforts, leaders must achieve buy-in from executive leadership, physician champions, and other champions from among the frontlines. Using a well-developed model of Lean transformation, such as the Shingo model,[32] will provide clear guiding principles, and a framework to help participants understand the various components of transformational change and how their particular work fits into the larger picture, which will encourage participation in the change effort.

There is a need to know more about the relationship between the maturity of Lean implementation in an organization and its ability to successfully achieve breakthrough improvements. What specific components or elements of the Lean management system are most strongly associated with breakthrough improvement? What are the roles played by having a True North aspirational vision for the organization, or frontline empowerment of people delivering care, or visual management, or the use of hoshin kanri? How might incremental improvements and breakthrough improvements best complement each other? How can the breakthrough improvements achieved be sustained over time? Building knowledge about these and related questions will help address some of the issues raised by the leaders we interviewed and, hopefully, contribute to more frequent and significant breakthrough improvements in the delivery of health care services.

Limitations

The study findings should be considered within the context of several limitations. The 10 study participants were selected using a purposive sampling method, chosen for their expertise in the field of Lean management. Although their expertise was crucial to the study, their views and experiences may not be generalizable or representative of others applying Lean in the health care sector. A single interviewer conducted the interviews. Although an interview guide was used to structure the conversation, other interviewers or multiple interviewers might have yielded additional information.

CONCLUSION

This research reveals some differences in experts' definitions of breakthrough improvement, and illuminates the value of human-centered design thinking, alone or as a complement to Lean management, in achieving breakthrough improvement in health care organizations. To achieve and sustain breakthrough improvements that move beyond incremental change, however, organizations should be ready to invest significant resources, dedicate attention to organizational culture, and demonstrate stronger leadership commitment beyond that needed to achieve incremental improvement.

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