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Lean Management and Hospital Performance: Adoption vs. Implementation

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Background: The Lean management system is being adopted and implemented by an increasing number of US hospitals. Yet few studies have considered the impact of Lean on hospitalwide performance.

Methods: A multivariate analysis was performed of the 2017 National Survey of Lean/Transformational Performance Improvement in Hospitals and 2018 publicly available data from the Agency for Healthcare Research and Quality and the Center for Medicare & Medicaid Services on 10 quality/appropriateness of care, cost, and patient experience measures.

Results: Hospital adoption of Lean was associated with higher Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience scores ($b = 3.35$, $p < 0.0001$) on a scale of 100–300 but none of the other 9 performance measures. The degree of Lean implementation measured by the number of units throughout the hospital using Lean was associated with lower adjusted inpatient expense per admission ($b = -38.67$; $p < 0.001$), lower 30-day unplanned readmission rate ($b = -0.01$, $p < 0.007$), a score above the national average on appropriate use of imaging—a measure of low-value care (odds ratio = 1.04, $p < 0.042$), and higher HCAHPS patient experience scores ($b = 0.12$, $p < 0.012$). The degree of Lean implementation was not associated with any of the other 6 performance measures.

Conclusion: Lean is an organizationwide sociotechnical performance improvement system. As such, the actual degree of implementation throughout the organization as opposed to mere adoption is, based on the present findings, more likely to be associated with positive hospital performance on at least some measures.

In the United States, the triple aim of improved quality, improved population health, and lower rate of growth in costs remain largely aspirational and elusive. Building on two seminal National Academy of Medicine (formerly the Institute of Medicine) reports, *To Err Is Human*[1] and *Crossing the Quality Chasm*,[2] a number of initiatives have been launched over the past 20 years, including quality improvement collaboratives, value-based payment models, the creation of Accountable Care Organizations, and patient-centered medical homes in both the public and private sectors.[3–7] Although there is evidence of some progress,[8–11] there remains wide variability in patient safety and quality of care,[12] slow uptake of screening for the underlying social determinants of health,[13] and continuing cost increases higher than the rate of inflation.[14] There is evidence that a large share of hospital spending results in little or no benefit, with an estimated $760 billion to $935 billion of waste in the system, representing approximately 25% of total health care spending.[15]

Given the above, there is growing recognition that more is needed to achieve substantial and sustainable improvement.[16] There is also growing understanding that the complexity of health care organizations makes it difficult to implement sustainable changes.[17] These and related factors have resulted in a call for transformational performance improvement efforts that propose a new way of leading and managing our nation's hospitals and other health care organizations.[18,19] These include the Lean management system,[20] Lean plus Six Sigma,[21] and Robust Process Improvement®, which adds a change management component.[22] Collectively, these programs emphasize creating a culture of continuous improvement embedded in an overall management/operating system that empowers frontline staff to solve problems and eliminate waste by standardizing work and eliminating unwarranted variation to improve the value of care delivered to patients. The most frequently used approaches in US hospitals include the Lean management system based on the underlying Shingo principles that emphasize culture, continuous improvement, alignment, and results.[23–27] Use of Lean has been best reflected to date in the small percentage of hospitals that have won the Baldrige Award for operational excellence.[18] The following question emerges: To what extent might the Lean approach to transformational improvement, if fully and widely implemented, provide a foundation for larger and more sustainable improvements in the quality and cost of care than the United States has achieved to date? This article provides some evidence addressing this question.

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LITERATURE REVIEW

The existing evidence on the impact of the Lean management system is mixed. Numerous small-scale studies of Lean applications in various hospital units/departments have shown generally positive results, perhaps reflecting publication bias.[28–31] Positive associations are most frequently reported for reducing waste, reducing patient wait times, increasing patient safety, and improving financial performance. There are also several book-length case studies of overall Lean adoption and implementation in selected hospitals, highlighting both the successes and the challenges of sustaining continuous performance improvement across an organization.[18,32–34] Several comparative case studies of hospitals in the United States,[35] Canada,[36] Sweden,[37] and England[38] have found largely disappointing results citing barriers involving inadequate resources for staff training and support, lack of focus, the challenge of addressing complex work processes, and inadequate communication and relationship building.

Five recent large sample studies have examined the association between hospital Lean management adoption, implementation, and organizationwide performance measures. Based on data from 1,222 hospitals, Shortell et al. found positive associations between measures of Lean implementation such as number of units doing Lean and leadership commitment with self-reported performance, including eliminating waste, increasing throughput in the emergency department, and reducing expenditures.[39] An analysis of a subset of 288 public hospitals found that 54.2% had adopted Lean, and Lean adoption was associated with higher earnings before interest, taxes, depreciation, and amortization (EBIDTA) financial performance and lower percentage of patients leaving the emergency department without being seen.[40] Related analyses of the national sample found positive relationships for the extent of Lean implementation in information technology, human resources, and finance support departments and positive self-reports of performance improvements.[41] A smaller study of 215 US hospitals found a positive association between Lean implementation and self-report of improved patient safety and lower cost.[42] Given the limitation of self-report data, recent work has examined the relationship between adoption of Lean (as opposed to degree of implementation) in the 1,222 US hospitals noted above and a portfolio of independent publicly available objective measures of quality, patient experience, and cost/efficiency. Results indicated little relationship between adoption of Lean and performance except for lower Medicare spending per beneficiary.[43] The present study represents a major extension of this work by linking Lean implementation data from the National Survey of Lean/Transformational Performance Improvement in Hospitals (NSL) administered in 2017 to publicly available performance measures in 2018.

HYPOTHESIS DEVELOPMENT

We examined both the adoption and the degree of implementation of Lean as of 2017. *Adoption* was defined by whether the hospital reported using Lean, Lean plus Six Sigma, or Robust Process Improvement as its primary method of performance improvement. *Implementation* was defined as the extent to which the Lean approaches were being used throughout all units or departments of the hospital. Based on previous research[43] and the challenges of implementing Lean on an organizationwide basis[17,35,38] our first hypothesis was that mere adoption of Lean by 2017 would not be significantly associated with hospitalwide measures of performance in 2018, including independent measures of clinical quality of care, patient experience, and efficiency/financial viability. In contrast, our second hypothesis, consistent with much of the literature on implementation,[44,45] was that the degree of implementation of Lean by 2017 would be positively associated with various measures of hospital performance in 2018 related to quality and appropriateness of care, patient experience, and efficiency/financial viability controlling for potentially confounding variables. Key to Lean implementation is empowering the frontline workforce throughout the organization to problem solve through the use of A3 thinking, daily huddles, Plan-Do-Study-Act (PDSA) rapid cycle improvement experiments, visual performance management, and improvement events called *kaizen*.[23,27] Workforce empowerment has been associated with improved hospital acute myocardial infarction outcomes and door-to-balloon times[46–49] and with implementing continuous quality improvement.[45,50] As a result, the NSL focused on the extent to which such empowerment and engagement had spread hospitalwide throughout many units and the support of such spread through strong leadership commitment, daily management behaviors, and practices and training of physicians, nurses, and staff in Lean principles, tools, and processes.

METHODS

Measures and Data Sources

The American Hospital Association fielded the NSL between May and September 2017. It was sent to 4,500 acute general medical and surgical hospitals in the United States to determine how many hospitals had adopted Lean and the degree of implementation throughout each adopting hospital. The survey took approximately 20 minutes to complete by the chief transformation officer, chief improvement officer, chief quality officer, or equivalent position title in each hospital. The overall response rate was approximately 27%, with 1,222 hospitals responding. There were small but statistically significant differences between responding and nonresponding hospitals, with not-for-profit hospitals being more likely to respond than public and investor-

owned, teaching hospitals more than nonteaching, and hospitals with 400 beds or more vs. those with less than 100 beds.[39] The sample used for this analysis includes 1,152 hospitals with full responses to the NSL. The survey was approved by the Institutional Review Board of the University of California, Berkeley.

Study Variables

The independent, dependent, and control variables are listed in Table 1, including names, descriptions, years measured, and data sources. Lean adoption was measured by whether the hospital had adopted Lean by 2017. Hospitals were counted as having adopted Lean if they were using Lean, Lean plus Six Sigma, or Robust Process Improvement. The degree of Lean implementation was measured by the number of hospital units using Lean out of a potential total of 29 units common to all general medical/surgical hospitals. Examples include the emergency department, operating room, ICU, medical/surgical floors, labor/delivery units, and laboratory. We validated the number of units using Lean by correlating it with independent measures from the survey, including a four-level self-reported measure of Lean maturity, an eight-item leadership commitment index ($\alpha = 0.80$); a nine-item daily management system index ($\alpha = 0.75$); and a training and education scale ranging from 0 to 3 ($\alpha = 0.82$) (see Appendix 1, available in online article). The respective correlations were 0.56, 0.43 0.47, and 0.30, all significant at $\alpha < 0.05$, supporting the use of number of units as a valid measure of degree of implementation hospitalwide. Assistance in developing the items for the above scales was received from 12 Lean performance improvement experts, increasing the content and face validity of the measures.

Our dependent variables of quality and appropriateness of care, patient experience, and efficiency/financial viability are also shown in Table 1. The 30-day risk-adjusted mortality index, the 30-day risk-adjusted unplanned readmission rate, the death rate among surgical patients with serious treatable conditions, and the composite imaging index were averaged over the period from July 1, 2015, to June 30, 2018. The remaining performance variables were based on 2018 data. The control variables were measured as of 2017. IBM Watson Health provided the de-identified performance data linked to the NSL.

Because Lean is a comprehensive approach to operational excellence, we felt it important to examine a comprehensive portfolio of performance measures that embrace the three domains of efficiency/financial viability, quality and appropriateness of care, and patient experience. The frequently used measures of efficiency/financial viability were Medicare spending per beneficiary, adjusted inpatient expense per patient discharge, EBIDTA margin, and the composite timeliness of care index. The quality of care variables were the 30-day risk-adjusted mortality index, the death rate among surgical patients with serious treatable conditions, the 30-day unplanned readmission rate, a composite patient safety and adverse event index, and an appropriateness composite imaging index (indicating low-value care). The overall Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) score measured patient experience corrected to a range of 100 (100% of patients rated the hospital low) to 300 (100% of patients rated the hospital high).

Our control variables, which served both as a partial adjustment for differences between survey respondents and nonrespondents and as potential confounders in the analysis of Lean and performance, were ownership, system/network membership, teaching status, location, bed size, market concentration, percent Medicaid discharges, and the primary care to specialist provider ratio. A number of these organizational and market characteristics have been found in previous research to be associated with various measures of hospital performance.[35,51–55] For example, the percentage of a hospital's patients covered by Medicaid may affect its ability to generate financial reserves to spend on performance improvement.[50] We also controlled for the number of years the hospital had been using Lean.

Data Analysis

We used multivariate regression models to assess the relationship between Lean management in 2017 and our specified measures of 2018 hospital performance. Linear regression was used for continuous dependent variables. Logistic regression models were used for binary dependent variables, and we report coefficients as odds ratios and calculated Tjur's pseudo-R^2 for each model (a measure of model fit for logistic regression that should be interpreted like a linear regression R^2).[56] The first group of models included one binary independent variable measuring Lean adoption by the time of the NSL in 2017. The second group of models was limited to hospitals reporting that they had adopted Lean and examined the extent of Lean implementation using the number of units using Lean at the time of the NSL. We performed sensitivity analyses with the full sample in which the non-Lean-adopting hospitals were scored zero for number of units using Lean. All analyses were completed using R, version 4.0.2 (R Foundation for Statistical Computing, Vienna).

RESULTS

Lean Adoption

Of the hospital respondents, 69.3% had adopted Lean or Lean plus Six Sigma or Robust Process Improvement by 2017.[39] Collectively, these hospitals are referred to as users of the Lean management system. When using data from a follow-up phone call to 96 randomly selected nonresponding hospitals, an adjusted 61.6% of US hospitals were Lean management users. Table 2 summarizes univariate relationships between adoption of Lean and our control

Table 1. Description of Independent, Dependent, and Control Variables

Variable	Description
Independent variables (2017)	
Lean adoption*	Binary indicator measured for each hospital. Yes = hospital reported adopting Lean, Lean plus Six Sigma, and/or Robust Process Improvement at the time of the 2017 survey; No = hospital reported that it had not adopted Lean, Lean plus Six Sigma, or Robust Process Improvement.
Number of years doing Lean*	Number of years since Lean adoption in the hospital (range 0.2–22.5).
Number of units doing Lean*	Number of hospital units that have adopted Lean (possible range 0–29).
Dependent variables (2018)—see Appendix 1 for additional details	
30-day risk-adjusted mortality index†	Percentage: 30-day risk-adjusted mortality, averaged across patients with heart failure, pneumonia, AMI, COPD, stroke (measure time frame is 7/1/2015–6/30/2018).
30-day unplanned readmission rate†	Percentage: patients readmitted to the hospital within 30 days of discharge / all discharges (adjusted for severity of diagnosis) (measure time frame is 7/1/2015–12/31/2018).
Adjusted inpatient expense per discharge‡	Cost: Cost per inpatient discharge adjusted for case mix and area wage indices. Extreme observations winsorized to the 99.5th percentile.
Composite: appropriate/efficient use of medical imaging†	Binary indicator: 1 = Better than national average; 0 = Same as or worse than national average. Hospital Compare Star Rating medical imaging group calculation based on 5 measures. (measure time frame is 7/1/2015–6/30/2018).
Composite: patient safety†	Binary indicator: 1 = Better than national average; 0 = Same as or worse than national average. Hospital Compare Star Rating patient safety group calculation based on 8 measures.
Composite: timeliness of care†	Binary indicator: 1 = Better than national average; 0 = Same as or worse than national average. Hospital Compare Star Rating timeliness of care group calculation based on 5 measures. (measure time frame is 7/1/2017–6/30/2018).
Death rate among surgical inpatients with serious treatable conditions§	Risk-adjusted in-hospital deaths per 1,000 adult elective surgical discharges (observed – expected / standard deviation). Extreme observations winsorized to the 99th percentile. (time frame is 7/1/2015–6/30/2018).
EBITDA margin‡	Percentage: Earnings before interest, tax, depreciation, and amortization / total operating revenue. Extreme observations winsorized to the 0.5th percentile.
HCAHPS score†	Index: Patient responses to the question "How do patients rate the hospital, overall?" (from a standard survey required by CMS) were coded into low, medium, and high categories, and a weighted scoring system was used to create a summary measure ranging from 100 (100% of patients rate the hospital low) to 300 (100% of hospitals rate the hospital high).
Medicare spending per beneficiary†	Ratio: spending per beneficiary / national median.
Control variables (2017)	
Ownership‖	Categorical: Public, not-for-profit, or investor owned.
Member of a system or network‖	Binary.
Core-based statistical area type‖	Categorical: Metropolitan (urban area of at least 50,000 people), micropolitan (urban areas between 10,000 and 50,000 people), or rural (nonurban area).
Member of Council of Teaching Hospitals‖	Binary.
Bed size‖	Categorical: 1–99 beds, 100–399 beds, or ≥ 400 beds
Market concentration#	Categorical: Unconcentrated (HHI from 100 to < 1,500), moderately concentrated (HHI from 1,500 to < 2,500), highly concentrated (HHI ≥ 2,500); measured at the county level.
Percent Medicaid discharges‡	Percentage: Number of discharges under Medicaid / total discharges.
Primary care/specialist provider ratio**	Ratio: primary care providers / (specialists + surgeons).

AMI, acute myocardial infarction; COPD, chronic obstructive pulmonary disease; EBITDA, earnings before interest, taxes, depreciation, and amortization; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems; CMS, Centers for Medicare & Medicaid Services; HHI, Herfindahl-Hirschman Index; MedPAR, Medicare Provider Analysis and Review; AHRQ, Agency for Healthcare Research and Quality; AHA, American Hospital Association.

* Source: 2017 National Survey of Lean/Transformational Performance Improvement in Hospitals.

† Source: 2018 CMS Hospital Compare (the Composite measures used the methodology for Star Rating groups: https://www.rand.org/content/dam/rand/www/external/health/projects/hospital-performance-report-card/StrRtgDec16PrevQUS_rept_110416.pdf).

‡ Source: 2018 Medicare Cost Report.

§ Source: 2018 MedPAR (AHRQ Quality indicator methodology: https://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V2020/TechSpecs/PSI_04_Death_Rate_among_Surgical_Inpatients_with_Serious_Treatable_Complications.pdf).

‖ Source: 2017 AHA Annual Survey.

Source: 2017 CMS Hospital Service Area file.

** Source: 2015 Area Health Resources Files.

Table 2. Comparison of Hospitals Based on 2017 Lean Adoption Status on Control and Dependent Variables

Variable	Have adopted Lean, *N* = 847*	Have not adopted Lean, *N* = 375*	*p*†
Ownership			< 0.001
Public	149 (17.8%)	133 (36.3%)	
Not-for-profit	649 (77.7%)	177 (48.4%)	
Investor-owned	37 (4.4%)	56 (15.3%)	
Missing	*12*	*9*	
Member of a system or network	687 (85.0%)	224 (68.5%)	< 0.001
Missing	*39*	*48*	
Core-based statistical area type			< 0.001
Rural	127 (15.2%)	177 (48.4%)	
Micro	135 (16.2%)	70 (19.1%)	
Metro	573 (68.6%)	119 (32.5%)	
Missing	*12*	*9*	
Member of Council of Teaching Hospitals	94 (11.3%)	11 (3.0%)	< 0.001
Missing	*12*	*9*	
Bed size			< 0.001
1–99 beds	298 (35.7%)	261 (71.3%)	
100–399 beds	383 (45.9%)	92 (25.1%)	
≥ 400 beds	154 (18.4%)	13 (3.6%)	
Missing	*12*	*9*	
Percent Medicaid discharges	9 (9)	10 (10)	0.191
Missing	*71*	*63*	
Market concentration			< 0.001
Unconcentrated (HHI 100 to < 1,500)	144 (17.3%)	21 (5.8%)	
Moderately concentrated (HHI 1,500 to < 2,500)	89 (10.7%)	20 (5.5%)	
Highly concentrated (HHI ≥ 2,500)	599 (72.0%)	324 (88.8%)	
Missing	*15*	*10*	
Primary care/specialist provider ratio	1.5 (3.7)	3.6 (6.2)	< 0.001
Missing	*20*	*22*	
30-day risk-adjusted mortality index	12.44 (1.10)	12.61 (1.14)	0.184
Missing	*349*	*278*	
30-day unplanned readmission rate	15.18 (0.74)	15.25 (0.62)	0.117
Missing	*48*	*36*	
Adjusted inpatient expense per discharge	7,660 (2,091)	7,872 (2,633)	0.344
Missing	*231*	*213*	
Composite: appropriate/efficient use of medical imaging			0.030
Same as or worse than the national average	534 (83.0%)	169 (89.9%)	
Better than the national average	109 (17.0%)	19 (10.1%)	
Missing	*204*	*187*	
Composite: patient safety			> 0.999
Same as or worse than the national average	338 (55.4%)	67 (55.4%)	
Better than the national average	272 (44.6%)	54 (44.6%)	
Missing	*237*	*254*	
Composite: timeliness of care			< 0.001
Same as or worse than the national average	517 (71.5%)	142 (54.4%)	
Better than the national average	206 (28.5%)	119 (45.6%)	
Missing	*124*	*114*	
Death rate among surgical inpatients with serious treatable conditions	0.10 (0.11)	0.07 (0.12)	0.006
Missing	*240*	*238*	
EBITDA margin	9 (23)	8 (43)	0.977
Missing	*27*	*19*	
HCAHPS score (range 100–300)	266 (10)	265 (14)	0.248
Missing	*64*	*85*	
Medicare spending per beneficiary	0.98 (0.07)	0.98 (0.10)	0.782
Missing	*225*	*214*	

HHI, Herfindahl-Hirschman Index; EBITDA, earnings before interest, taxes, depreciation, and amortization; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems; SD, standard deviation.

* Statistics presented: *n* (column %); mean (SD); *N* missing values.

† Statistical tests performed: chi-square test of independence; *t*-test.

and dependent variables. All of the proposed control variables significantly differed by Lean adoption status, except for percent Medicaid discharges ($p = 0.191$). Considering other research demonstrating a relationship between percent Medicaid and potential performance improvement,[51] we continued to include it in our models. Among the dependent variables, three had a significant univariate association with Lean adoption (two in the opposite direction than predicted). Lean adoption was associated with higher death rate among surgical inpatients with serious treatable conditions, a lower likelihood of being better than the national average on a timeliness composite, and more likely to be better than the national average on appropriate/efficient use of medical imaging.

Table 3 summarizes the regression results for the models including Lean adoption by 2017 as the independent variable. As shown, after controlling for organizational and market factors, Lean adoption is positively associated (b = 3.35, $p < 0.0001$) with 2018 HCAHPS scores but with none of the other performance variables. Full model results are shown in Appendix 2.

Degree of Lean Implementation

Table 4 provides the regression results for the degree of Lean implementation as measured by the number of units using Lean. The degree of Lean implementation is significantly associated with lower adjusted inpatient expense per admission (b = -38.7, $p < 0.001$), lower 30-day unplanned readmission rate (b = -0.01, $p = 0.007$), appropriate/efficient use of imaging above the national average—a measure of low-value care—(odds ratio = 1.04, $p = 0.042$), and higher HCAHPS patient experience scores (b = 0.12, $p = 0.012$). There was no relationship between the degree of Lean implementation and the other performance variables. The results of sensitivity analysis using the full sample of responding hospital in which non-Lean-adopting hospitals were scored zero for number of units using Lean revealed almost identical results.

Examination of hospitals scoring in the top vs. bottom quartiles on various combinations of the quality, efficiency/financial viability, and patient experience variables revealed no significant differences. However, those scoring in the top quartile on efficiency/financial viability and HCAHPS measures had a significantly greater number of units using Lean (15.9, standard deviation [SD] = 7.24) than those in the bottom quartile (11.4 units, SD = 8.01, $p < 0.025$). Examination of hospitals scoring in the top quartile on number of units using Lean (20–29 units) vs. the bottom quartile (0–9 units) revealed that those in the top quartile had adjusted inpatient expense per discharge nearly

Table 3. Summary of Regression Estimates of the Relationship Between Lean Adoption and Each Hospital Performance Measure, Controlling for Organizational and Market Variables*

Dependent variable	*N* observations†	b (OR where noted) and 95% CI for independent variable: reported adopting Lean	Adjusted R^2	F-test statistic (*p*)
30-day risk adjusted mortality index	552	-0.005 (-0.24–0.23)	0.214	12.508 ($p < 0.001$)
30-day unplanned readmission rate	984	-0.06 (-0.17–0.05)	0.065	6.26 ($p < 0.001$)
Adjusted inpatient expense per discharge	715	-68.194 (-461.30–324.91)	0.111	7.835 ($p < 0.001$)
Composite: appropriate/efficient use of medical imaging	760	OR = 0.76 (0.42–1.41)	Tjur's pseudo-$R^2 = 0.099$	N/A
Composite: patient safety	674	OR = 0.982 (0.64–1.52)	Tjur's pseudo-$R^2 = 0.034$	N/A
Composite: timeliness of care	875	OR = 0.903 (0.62–1.32)	Tjur's pseudo-$R^2 = 0.196$	N/A
Death rate among surgical inpatients with serious treatable conditions	677	0.016 (-0.01–0.04)	0.089	6.095 ($p < 0.001$)
EBITDA margin	1,000	0.606 (-2.80–4.01)	0.003	1.252 ($p = 0.237$)
HCAHPS score	952	3.351‡ (1.75–4.95)	0.212	20.643 ($p < 0.001$)
Medicare spending per beneficiary	718	-0.006 (-0.02–0.01)	0.127	9.024 ($p < 0.001$)

OR, odds ratio; CI, confidence interval; N/A, not applicable; EBITDA, earnings before interest, taxes, depreciation, and amortization; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems.

* Control variables include ownership, system or network membership, core-based statistical area type, bed size, teaching status, percent Medicaid discharges, market concentration, primary care/specialist provider ratio.

† Number of observations varies due to missing data.

‡ $p < 0.0001$.

Table 4. Summary of Regression Estimates of the Relationship Between the Number of Units Using Lean and Each Hospital Performance Measure, Controlling for Number of Years Using Lean and Organizational and Market Variables*

Dependent variable	*N* observations†	b (OR where noted) and 95% CI for independent variable: number of units using Lean	Adjusted R^2	F-test statistic (*p*)
30-day risk-adjusted mortality index	421	0.006 (-0.01–0.02)	0.197	8.367 ($p < 0.001$)
30-day unplanned readmission rate	655	-0.011‡ (-0.02–0.00)	0.066	4.323 ($p < 0.001$)
Adjusted inpatient expense per discharge	511	-38.668§ (-59.59 – -17.75)	0.104	5.207 ($p < 0.001$)
Composite: appropriate/efficient use of medical imaging	536	OR = 1.037‖ (1.00–1.08)	Tjur's pseudo-$R^2 = 0.108$	N/A
Composite: patient safety	511	OR = 1.017 (0.99–1.04)	Tjur's pseudo-$R^2 = 0.035$	N/A
Composite: timeliness of care	597	OR = 1.012 (0.98–1.04)	Tjur's pseudo-$R^2 = 0.225$	N/A
Death rate among surgical inpatients with serious treatable conditions	507	0 (-0.00–0.00)	0.076	3.989 ($p < 0.001$)
EBITDA margin	669	0.12 (-0.13–0.37)	0.009	1.45 ($p = 0.125$)
HCAHPS score	648	0.122‖ (0.03–0.22)	0.235	15.191 ($p < 0.001$)
Medicare spending per beneficiary	517	0.001 (-0.00–0.00)	0.111	5.612 ($p < 0.001$)

OR, odds ratio; CI, confidence interval; N/A, not applicable; EBITDA, earnings before interest, taxes, depreciation, and amortization; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems.

* Control variables include number of years using Lean, ownership, system or network membership, core-based statistical area type, bed size, teaching status, percent Medicaid discharges, market concentration, primary care/specialist provider ratio.

† Number of observations varies due to missing data.

‡ $p < 0.01$.

§ $p < 0.001$.

‖ $p < 0.05$.

$1,000 lower ($7,195, SD = $1,532) than those in the bottom quartile ($8,000, SD = $2,285, $p < 0.001$).

DISCUSSION

The Findings

Consistent with current evidence,[43] we found support for our first hypothesis that the mere adoption of Lean is, with only one exception (the HCAHPS patient experience measure), not associated with better hospitalwide performance on quality and appropriateness of care, efficiency/financial viability, or patient experience measures. This finding is consistent with the idea that adopting Lean as a targeted intervention or program is insufficient—rather, adopting and implementing Lean as an overall comprehensive sociotechnical management and leadership system requiring widespread and ongoing implementation over time is needed to achieve positive changes in hospitalwide performance.[57,58] Our second hypothesis directly examining the degree of implementation is partially supported. The greater the number of hospital units using Lean, the lower were the risk-adjusted inpatient expenses per discharge, the lower were the risk-adjusted 30-day unplanned readmissions, the lower was the use of imaging for nonrecommended conditions, and the higher were the HCAHPS patient experience scores, although some of the effect sizes are small. There were no significant associations between the number of hospital units using Lean and hospital profitability, Medicare spending per beneficiary, 30-day risk-adjusted mortality, death rate for surgical inpatients with serious treatable conditions, a composite safety and adverse events index, or a composite timeliness index.

Consistent with self-reported hospital performance measures, the degree of Lean implementation appears to be somewhat more consistently related to efficiency/financial viability measures than quality measures.[39] This may reflect Lean's focus on eliminating waste, and thus lowering expenses, despite the view that Lean applications in health care should not be restricted to cutting costs. The positive association of degree of implementation with the HCAHPS patient experience scores (as was also found for adoption) is consistent with Lean's focus on the voice of the customer and empowering the frontline workforce to meet patient needs and preferences.

The lack of support for many of the performance measures may reflect the inherent complexity of providing hos-

pital care requiring widespread, sustained effort over time. Many efforts may still be focused on improving performance in targeted units, departments, or programs that do not quickly affect the type of publicly available organizationwide performance measures we examined. We do not know, for example, the extent to which the hospitals involved specifically targeted any of the performance measures for improvement.

It may also be the case that the comparison hospitals not using Lean as their primary performance improvement method or approach may have adopted other performance improvement methods, such as FOCUS-PDCA, and implemented them in varying degrees across units. Some of the comparison hospitals may not have implemented any of the other methods, while others may have implemented some, and still others may have implemented them widely. The heterogeneity in the implementation of the other adopted performance methods may be one reason for the lack of more significant performance differences between Lean hospitals and the comparison hospitals regarding adoption. However, this cannot explain the degree of implementation findings (Table 4), as this analysis is restricted to Lean-adopting hospitals with no comparison to those not adopting Lean.

Degree of Implementation Is Key

The Lean management system based on the underlying Shingo principles is a comprehensive organizationwide sociotechnical system designed to address the complexity of increasingly large-scale health care organizations by removing unwarranted wasteful complexity that does not add value to patients. The current findings highlight that the degree of implementation and spread throughout the entire organization determine success. Although the findings suggest some encouraging associations between the degree of implementation and performance, hospital care is not yet at the tipping point of sustainable organizationwide improvement. This is also confirmed by a recent national survey of health systems, hospitals, and physician practices revealing that out of six choices by which clinicians could be informed of best practices of providing care, the use of the Lean management system performance improvement events (*kaizen*) was least selected; in the case of systems, it was only "rarely or sometimes" used.[59]

Given the gaps in care and continued growth in costs, there is a need to move beyond the use of Lean for incremental quality improvement to its use in making breakthrough improvements.[60] Given that various initiatives over the past 20 years have resulted in at best modest and highly uneven improvement in US health system performance,[12,14,15] it may be time for policy makers, payers, and related change makers to explicitly promote health sector–wide implementation of the underlying Shingo principles of the Lean management system and address the deep-seated cultural barriers to frontline empowerment of the workforce. This could be done, for example, through the stipulation in payer contracts that providers supply evidence of use of the Shingo principles and reward performance improvement from year to year. In general, payment systems that align with hospital goals of continuously improving care are needed.

Limitations

The findings need to be considered within the context of a number of limitations. First, although the survey was completed by a well-informed and knowledgeable person within each organization (based on input from hospital leaders, Lean industry experts, and pilot testing), others in the organization may have responded to certain questions differently. There were also some small but statistically significant differences between responding and nonresponding hospitals to the NSL on such variables as ownership, size, and location. This limits somewhat the generalizability of the Lean adoption/nonadoption findings to all hospitals. We controlled for these variables in the analysis. We are also cautious in claiming that the implementation findings are causal even though the implementation measures were collected in 2017, the year before most of the 2018 performance measures. Four of the performance measures (30-day risk-adjusted mortality, 30-day unplanned readmissions, the composite imaging index, and the death rate among surgical patients with serious treatable conditions), however, were three-year averages (2015–2018), while our measure of implementation is for 2017 only. Further, it is possible that there are unobserved organizational and/or market variables that influence both Lean implementation and the observed performance measures. Ongoing collection of performance data over ensuing years would permit trending performance since 2018 over time, potentially strengthening the ability to draw causal inferences. Future research might also examine improvement in performance over time as a function of when the hospital first adopted and began implementing Lean. Although widely used, there are also limitations to some of our performance measures[61–63] and disagreements on ratings of hospital performance.[64] Finally, although we used multiple measures of implementation based on existing literature to validate the widespread use of Lean throughout the hospital, it is possible that there are other aspects of Lean implementation that we did not capture. For example, we have no direct measures of the quality of implementation. This is an area for future research best addressed through qualitative research involving site visits and observation along with focused surveys of multiple workforce respondents

CONCLUSION

Although the existing literature generally supports the success of Lean's use in individual projects or units, there is little evidence of its use in health care as an organization-

wide performance improvement system. The present findings suggest that it is the degree of implementation that is associated with some measures of hospitalwide performance rather than mere adoption. However, the lack of association with other performance measures suggests that there is much work to be done. Inherent in the Lean approach is the development of a continuous improvement culture that empowers the frontline workforce with the problem-solving tools and processes to provide the best value care for patients. Creating such a culture on a sustainable basis and spreading it throughout the health care sector is a major challenge likely to influence the success of ongoing health care reform efforts.

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SUPPLEMENTARY MATERIALS

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