Multiple-Hospital Lean Initiative To Improve Congestive Heart Failure Care: A Mixed-Methods Evaluation

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ABSTRACT

Objective: To evaluate a multi-hospital Lean Initiative to understand its implementation and effects on improving congestive heart failure (CHF) care.

Data sources/Study setting: Primary data collection concurrent with a Lean Initiative in four California public hospitals for 16 months. These hospitals received a grant to implement Lean to improve CHF core measures.

Study design: The evaluation was guided by a logic model adapted from "Chain of Action" and used a multi-case mixed-methods design. Each hospital was assessed for the extent of Lean implementation, organizational capacity for improvement, and CHF core measures and hospital readmission rate.

Data collection/extraction methods: Lean implementation data were collected through multiple site visits, coupled with key informant interviews. A capacity-for-improvement survey was administered and analyzed in Lean participants versus non-participants. Monthly CHF core measure of Discharge Planning and 30-day all-cause readmission rate before and after Lean implementation were analyzed.
Principal findings: The hospitals used a number of Lean principles and tools to improve care, standardize work, and eliminate waste. They modestly fused discrete evidence-based care elements into continuous standardized flow of CHF care, but encountered many barriers. Only one site showed a significant positive improvement trend on the core measures and two sites significantly reduced the trends of readmission rate. There were issues with using core measures for performance tracking, but the survey and interviews found organizational contexts, such as improvement fatigue or localized efforts, that limited the effects of Lean for performance improvement.

Conclusions: This mixed-methods evaluation found evidence of applying Lean to improve CHF care.

INTRODUCTION

As health care leaders search for viable options to cross the quality chasm in efficiency, effectiveness, timeliness, and patient safety, many are contemplating adoption of Lean principles (Lean), a management philosophy pioneered by Toyota. Incorporating quality theories such as standardized process and the “plan-do-study-act” (PDSA) continuous improvement cycle, Lean uses a unique flow perspective and accompanying tools to address the “value stream” of manufacturing or service processes. Lean is meant to continuously and incrementally improve operational processes through redesigning and standardizing work flows with the processes customers find valuable (called value-added) and hence eliminating non-value-added waste in time, effort, or resources (Spear & Bowen, 1999). This method aims to ensure quality services and promote a customer-focused and continuous improvement culture throughout the organization. Lean has been successfully applied in the manufacturing industry and some pioneering health care institutions, resulting in improved efficiency and cost saving (Bush, 2007; Pham, Ginsburg, McKenzie, & Milstein, 2007). With the conceptual ease of transferring to health care delivery (Spear, 2005), Lean principles have been increasingly adopted by hospitals and clinics as a management strategy and as tools for performance improvement (Jones & Mitchell, 2006; McCulloch et al., 2010; Radnor, Walley, Stephens, & Bucci, 2006). To date, however, there is little evidence about implementation of Lean principles in safety-net public hospitals with a focus on improving congestive heart failure (CHF) care.

Health care safety-net organizations include public hospitals and community health centers that deliver care mainly to Medicaid, uninsured, and other vulnerable patients. Although these institutions account for only 10% of U.S. health care expenditures, they provide care to 25% of the population (Lewin & Altman, 2000). The Institute of Medicine (IOM) warns that safety-net providers are “endangered” because of their precarious financial situation (Lewin & Altman, 2000). To meet the needs of the indigent population while maintaining organizational viability, safety-net organizations are seeking ways to improve operational efficiency and quality of care simultaneously.

Intrigued by Lean’s potential, the California Health Care Safety Net Institute (SNI), with funding from the California HealthCare Foundation (CHCF), designed a pilot project called Lean Core Measures Improvement Initiative (Lean Initiative hereafter) to introduce this approach in four California public hospitals. The primary objectives were to improve efficiency and quality of care, with a focus on
improvement in Centers for Medicare & Medicare Service (CMS) National Hospital Quality Measures, specifically the Discharge Instructions1 in CHF core measures, 30-day all-cause readmission rates, and the use of Lean principles to promote organizational culture change to achieve continuous, sustainable improvement.

The authors evaluated the Lean Initiative independently using a mixed-methods approach. This approach was chosen in order to answer the following research questions.

1. How were Lean principles and tools introduced to interested hospitals and how did these hospitals utilize and implement Lean to improve CHF care?

2. What were the effects of Lean implementation on CHF Discharge Instructions core measure, readmission rate, and organizational capacity to change?

3. What were facilitators, barriers, and critical organizational contexts that impacted the implementation and effects of Lean?

The goal was to help researchers, safety-net providers and practitioners, and policy makers contemplating the implementation of Lean principles to better understand the Lean implementation process, effects, and contextual factors that promote or hinder effective implementation in new settings.

BACKGROUND

Application of Lean Principles in Health Care

The Lean management approach was developed by Toyota during the 1950s to make the company’s automobiles more competitive internationally. Called the “Toyota Way,” it was adopted by many manufacturing organizations and, eventually, service organizations. Increasingly, health care providers have begun to use the Toyota Management System or “Lean Thinking” approach. Examples include Virginia Mason Medical Center (VMMC), Seattle Children’s Hospital, St. Joseph Health System, Park Nicollet Hospital, and Denver Health (Meyer, 2010). VMMC used the concept of Jidoka, which empowers anyone involved in production work to stop the line if the quality does not meet the organization’s standards, to build an alert and rapid-response mechanism to ensure patient safety (Furman & Caplan, 2007). VMMC decreased ventilator-acquired pneumonia (VAP) cases from 40/year in 2000 to 5/year in 2006 by implementing a VAP care bundle under the Lean principle of zero defects (Bush, 2007). Other studies have reported that standardizing processes using Lean principles reduced medical and diagnostic error (Raab et al., 2006; Spear, 2005). However, when systematically assessed, researchers argue that the utility of the original Lean tools in health care may be limited and more attention should be paid to the dynamics of the Lean implementation process (Joosten, Bongers, & Janssen, 2009; Young & McClean, 2008). To help more health care organizations interested in adoption of Lean principles benefit from it, studies are needed to document implementation models and discern facilitators and barriers of Lean implementation.
Rationale and Evidence of Improving Quality of Care for CHF Patients

CHF affects more than 5.8 million Americans and is a leading cause of hospitalization and readmission, causing an estimated direct and indirect cost of $39.2B in 2009 (Lloyd-Jones et al., 2010). Recent empirical evidence has shown that, among Medicare beneficiaries, one-fifth of patients were readmitted within one month and they had a longer length of stay at rehospitalization (Jencks, Williams, & Coleman, 2009). The Affordable Care Act created a financial penalty for “excessive” readmissions at hospitals. Reducing CHF readmission is a priority of SNI because it is an area in which safety-net providers can simultaneously improve outcomes for patients and reduce costs.

Numerous randomized control trials have been conducted to improve CHF quality of care and reduce readmissions (Blue et al., 2001; Harrison et al., 2002; Krumholz et al., 2002). One meta-analysis showed that a combination of comprehensive discharge planning plus post-discharge support could significantly reduce CHF readmissions (Phillips et al., 2004). Existing literature and clinical guidelines have identified other evidence-based care approaches and experiential best practices (Lindenfeld et al., 2010). To promote evidence-based care for CHF patients, the CMS and the Joint Commission together developed four standardized evidence-based performance core measures (The Joint Commission, n.d.). SNI found that California public hospitals on average did fine on three of the four but underperform for Discharge Instructions; only 46% of patients were given full discharge instructions according to 2007 data.

Thus, the Lean Initiative focused on improving performance on Discharge Instructions and on reducing CHF readmission by developing standardized evidence-based discharge; through the process, it was hoped Lean principles would help advance organizations’ capacity to conduct continuous improvement.

Design of the Lean Initiative

The Lean Initiative was launched in April 2009 and continued for four months of consulting plus 12 months of data collection. SNI selected a firm to bring Lean management consulting services to four member hospitals of California Association of Public Hospitals and Health Systems (CAPH). Both the firm and the hospitals were chosen through a grant application process. Desired outcomes included: (1) successful introduction and implementation of Lean management in four California public hospitals, (2) demonstrated improvement of the CHF discharge instruction core measure and reduction of readmissions for CHF patients, and (3) spread of Lean principles to promote organizational culture change to achieve continuous, sustainable improvement.

The hired consulting team provided training in Lean principles and tools, and facilitated improvement events; these included an executive orientation, one week of value stream mapping (VSM), and three one-week rapid-cycle Kaizen workshops over a four-month period. Value stream mapping is a Lean technique to analyze flow (e.g., steps and cycle times) of work processes for value-adding vs. non-value-adding, in order to design or redesign an optimal flow to bring a product or service to a consumer or a patient. Kaizen, the Japanese word for “improvement,” in Lean technique means bringing workers
together for the improvement of processes and work methods to increase productivity or performance. Figure 1 shows the basic outline of the Lean Initiative and a typical agenda of a Kaizen week.

Figure 1. Basic outline of the Lean Initiative and a typical agenda of a Kaizen week

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Opening remarks</td>
<td>• Hansei/review</td>
<td>• Hansei/review</td>
<td>• Hansei/review</td>
<td>• Verbal critique of</td>
</tr>
<tr>
<td>• Education for team</td>
<td>• Complete idea</td>
<td>• Continuous</td>
<td>• Continuous</td>
<td>the week</td>
</tr>
<tr>
<td>members</td>
<td>generation,</td>
<td>improvement work</td>
<td>improvement work</td>
<td>Report out to</td>
</tr>
<tr>
<td>• Team exercise</td>
<td>prioritization, and</td>
<td></td>
<td>Complete</td>
<td>organization</td>
</tr>
<tr>
<td>• Waste walk, idea</td>
<td>plan</td>
<td></td>
<td>improvement work and</td>
<td>followed by</td>
</tr>
<tr>
<td>generation, and review</td>
<td>Continuous</td>
<td></td>
<td>preparation for</td>
<td>comments from</td>
</tr>
<tr>
<td>• Review A3 and</td>
<td>improvement work</td>
<td></td>
<td>report out</td>
<td>consultant and</td>
</tr>
<tr>
<td>agenda plan</td>
<td></td>
<td></td>
<td></td>
<td>hospital sponsor</td>
</tr>
</tbody>
</table>

Mixed-Methods Evaluation Design and Data Collection

Evaluation Design

The authors evaluated the Lean Initiative independently and concurrently. The study sites included two in northern and two in southern California. Using a multi-case mixed-methods evaluation design guided by a logic model (Figure 2) adapted from the Chain of Action system change model (Whyte, 1991), we assessed the extent of Lean implementation, organizational capacity for improvement, and CHF core measures and hospital readmission rate for each hospital individually and then compared among them.
The logic model “chain” began with participating organizations in an environment requiring organizational adaptation. These organizations’ culture and the leadership’s commitment to high performance (like those who responded to the SNI Lean request for proposals) propelled the organizations to respond to the adaptation needs. Organizations responded by creating a workgroup staffed with motivated individuals and teams that were able to effectively work together to make changes. The Initiative was intended to enhance the workgroup’s effectiveness through Lean principles and consultation services. Effective teams learned from the clinical evidence (e.g., CHF treatment guideline) and Lean activities (e.g., VSM workshop, Kaizen workshops, and their own continuous improvement mechanism) to make changes in CHF delivery processes (e.g., discharge planning, post-discharge support) and other processes (e.g., process redesign in emergency room). The system redesign, in turn, could result in value-maximized, waste-eliminated care processes for individual patients. These changes would improve outcomes in terms of CHF care and hospital operations and hence improve financial outcomes and result in organizational long-term outcomes (e.g., sustaining a Lean culture). This evaluation logic model was reviewed and approved by the Lean consultants, CHCF, and SNI.
Data Collection

The qualitative data were collected via site visits and key informant interviews. We visited each hospital at least twice to observe implementation of the CHF value stream events, inquire about staff experiences, and check documents. We also conducted semi-structured interviews during site visits with senior hospital executives, Lean Initiative team leaders, and team members. The interview questions assessed leadership expectations and support, team composition and functioning, the quality of Lean Initiative facilitation by the consultants, the changes made during the project, and key facilitators and barriers. To supplement our understanding, we sent a log of changes (pre-filled with data from the interviews) to each hospital and asked them to expand this information by recording specific details regarding changes they made as a result of the Lean Initiative.

To assess organizations' capacity for continuous improvement, we conducted an online survey using SurveyMonkey®. We adapted the survey items developed by the First National Demonstration Project on Practice Transformation to Patient-centered Medical Home (Dr. CR Jaen, personal communication, Nov., 2009). The survey asked respondents to rate their extent of agreement with 23 statements to comprehensively assess different aspects of organizational capacity for change. There were five response categories for each item: Strongly disagree = 0; Disagree = 25; Neutral = 50; Agree = 75; Strongly agree = 100.

All Lean Initiative hospitals were asked to invite their Lean participants and comparable staff members to respond to the self-administered survey, and the subjects were aware that the survey was conducted anonymously. There were two sections in the survey. Both Lean participants and non-participants were asked to finish Section 1, where 23 statements asked about organizational level. Only Lean participants completed Section 2, where a similar set of questions were asked but only to gauge the impact of the Lean Initiative. The survey collection period was from February 2010 (10 months after the initial Lean initiative orientation by the consultants) to May 2010. With the help of SNI, the four participating hospitals sent the evaluation team CHF core measure of discharge instructions and 30-day readmission rates that were tracked monthly beginning in June 2008 for 24 months. Also, for comparison, we obtained the public reported CHF core measure data (quarterly data) from CAPH for all California public hospitals to understand changes attributable to Lean implementation.

Data Analysis

The four hospitals were compared and contrasted as four case studies using their implementation data, survey data, quantitative data, and organizational characteristics to identify common and different Lean implementation, effects, facilitators, barriers, and specific organizational contexts driving differences. Qualitative data were analyzed by at least two researchers independently and then discussed to reach analytical agreement. The analysis was fed back periodically (1 to 3 months) to SNI, CHCF, and Lean consultants for formative evaluation purposes but also served as a verification of activities. The survey data were analyzed using factor analysis for all items and to abstract subscales. The internal consistency reliability was analyzed using Cronbach’s alpha. Boxplots of scale score (range 0 to 100) was used to
compare Lean participants and non-participants on their responses to Section 1 of the survey. Descriptive statistics and t tests were performed comparing Section 1 and Section 2 of the survey among Lean participants to compare capacity for improvement before and after Lean implementation.

The discharge instruction core measure and the 30-day readmission data were tracked as run charts. In addition, these data are analyzed by segmented regression analysis of interrupted time series 12 months before- and after the Lean implementation (Wagner et al., 2002). We defined the pre-intervention period from June 2008 – May 2009 and post-intervention period from July 2009 – June 2010. Both periods have 12 monthly data points, which meets the general requirement of sufficient number of data points and allows detection of seasonality (Wagner et al., 2002). The first month after the Lean sites conducted their first Kaizen workshop, June 2009, is considered as the transition period and is therefore excluded from the analysis. The statistic analysis was conducted in SAS 9.1. The intervention effects are also used to estimate cost savings to the participating hospitals. The cost savings was derived by two-step estimation. First calculated the estimated change in the number of readmissions by multiplying the intervention effect on the readmission rates before and after the Lean implementation by the average number of eligible CHF hospitalized patients for each hospital over the 24 months. Then valued each averted CHF readmission at $9540 of 2013 dollar (equivalent to $7000 in 2005 dollar used in Anderson et al., 2005).

RESULTS

Introduction and Implementation of Lean Principles and Tools

The four hospitals entered the program because of SNI grant opportunity, with an incomplete understanding of Lean principles. For most, the executive orientation or first day of a Lean event (see Figure 1) was the first opportunity to learn about Lean principles.

Because the Lean Initiative aimed to transform organizational culture regarding performance improvement, the Lean Initiative teams were larger than typical quality improvement teams, consisting of 12-20 staff members in each participating hospital. The hospital executives handpicked these participants. Some sites had different people rotate into the Lean Initiative events so that as many staff members as possible could receive training. The main participants were nurses (from CHF-related nursing units as well as the Emergency Department). Other participants were from pharmacy and quality improvement departments, and, in some hospitals, a few physicians also participated.
Table 1. Summary of Lean Implementation

<table>
<thead>
<tr>
<th>Lean Implementation</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital size, type</td>
<td>456 beds, county safety net</td>
<td>118 beds, county safety net</td>
<td>371 beds, county safety net</td>
<td>223 beds, county safety net</td>
</tr>
<tr>
<td>Lean training participation</td>
<td>Kaizens 10 to 12 staff, mostly nursing.</td>
<td>Kaizens often 20 people or more, mix of hospital staff</td>
<td>Kaizens 8 to 10 staff, mostly nursing.</td>
<td>Kaizens 8 staff, mostly nursing.</td>
</tr>
<tr>
<td>Lean implementation team</td>
<td>Led by senior supervisors, mostly nursing</td>
<td>Physicians, broad set of clinical and non-clinical staff</td>
<td>Mostly nursing staff</td>
<td>Mostly nursing staff</td>
</tr>
<tr>
<td>Management participation</td>
<td>Limited involvement by senior management</td>
<td>CEO actively involved, senior management participated</td>
<td>Involvement by senior management at start</td>
<td>Led by Chief Nursing Officer</td>
</tr>
<tr>
<td>Hospital units involved</td>
<td>Admissions, ED, CHF inpatient care</td>
<td>Admissions, ED, CHF inpatient care, long term care clinic</td>
<td>Admissions, ED, CHF inpatient care, long term care clinic</td>
<td>Admissions, ED, pharmacy, CHF inpatient care</td>
</tr>
<tr>
<td>Staff given assigned time to improve CHF care</td>
<td>Some, but not an explicit amount</td>
<td>Tasks assigned but not time explicit</td>
<td>Tasks assigned but not time explicit</td>
<td>No</td>
</tr>
<tr>
<td>Involvement of physicians</td>
<td>Limited to few participants</td>
<td>Yes, several</td>
<td>Led by a physician</td>
<td>No</td>
</tr>
<tr>
<td>Involvement of patients</td>
<td>No</td>
<td>One patient participated throughout</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Follow-up mechanism after Kaizen</td>
<td>Limited</td>
<td>Yes, on a couple topics of improvement</td>
<td>Yes, regular team and senior leader meetings about CHF improvement</td>
<td>Not explicit to this Lean work</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------</td>
<td>---------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Ongoing spread of Lean &amp; related organizational change</td>
<td>Unclear, mixed opinion at management levels</td>
<td>Intend to apply to other functions, planned new projects</td>
<td>Other Lean projects begun but CHF is a main focus</td>
<td>Intend to apply to other functions, county govt. supportive</td>
</tr>
</tbody>
</table>
| Lean concepts used | Used and implemented  
- Standardized process  
- Value stream mapping, measurement  
- Kaizen – events as defined and lead by consultant  
- Gemba (direct observation), 5S (organize work area)  
Used in a limited way, primarily as part of training  
- Waste reduction  
- Continuous improvement  
- Customer Focus  
- Spaghetti diagrams when applicable  
- Root cause analysis  
- Hoshin Kanri, policy deployment  
- Andon, visual feedback & controls  
Generally not used, mentioned in training  
- Ongoing A3 monitoring, PDSA, Kanban-pull system, Takt time, Poke Yoke, Broad organizational maturity | |
| Some common outputs |  
- Customer-focused patient education booklets  
- Standardized discharge procedures  
- Monitoring of relevant core measure  
- Trained staff, understanding of Lean tools, but limited to Kaizen participants | |

Facilitated by consultants, the Lean Initiative team completed value stream mapping and all Kaizen workshops during a four-month period, as specified in the project schedule. In value stream mapping, the team mapped current CHF care processes, differentiating value-added processes from non-value-added ones. Defects, delays, and other problems were identified, and efforts to address these were part of subsequent Kaizen workshops. At the beginning of every Kaizen workshop, the consultant first provided theoretical training about Lean principles and tools, and each team developed their “A3” report, which summarizes their identified problems, proposed actions, and improvement targets on one piece of A3 (11” by 17”) paper. During Kaizen, the team conducted rapid PDSA improvement cycles to generate improvement ideas, develop tools, and create standard work for new or redesigned practices. On the last day of Kaizen week, team members reported changes they planned to or had implemented.
to hospital executives, physicians, and other staff members. There were three weeks between each Kaizen workshop for the team to test the effects of their redesigned processes. Two hospitals developed formal follow-up meetings between Kaizen weeks to track their progress of the PDSA changes; the other two used informal tracking by team leaders. The leadership involvement varied by hospital, but all showed support by appearing at the executive orientation and again for some report-outs at the end of Kaizen week.

The four hospitals used Lean principles to implement clinical practice changes in CHF care. All developed customer-focused patient education booklets and standardized their discharge procedures. Clinical pathways were also developed and tested in some hospitals. One hospital initiated a telephone follow-up for discharged patient to make sure that they understood the educational material and made follow-up appointments with their primary care physician. Another hospital established a new mental health support center because 40-50% of their all-cause readmissions were mental health-related.

The most widely used Lean tools were value-stream mapping, standard worksheets, A3 reports, and spaghetti diagrams (a visual representation of actual movement and distances involved in a work process in order to identify flow problems or improvement opportunities). We found the latter two had limited use after their creation. The main Lean principles (Flinchbaugh, 2006; Liker, 2004) used were (1) growing Lean leaders and multidisciplinary team members, (2) directly observing work to understand connections and issues (gengchigenbutsu), and (3) standardizing tasks for continuous improvement. Two of the four hospital leaders sent tens of their staff to participate in the week-long Kaizen workshops. As these leaders were willing to adopt Lean as their management principles, they wanted to build a critical mass to continue Lean beyond the Initiative. Through the staff’s participation in the Kaizen meetings, there was modest evidence for the beginnings of a learning organization in all four hospitals. Some interviewees indicated that they now realized that the patient was their real customer, and they had started to consider the work they did as value-added or non-value-added from the patient’s perspective. Some hospitals also took advantage of the Lean Initiative to improve other patient flow and to reduce inventory waste.

**Impact on CHF Discharge Instructions Core Measure, Readmission Rate, and Costs**

For the core measure of Discharge Instructions (Figure 3), the segmented regression analyses of interrupted time series showed two of the four sites having statistically significant changes at $\alpha = .05$ level (Site 1 and Site 2). Site 1 had worse mean performance in the post-intervention period than the pre-intervention period, but its time trend in the post-intervention period showed significant improvement over time. Site 2 had significant upward trend since pre-intervention, but the trend slowed down after the Lean Initiative, likely due to the ceiling effect. Site 3 showed a positive trend of improving performance, but did not reach statistical significance at $\alpha = .05$ level. Site 4 was a high-performer before the Lean implementation and remained consistently high performing after Lean.
Figure 3. 12-month pre and post Lean Initiative CHF core measure of discharge instructions by site
Site 3 Discharge Planning

Site 4 Discharge Planning
Figure 4 shows before the Lean implementation the 30-day all-cause readmission rates of all four hospitals were increasing. The trend reversed after the Lean Initiative and showed a declining rate over time for all hospitals. Site 1 and Site 3, which had larger average number of CHF patients per month (36.2 and 24, respectively, vs. 20.7 and 11.9 in Site 2 and Site 4), reached statistical significance (p< .05) in the trends of reducing readmission rate.

Figure 4. 12-month pre and post Lean Initiative 30-day all-cause readmission rate by site
The reduction in readmission rate resulted in 87 averted readmissions for the 4 hospitals from July 2009 to June 2010 (ranging from 1 to 31 by sites). By valuing each averted readmission at $9540, there was a saving of approximately $830,000 associated with the Lean implementation.

**Impact on Organizational Capacity to Change**

One year after the Lean Initiative, the key informants, including hospital administrators and Lean Initiative leaders, were interviewed. The Lean effort was considered successful by leadership of all four hospitals, and all intended to continue to apply Lean principles in future. Lean was said to be more powerful than the hospital’s usual quality improvement approach, which was to set up a committee or
task force to solve a problem. At each hospital, one or more individual felt that they gained sufficient experience to lead future Lean projects.

The survey of organizational capacity to change, however, revealed a less positive finding. In all, 93 Lean participants and 63 non-participants completed the survey. Contrary to expectations, in 3 of the 4 sites (not Site 3), Lean participants perceived lower average scores of capacity for change than non-participants from Section 1 of the survey (Figure 5). When comparing results from Section 2 (Lean improvement team level) with Section 1 (organizational level), Lean participants felt significantly (p < 0.05) more positive on seven statements regarding collegial interactions, cooperation, and information available among the Lean improvement team. Yet, Lean participants perceived no change for the statements describing organizational environment and leadership support.

Figure 5. Boxplot of overall organizational capacity for change cores by Lean participation by site
Facilitators, Barriers, and Organizational Contexts

Although all four hospitals followed the same training conducted by the same consulting firm, the effects of the Lean Initiative differed. The comparative case analysis identified common facilitators, barriers, and plausible organization-specific contexts that may explain the mixed results.

Continuously visible leadership support was the most cited facilitator mentioned. The Lean Initiative consultants, acting as outside resources, were considered indispensable in launching the project. Outside financial aid such as the CHCF grant supporting the consultant services in the Lean Initiative was necessary to initiate a broad-based improvement process for public hospitals that usually face financial difficulties. A core team with assigned time and responsibility for facilitating improvement was another facilitator. Additionally, sharing experiences among the four hospitals was perceived as beneficial; this was made possible by SNI, who organized two one-day workshops. Other major facilitators included a follow-up mechanism to conduct continuous improvement and multidisciplinary and interdepartmental collaboration.

There were, however, common barriers in Lean implementation. One barrier was the lack of physician involvement in Lean Initiative events, though they often were the process owners of the CHF value stream. When they did participate, they often saw the value of Lean and contributed ideas and approved changes, which gave nurses more confidence in conducting further improvement. A second barrier was the lack of provider awareness of the importance of patient involvement. Despite Lean’s focus on customers, only one hospital included this aspect in its implementation. Another barrier was suspicion and resistance from frontline staff who were unfamiliar with Lean principles. The teams addressed this obstacle through hospital-wide communication efforts (e.g., project posters in conference rooms and hospital newsletters) to publicize Lean implementation efforts and outcomes. Technical difficulty incorporating the new clinical pathway into electronic health record (EHR) systems was also a challenge in some hospitals. In addition, financial constraints and, at the time of the study, fee-for-service reimbursement or subsidy of costs for CHF readmissions challenged the motivations of the public hospitals to improve care.

Specific contexts at each site affected Lean implementation. Site 1 was a large hospital and had its own performance improvement department, from which most Lean Initiative participants came. Site 1 used its existing project-based improvement model to address the CHF value stream and was localized in a pilot inpatient unit, not system-wide. Lean Initiative was one of many projects improvement staff members worked on. Site 2 was a small hospital; the leadership mobilized a large number of employees in the Lean Initiative, regardless of their role in the CHF value stream. Except for four key team leaders, the rest of participants rotated monthly, aiming to train as many staff as possible. The organization had gone through many quality improvement endeavors since new leadership came on board two years ago. From our interview, this caused improvement fatigue and complaints among the staff, especially the same staff that had participated in multiple improvement endeavors. The hospital also encountered
"broken value stream" during inpatient-to-outpatient transition. The outpatient departments did not collaborate with the hospital to provide follow-up care.

Sites 3 and 4 had more appropriate numbers of participants for their size. Before the Lean Initiative, Site 3 underperformed on the Discharge Instructions core measure (about 60%); Site 4 was already a high performer (nearly 100%). Site 4 was satisfied with their performance but still participated to learn Lean principles and tools. Because the objective was not aligned with improving CHF, less attention was paid to CHF care and few improvements were made to CHF care process. Meanwhile, Site 3 achieved significant improvement in its core measure and reduction in readmission. The leadership gave the Lean team ample time to find solutions in the CHF value stream, including changing physical layouts of inpatient rooms to facilitate better communications about CHF patients, streamlining processes with EDs, and collaborating with the affiliated long-term care facility for better follow-up care. The senior leaders asked the Lean team to report to the senior management team meetings on a regular basis, including core measure data review. In our two site visits, participants in Site 3 changed from passive participants in Lean to an active and motivated improvement team.

DISCUSSION

With Lean principles proven effective for operational improvements in many hospitals, this Initiative extended the knowledge of Lean to clinical improvement, which is valuable for other health care settings in need of clinical improvement and contemplating Lean implementation. The mixed-methods evaluation assessed the initiative from various aspects and multiple perspectives, guided by the “Chain of Action” logic model to genuinely and comprehensively understand the Initiative’s implementation process and effects, as well as factors and organizational contexts explanatory for the findings.

Despite the four study sites had nearly no effects on improving the CHF core measure of Discharge Instructions, they all had reversed the upward trend of hospital readmission rate to a downward trend. The results not only improved clinical outcomes, but also averted nearly $1 million cost. There were organizational commitments from all 4 hospitals to sustain the gain by continuing the use of Lean. However, survey data showed signs of “change fatigue” among many Lean participants. Only the site that had the lowest baseline performance (Site 3) their Lean participants scored higher on the adaptive reserves than non-participants. Lean participants were understandably fatigued because they were battling barriers described above. It will be important for hospital leadership to monitor closely to avoid or detect early any change casualties, such as tension among physicians and practice staff that results in a stalemate.

Lean principles provide a unique value stream perspective to integrate discrete evidence-based care elements into the continuous standardized flow of the care process, with operation time, place, tools, and operator clearly identified. With the standard workflow of best practices, ambiguities and care variation could be significantly reduced, as perceived by the participants of the Lean Initiative. Moreover, as waste is eliminated, clinical workers (especially nurses, who are burdened with non-value-added work) could spend more time at the bedside, resulting in better quality of care (Nelson-Peterson
& Leppa, 2007). For example, applying Lean principles has shown improved ER patient flow (Ng, Vail, Thomas, & Schmidt, 2010). Our evaluation found encouraging findings in the trend of reducing readmission rates. To achieve more significant effects, CHF patients need a continuum of care after hospital discharge to reduce readmission (Phillips et al., 2004). Merely improving hospital care may not have enough impact on the quality of CHF care and readmission measures. Hernandez and colleagues showed that discharged patients who received early follow-up from outpatient physicians had lower risk of readmission (Hernandez et al., 2010). Hospitals could argue that readmission is due to factors beyond their control, such as patients lacking a primary care provider or the provider not following up after the patient is discharged. In Lean terms, it is an incomplete value stream if only hospital care processes are mapped. Therefore, it is hard for the Lean team to find improvement opportunity to reduce readmission rates solely based on the inpatient process value stream mapping that was done by the four study hospitals. Hence, we conclude that future Lean implementation in CHF care should be conducted by a multidisciplinary team composed of inpatient, outpatient, and home care providers, and a complete care delivery process value stream mapping, including patient admission to ER, inpatient care, post-discharge follow up, and home support, should be developed by the multidisciplinary team as shown in Figure 6. Based on this continuum of care value stream mapping, the team then can identify improvement opportunity, improve care delivery process and coordination between multiple providers, continuously reduce waste (e.g., readmission), and monitor the outcomes. The evaluation also found appropriate incentive mechanisms need to be created to promote collaboration and shared accountability between inpatient and outpatient providers (Epstein, 2009).

Figure 6. The comprehensive CHF care process

All hospitals are required to collect and report CHF core measure data, which was one reason why core measures were selected (i.e., no new or additional measurement was required, and the results were publicly reported). The CHF quality indicators, such as the core measures, are costly to collect and are argued not fully reflect the results of quality of care. For example, in a large-scale analysis conducted by Jha et al. (2009), the authors showed a weak, not statistically significant association between CHF
readmission rates and discharge instruction measures. Using the segmented regression analysis of interrupted time series 12 months before- and after the Lean implementation, we increased the sensitivity of estimating the intervention effects by detecting changes both in the mean values and in the trends (or slopes of trend lines) before- and after the intervention. Taking the example of Site 1, before the Lean Initiative, the nursing units of Site 1 only had one general discharge guideline used for all diagnoses. During the Lean Initiative, they developed a comprehensive discharge process including education package and discharge procedures designed specifically for CHF patients and created a follow-up mechanism. The regression trend lines (or slopes) of discharge instruction core measures and CHF readmission rates both captured such improvements on clinical care; but the mean values did not. Other sites showed no improvement in Discharge Instruction core measure, but they all reversed the trends of hospital readmissions. Despite appropriate statistical analyses can improve the precision of estimating intervention effects, our modest findings due to ceiling effects and small samples echo the argument made by Chassin et al. (2010) that there is a need to redesign value-adding performance metrics to promote effective quality improvement and monitoring.

The findings are subject to several limitations. One limitation is generalizability because all the participating hospitals were public safety-net hospitals. Also, the way in which Lean was implemented and the outcome measures were determined by external entities (e.g., SNI, Lean consultants). However, we believe the findings still serve well as lessons learned for other health care organizations contemplating Lean implementation. Another limitation is lack of comparable comparison group due to the design of the Lean Initiative. Thus, we compared the time trends before and after the implementation. Thirdly, the true effects of Lean implementation were difficult to establish from the selected quantitative measures (i.e., core measure and CHF readmission rate) due to ceiling effects of the measures, the small number of CHF cases in the hospitals, no patient risk adjustment for aggregated measures, and the incomplete CHF care value stream under control of the hospitals. The core measure and readmission results are meant only to support our analysis of the adoption of Lean, not to be interpreted as clinical evidence.

In conclusion, our mixed-methods evaluation found noticeable effects of applying Lean to improve CHF care and how implementation and organizational contexts of implementation affected the effects. Transformation to a high-efficiency and quality health care organization is a long developmental process. Applying Lean in the right clinical focus with attentions to the organizational contexts holds promise as an improvement methodology to improve care for the larger population.

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