Contrasting continuous quality improvement, Six Sigma, and lean management for enhanced outcomes in US hospitals

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Abstract
Purpose – Rapidly rising healthcare costs, partially due to preventable medical errors, have led hospitals to redouble their process improvement (PI) efforts. The purpose of this paper is to examine how PI initiatives mediate the effect of medical error sources to enhance three hospital outcomes (patient safety, operational effectiveness, and competitiveness).

Design/methodology/approach – Drawing from Dynamic Capabilities Theory, the authors develop a framework to explore three PI initiatives: Continuous Quality Improvement (CQI), Six Sigma Initiatives (SSI), and Lean Management Initiatives (LMI). Hierarchical regression analysis is employed to test the proposed model, using data from a nationwide survey of 210 US hospitals.

Findings – For enhancing patient safety outcomes, it was found that CQI and LMI were significant in mediating hospital error sources; however, SSI was not significant after accounting for the other two PI types. For improving organizational effectiveness, CQI and SSI were significant; whereas LMI was not significant over and above the other two PI types. Finally, only SSI was significant for superior sustainable competitive advantage.

Research limitations/implications – The paper provides insight into which PI initiatives were most effective for various hospital outcomes. The findings can benefit healthcare practitioners as they select among different PI programs for enhancing healthcare results. Limitations of the study include the use of perceptual measures, relatively small sample size, and potential alternate relationships relevant to the outcome variables.

Originality/value – This is the first study to explore the mediating effects of three PI programs for the impact of medical errors on each of three hospital outcomes.

Keywords United States of America, Hospitals, Quality improvement, Six Sigma, Continuous Quality Improvement, Lean, Healthcare operations, Patient safety

Paper type Research paper

Introduction
Medical errors and soaring healthcare expenditures continue to be the focus of accelerated national attention. Slow progress has occurred since the Institute of Medicine report (Kohn et al., 2000), which estimated that about 58 percent of US medical errors may be preventable (Leape and Berwick, 2005). Hospital errors cause longer stays and cost about $17 billion annually (Van den Bos et al., 2011). Medical errors and other sources of costs cause a greater proportion of annual personal income and national economic resources
to shift toward healthcare (Chernew et al., 2009). About $2.6 trillion is spent on healthcare, which is 17.9 percent of US gross domestic product (GDP) and accounts for 54 percent of total federal revenue (Martin et al., 2011). Due to the trend of medical costs increasing at a rate exceeding that for GDP growth in all developed countries, the worldwide concern about medical expenditures has promoted an awareness of the need for greater effectiveness in healthcare systems (Kumar et al., 2011).

Process improvement (PI) initiatives are designed to help reduce or eliminate sources of errors. In hospitals, frequent sources of errors relate to communication, system and culture failures (Garbutt et al., 2008). Error sources, such as poorly designed tasks/jobs, equipment failure/malfunction, lack of employee expertise/knowledge, willful employee misconduct, infrastructure issues (public/internal backup services), unplanned circumstances/events, and computer issues, cause healthcare process inefficiencies (Spath, 2011). The most common sources are poorly designed tasks that contribute to human error (Leape, 2009). Hospital errors can also arise from other systemic factors such as infrastructure breakdown, and system malfunction due to internal or external demand surge (Barry et al., 2002). Infrastructure breakdowns include power outages, shortages of water supply, and disruptions in communication systems. Internal demand relates to things like unplanned shortage of capacity, errors in scheduling, fatigued staff, and unexpected demand for personnel in one specific area of the hospital (Pham et al., 2012). In contrast, external demand is beyond the control of the hospital and can result from natural disasters, such as earthquakes, chemical spills or forest fires, where many people require immediate medical attention. While sources of errors can cause frustration, impede employees, and decrease overall hospital performance, they nonetheless provide improvement opportunities, potentially resulting in organizational learning and increased performance (Tucker, 2004).

Despite the possible benefits, most organizations find it challenging to learn from errors (Carroll et al., 2002). Traditional means of addressing sources of hospital errors alone seem to fall short of their potential to improve organizational performance (Tucker, 2004).

The purpose of this study is to examine hospital error sources (HES) and how PI initiatives enhance hospital outcomes such as patient safety results (PSR), organizational effectiveness results (OER), and sustainable competitive advantage (SCA). We expect that the implementation of PI initiatives, such as continuous quality improvement (CQI), Six Sigma initiatives (SSI), and lean management initiatives (LMI) may mediate the relationship between HES and outcomes. Moreover, we propose that improved hospital performance can be achieved by an integrated PI approach, including CQI, SSI and LMI. Figure 1 graphically shows our conceptual model that guides this study.

Figure 1.
Framework for the impact of hospital error sources (HES) on patient safety results (PSR), organizational effectiveness results (OER), and sustainable competitive advantage (SCA), mediated by continuous quality improvement (CQI), Six Sigma initiatives (SSI), and lean management initiatives (LMI).
PI initiatives have been applied in manufacturing for many years, resulting in numerous benefits for successful PI adoption. More recently, service organizations have learned the value and importance of PI techniques in increasing quality, reducing costs and improving customer service. An empirical study by Gowen and Tallon (1999) found that manufacturing firms reported a significantly greater perceived use of PI techniques, and experienced greater success in achieving competitive advantage than service firms. However, PI initiatives have evolved over time and today are more adaptive to the unique challenges of the service sector (Hilton et al., 2008).

The application of PI techniques has increased in popularity especially for healthcare (DelliFraine et al., 2010). To resolve medical errors, hospital personnel have recently rated PI initiatives as more important than previously reported and experienced more frequent improvements in patient safety, quality, employee satisfaction, and competitiveness (Lighter, 2011). In hospitals, PI programs include quality teams that deploy PI tools to improve process outcomes such as decreased emergency room visit time (Arthur, 2009), lower clinical tray contamination (Lacey, 2009), and reduced radiology waiting time (Lodge and Bamford, 2008). During the past few years, healthcare organizations have increasingly embraced PI as an effective technique for improving productivity, profitability, quality, and competitiveness (Arthur, 2011b).

CQI, SSI and LMI are the leading types of PI techniques (Inozu et al., 2011). Over the last 20 years, CQI has been deployed by nearly all hospitals (Kazandjian, 1997). According to a survey by the American Society for Quality, 42 percent of US hospitals use some form of SSI and 53 percent of US hospitals use some type of LMI (Henke, 2009).

CQI is an incremental approach toward process improvement and takes an organization-wide systems perspective, which is tied to the strategic goals and aligned with a culture of quality (Sollecito and Johnson, 2011). CQI initiatives used in healthcare include the plan, do, check/study, and act (PDCA/PDSA) method, the use of quality improvement employee teams, employee recognition and rewards, promotion opportunity, patient satisfaction measures, and competitive benchmarking (Evans and Lindsay, 2011; Ryan and Thompson, 1998). Employee teams implement the PDCA/PDSA cycle in order to take advantage of the diversity in team member skills, experience, and knowledge. Employee recognition, rewards and promotional opportunities are linked to PI program success to promote individual, team and organizational performance. Patient satisfaction assessment consists of utilizing measures, identifying causes of dissatisfaction, and implementing process improvements to enhance patient satisfaction and retention. Finally, competitive benchmarking involves evaluating a hospital’s processes against those that are best-in-class at other facilities.

In contrast, Six Sigma is a radical breakthrough approach that is heavily focused on bottom line results, specifically for process improvement projects (George, 2003; Nair et al., 2011; Van der Meulen et al., 2011). Critical Six Sigma concepts for healthcare include the define, measure, analyze, improve, and control (DMAIC) process, green belt and/or black belt employee training, statistical process/quality control, and project review and closure (Furterer, 2011). Six Sigma problem-solving projects utilize the DMAIC methodology that incorporates a wide variety of statistical tools and process improvement techniques (George et al., 2005). The success of a Six Sigma team depends on employee Black Belt and Green Belt training in statistical techniques, team building, leadership, and project-selection skills (Stamatis, 2010). Six Sigma teams apply statistical process control to measure and monitor variation in a process over time. Finally, Six Sigma requires
project reviews and project closure to determine the success of each project and to communicate the resulting best practices throughout the organization.

The implementation of lean management is motivated by the relentless pursuit of efficiency, reduced costs, and increased delivery speed of products and services (Arthur, 2011a). Healthcare non-value added is estimated at 95 percent of healthcare operations, leaving room for substantial efficiency improvement (Hagan, 2011). Common lean management tools in healthcare include process mapping, value stream mapping, Kaizen improvement events, just-in-time process management, and “5S” principles (Cottington and Forst, 2010; Graban, 2009; Protzman et al., 2010). The “5S” principles reduce waste by deploying five steps:

1. sort for necessity;
2. simplify the workplace;
3. shine for cleanliness;
4. standardize processes; and
5. sustain standard processes.

Process mapping requires the analysis of individual steps and leads to potential efficiencies by redesigning the process to eliminate unessential elements. Value stream mapping visually displays the process flow, distinguishes between value-added and non-value-added activities, assists in pointing out root causes of waste, identifies problems and opportunities for improving workflow, and shows how the future workflow would look. A Kaizen improvement event consists of defining the problem, analyzing workflows, cycle times, and value stream maps, testing improvement alternatives, deploying the selected solution, and reporting out to top management. Finally, just-in-time (JIT) process management eliminates waste and streamlines operations through reduction in waiting time delays, inventories, employee motion, and transportation.

CQI, LMI and SSI often provide synergistic benefits. For instance, organizations tend to couple lean with Six Sigma for greater overall outcomes (Bisgaard, 2009). Both focus on customer requirements, reducing cost, and making a significant financial impact (Arthur, 2009). However, a clear difference is that they attack different types of problems. Lean focuses on speed and the more visible problems in processes such as inventory, material flow and safety (Arthur, 2011a), while Six Sigma focuses on precision and accuracy, which are less visible problems of variation in performance (Antony, 2011). Similarly, SSI complements CQI as both seek to improve quality and customer satisfaction for long-term results (Revere et al., 2004).

**Conceptual development**

As a theoretical basis for research of healthcare PI initiatives, the dynamic capabilities model (DCM) emphasizes designing sources of competitive advantage. The DCM requires dynamic alignment of organizational resources in a changing business environment. A recent review identifies four dimensions of dynamic capability as the:

1. propensity to make market-based decisions for changing customer needs;
2. assessment and taking advantage of opportunities and threats;
3. ability to make timely decisions; and
4. realignment of the firm’s resource base (Barreto, 2010).
The DCM approach is a relational view that has evolved from the resource based view over more than two decades (Acedo et al., 2006; Barney et al., 2011). The classic concept of dynamic capability effectiveness is captured by the extent that they are a means for adapting, integrating, and reconfiguring resources to benefit from and create market change (Eisenhardt and Martin, 2000; Teece et al., 1997). The focus on organizational change distinguishes dynamic capabilities from ordinary capabilities, but the difference can be blurry (Helfat and Winter, 2011). Resources can be explicit and tangible (e.g. land, buildings, and equipment), tacit and intangible (e.g. brand names, reputation, patents, copyrights, technology, and other intellectual property) or human factors (e.g. culture, empowerment, and commitment). In practice, PI initiatives can produce competitive advantage more for tacit than explicit resource utilization (Reed et al., 2000). The DCM is appropriate for this study because healthcare organizations emphasize reconfiguring tacit resources to produce dynamic capabilities, such as process and quality systems, to improve patient safety.

CQI, Six Sigma and lean management practices have already been studied through the lens of dynamic capabilities. In general, studies suggest PI initiatives result in competitive advantages regardless of the organizational context, such as culture and nationality (Sila, 2007; Tari et al., 2007; York and Miree, 2004). Multi-industry field research, applying a DCM approach, reported effective application of several PI practices for dynamic capabilities (Anand et al., 2009). Successful PI initiatives consisted of three infrastructure elements:

1. **Purpose.** Evidenced by mission and goals, as well as balanced innovation and improvement.

2. **Process.** Consisting of a culture of constant change, parallel participation structures, and standardized processes and improvement methods.

3. **People.** Comprised of training and career paths, and information technology support.

For a study of acute care hospitals, Goldstein and Iossifova (2011) found that a high degree of financial resource slack was related to successful implementation of a PI initiative for reducing four adverse medical conditions. Previous healthcare research reported that effective deployment of PI programs depends on other dynamic capabilities, such as organizational structure, hospital ownership, and leadership style (Douglas and Judge, 2001; Douglas and Fredendall, 2004).

The Six Sigma literature supports successful creation of dynamic capabilities from SSI implementation. Deployment of SSI practices enhances healthcare processes but SSI has been implemented in hospitals relatively recently (Hilton et al., 2008; Kennedy and Fiss, 2009). Hospitals have tended to use Six Sigma to tackle strategic or non-clinical issues such as streamlining processes (Buell, 2010). While Six Sigma has not been widely applied to areas of direct patient care, it has potential to make significant contributions (Revere et al., 2004). Six Sigma requires training employees as change agents who work together on projects (Summers, 2010) to solve problems such as nurse turnover (Taner and Sezen, 2009) and patient safety issues (Carboneau et al., 2010). Effective human resources have been reported as one of the most important keys to Six Sigma success in healthcare (Pocha, 2010). Case studies demonstrate the efficacy of healthcare Six Sigma programs in reducing costs and improving quality (Bisgaard, 2009; De Koning et al., 2006; Dusharme, 2009; Kim et al., 2006). However, a review
of 177 studies of Six Sigma programs in healthcare suggests that the actual degree of quality improvement results is only moderate (DelliFraine et al., 2010). Likewise, a review of 47 healthcare studies concluded that many Six Sigma and lean initiatives were successful, but up to 62 percent failed due to lack of stakeholder acceptance (Glasgow et al., 2010).

Research also supports effective reconfiguration of dynamic capabilities from LMI implementation. LMI can be effectively applied to healthcare by the achievement of critical success factors and key performance indicators for numerous lean techniques (Kollberg et al., 2007). The application of lean thinking can transform an organization toward a patient safety culture (Wellman et al., 2011). For the Seattle Children’s Hospital program that began in 2007 with first-hand observation of lean programs in Japan, their lean management initiative resulted in dramatically reducing surgical-site infection rates, patient length of stay, supply costs, and new facility expenses (Hagan, 2011). A review of lean studies reveals that a program requires training of appropriate employees, initiating pilot projects, and deploying cross-functional teams (Poksinska, 2010). Hospital case studies have demonstrated that lean initiatives are successful in implementing the “5S” principles (Esain et al., 2008), decreasing rounding time per patient (Vats et al., 2011), reducing waiting times (Lodge and Bamford, 2008), cutting costs for regulated medical waste (Stonemetz et al., 2011), and comprehensively redesigning a hospital for patient-centered care (Kenney, 2010). Finally, a longitudinal field study of outpatient clinics revealed dramatic efficiency gains for a lean PI project, as well as improvements in service capacity, workflow, resource alignment, appointment scheduling, and no-show rates (LaGanga, 2011).

Simultaneous implementation of different types of PI initiatives provides enhanced outcomes for healthcare organizations. Several studies have reported improvements in patient safety by implementing CQI (Kennedy and Fiss, 2009; Shortell et al., 1995), Six Sigma (Jing, 2009; Gowen et al., 2008), and lean management tools (Proudlove et al., 2008). However, an integrated PI program can consist of a combination of CQI, Six Sigma and lean, which mutually reinforce each other when used simultaneously for superior results (Gowen and Johnson, 2009). Using a sample of 226 US manufacturing plants, Zu et al. (2008) found that SSI complemented traditional CQI practices. A healthcare study by Revere et al. (2004) proposed a framework for integrating Six Sigma with CQI for improving patient care. Similarly, lean tools can enhance the effectiveness of Six Sigma programs in hospitals, as demonstrated by several studies (Arthur, 2011b; Buell, 2010; Furterer, 2011; Pocha, 2010; Shah et al., 2008).

Based on the DCM, it is expected that implementing PI initiatives will mediate the effect of error sources on patient safety results. Past literature has defined patient safety results in terms of heightened awareness and understanding of errors, as well as the reduction in the frequency and impact of errors (Gowen et al., 2006b; Katz-Navon et al., 2005; McFadden et al., 2004). Furthermore, studies have reported improved patient safety outcomes through the implementation of PI initiatives (McFadden et al., 2006b; Shortell et al., 1995; Stock et al., 2007). Therefore, the literature leads to the following research hypothesis:

**H1.** The effect of hospital error sources on patient safety results will be mediated by: (a) continuous quality improvement (b) Six Sigma initiatives, and (c) lean management initiatives.
The DCM also suggests that organizational effectiveness can be enhanced by PI initiatives (Reed et al., 2000) such as CQI, Six Sigma, and lean management programs. PI practices are proprietary processes that convert organizational resources into customer value, especially for patient relationship management in healthcare (Liu and Lin, 2007). Dynamic capabilities evolve from learning mechanisms, such as experience accumulation, knowledge articulation, and knowledge codification. Halbesleben and Rathert (2008) reported that enhanced experience and knowledge from CQI programs resulted in improved work effectiveness in hospitals. Environmental change and heterogeneity enhances the impact of dynamic capabilities on organizational performance (Drnevich and Kriauciunas, 2011). A multi-industry study including healthcare found that PI initiatives served as dynamic capabilities through enhancement of organizational purpose, processes, and people (Anand et al., 2009).

Empirical research also suggests that PI implementation is associated with improved organizational effectiveness, in terms of service quality, customer satisfaction, net cost savings, and patient satisfaction (Marley et al., 2004). Widespread adoption of PI programs has expanded dramatically for healthcare organizations (Carrigan and Kujawa, 2006). As a means of resolving quality issues, many healthcare organizations have undertaken PI initiatives targeted towards improving organizational performance (Hilton et al., 2008; Lloyd and Holsenback, 2006). Empirical studies have found the level of CQI practices adopted by hospitals was positively and significantly related to organizational performance (Shortell et al., 1995; Douglas and Judge, 2001). Similarly, case studies of SSI programs have resulted in diverse pragmatic improvements, such as clinical, operational, and service benefits (Bisgaard, 2009; Craven et al., 2006; Neri et al., 2008). Therefore, the literature leads to the following research hypothesis:

**H2.** The effect of hospital error sources on organizational effectiveness results will be mediated by: (a) continuous quality improvement (b) Six Sigma initiatives, and (c) lean management initiatives.

According to the dynamic capabilities theory, sustainable competitive advantage can also result for hospitals that successfully implement PI initiatives (Barney et al., 2011; Thompson et al., 2008). Competitive advantage can be achieved through dynamic capabilities that are characterized by four factors: valuable, rare, in-imitable, and non-substitutable (Hitt et al., 2010). Valuable refers to the degree to which the firm’s resources enable the organization to respond to external threats and opportunities. Rare concerns the degree to which competing firms do not possess the organization’s particular valuable resources. In-imitable focuses on the cost disadvantage faced by other firms that do not possess a certain resource. Non-substitutable captures the degree to which a resource has no strategic equivalent. Practically, an organization has only some measure of each factor. Certain PI factors, such as DMAIC and value stream mapping, can lead to value and rareness through enhanced effectiveness and efficiency (De Mast, 2006). Also, adaptation of PI factors to unique hospital conditions and patient needs could increase the level of in-imitability and non-substitutability.

The literature has also reported PI initiatives as a potential source of competitive advantage. Reed et al. (2000) provided preliminary evidence that firms which implement CQI principles achieve a competitive advantage over those firms that do not adopt such principles. Douglas and Judge (2001) found strong empirical support for the relationship between the degree of adoption of CQI practices and the degree of sustainable
competitive advantage achieved for a hospital. The theory and empirical research suggests that CQI, SSI and LMI should mediate the relationship between error sources and competitive advantages in a hospital. Therefore, the literature leads to the following research hypothesis:

$H3$. The effect of hospital error sources on sustainable competitive advantage will be mediated by: (a) continuous quality improvement (b) Six Sigma initiatives, and (c) lean management initiatives.

Methodology
We employed a survey methodology to collect data in order to test our research hypotheses. An initial questionnaire was tested in a pilot survey sent to several hospital quality directors in our local area. To obtain the list of US hospitals, we utilized a directory of medical organizations posted on the web site Hospitalink.com. Web site searches revealed telephone numbers for 3,061 hospitals, after eliminating non-hospital organizations (e.g. associations and clinics). We made multiple attempts to call the director of performance improvement, patient safety, quality, risk, or patient care services. Calling throughout 2010 and early 2011, we were able to personally speak to 499 administrators at 339 hospitals, seeking multiple responses from each hospital. At the time of the initial call, we explained the purpose of our survey and ensured that the survey was directed towards the appropriate individuals within the hospital. The survey was sent as an e-mail attachment to administrators at each of these hospitals. The respondents were promised confidentiality as well as a report of the averaged results. Three rounds of e-mail reminders were sent at monthly intervals. Completed surveys were received from 210 hospitals, which is a 62 percent response rate. This compares favorably with the response rates cited in other published survey-based research studies in the field of operations management (Flynn et al., 1990).

This sample was examined for several characteristics. There were multiple raters completing the questionnaire at 128 of the 210 hospitals. The Cronbach’s $\alpha$ inter-rater reliability exhibited an average value of 0.71, which is deemed acceptable (Flynn et al., 1990). Therefore, the multiple rater responses for each item were averaged to give a value for that indicator from each hospital. The sample includes hospitals from each of the 50 USA. The regional distribution of the respondent hospitals included 19 percent Western, 32 percent Midwestern, 20 percent Southern, 11 percent Southwestern, and 18 percent Eastern hospitals. This distribution was not statistically different from the regional distribution of all hospitals included in the Hospitalink.com directory ($\chi^2 = 5.22, df = 4; p = 0.27$).

Our questionnaire included items based on past research related to HES, CQI, SSI, LMI, PSR, OER, and SCA (which are listed in the Appendix for all of the items for each of these seven constructs). Hospital error sources variable is assessed by a seven-item scale developed from concepts described by Barry et al. (2002) and Spath (2011), and published previously (Gowen et al., 2006b). CQI is measured by five items adapted from common elements of several past reviews and studies (Flynn et al., 1995; Goldstein and Schweikhart, 2002; Ryan, 2007; Sila and Ebrahimpour, 2002; Tari, 2005). The Six Sigma initiatives construct consists of four items that were reported in Gowen et al. (2008) and similar to other study items (Zu et al., 2008). Lean management initiatives are measured by five items that were adapted from the literature (Arthur, 2011b; Graban, 2009; Protzman et al., 2010). The patient safety results include four items that were published
previously (McFadden et al., 2004, 2006a, b, 2009; Stock et al., 2007). The four-item organizational effectiveness results scale consists of four items that were reported in past studies (Gowen et al., 2006a, b). Sustainable competitive advantage is measured by Barney’s (1991, 2002) scale which contains four items. In addition to the variables presented above, we also examined three control variables that could have impacted the study variables – hospital size (number of beds), quality staff (number of FTE employees dedicated to process improvement and study of hospital errors), and PI program experience (number of years that a hospital had a PI system in place).

The construct descriptive statistics, correlations and reliabilities (Cronbach’s α coefficients) are presented in Table I. The Cronbach’s α scale reliability values for the seven constructs consisted of a range of 0.68-0.87, which is beyond the minimum acceptable level of 0.60 for exploratory research (Flynn et al., 1990). Confirmatory factor analysis using Varimax rotation with Kaiser normalization is utilized for all of the constructs of this study, as advocated by Hinkin (1995). The results in Table II indicate discriminant validity among the three mediators, by the observation that the five CQI items loaded on component 3, the four SSI items loaded on component 2, and the five LMI items loaded on component 1. Additionally, we used Harman’s one-factor test to check whether common method bias was present (Podsakoff et al., 2003). This test

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
<th>HES</th>
<th>CQI</th>
<th>SSI</th>
<th>LMI</th>
<th>PSR</th>
<th>OER</th>
<th>SCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>HES</td>
<td>1.93</td>
<td>0.67</td>
<td>(0.76)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CQI</td>
<td>3.97</td>
<td>0.62</td>
<td>0.142*</td>
<td>0.415***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSI</td>
<td>3.29</td>
<td>1.04</td>
<td>0.234***</td>
<td>0.415***</td>
<td>0.186**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LMI</td>
<td>1.10</td>
<td>1.37</td>
<td>0.077</td>
<td></td>
<td>0.121</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSR</td>
<td>3.37</td>
<td>0.64</td>
<td>0.190**</td>
<td>0.252***</td>
<td>0.176*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OER</td>
<td>3.18</td>
<td>0.70</td>
<td>0.242***</td>
<td>0.314***</td>
<td>0.282***</td>
<td>0.191</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCA</td>
<td>2.40</td>
<td>0.85</td>
<td>0.151*</td>
<td>0.242***</td>
<td>0.296***</td>
<td>0.042</td>
<td>0.347***</td>
<td>0.491***</td>
</tr>
</tbody>
</table>

**Note:** Significant at: *p < 0.05, **p < 0.01 and ***p < 0.005

Table II. Confirmatory factor analysis for continuous quality improvement, Six Sigma initiatives, and lean management initiatives indicators
resulted in nine factors accounting for 64.1 percent of the variance, with the first factor at 19.1 percent. Because no factor accounted for most of the variance, the single method of data collection appears to be an acceptable risk. Finally, the items for each scale were averaged to create the variables used in the subsequent regression analysis.

## Results

To test our hypotheses, we applied hierarchical regression analysis using theoretically grouped sets of variables (Cohen et al., 2002). In this approach, the independent variable, hospital error sources, was first entered into multiple regression analysis. Then, each potential mediator was entered into the regression model, and an $F$ statistic was calculated to determine whether the change in variance explained ($R^2$) by the additional variable was statistically significant. Tables III-V show the cumulative result for each dependent variable by entering the independent variable, then CQI, SSI, and LMI individually, and finally all three potential mediators into the overall regression model. The findings from the statistical analysis indicate that the impact of hospital error sources is significantly mediated by PI programs.

For each of the regression models reported in the following tables, the three control variables (hospital size, quality staff, and PI program experience) were entered before any of the independent and moderator variables. For all regressions, the coefficients for the control indicators were not statistically significant. Therefore, the control variables were not included in the subsequent analysis.

### Table III.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
<th>Model 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>HES</td>
<td>0.190 **</td>
<td>0.158 *</td>
<td>0.158 *</td>
<td>0.176 **</td>
<td>0.150 *</td>
</tr>
<tr>
<td>CQI</td>
<td>0.230 ***</td>
<td></td>
<td>0.139 *</td>
<td>0.049</td>
<td></td>
</tr>
<tr>
<td>SSI</td>
<td></td>
<td>0.184 **</td>
<td></td>
<td>0.148 *</td>
<td></td>
</tr>
<tr>
<td>LMI</td>
<td>0.036</td>
<td>0.088</td>
<td>0.055</td>
<td>0.070</td>
<td>0.109</td>
</tr>
<tr>
<td>Change $R^2$</td>
<td>0.052 ***</td>
<td>0.018 *</td>
<td>0.034 **</td>
<td>0.073 **</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>7.82 **</td>
<td>9.97 ***</td>
<td>5.98 ***</td>
<td>7.78 ***</td>
<td>8.40 ***</td>
</tr>
</tbody>
</table>

**Notes:** Significant at: * $p < 0.05$, ** $p < 0.01$ and *** $p < 0.005$; table entries show standardized regression coefficients

### Table IV.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
<th>Model 5</th>
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</thead>
<tbody>
<tr>
<td>HES</td>
<td>0.242 ***</td>
<td>0.201 ***</td>
<td>0.268 ***</td>
<td>0.228 ***</td>
<td>0.175 ***</td>
</tr>
<tr>
<td>CQI</td>
<td>0.286 ***</td>
<td></td>
<td>0.312 ***</td>
<td></td>
<td>0.147 *</td>
</tr>
<tr>
<td>SSI</td>
<td></td>
<td>0.174 **</td>
<td></td>
<td>0.122</td>
<td></td>
</tr>
<tr>
<td>LMI</td>
<td>0.058</td>
<td>0.138</td>
<td>0.112</td>
<td>0.088</td>
<td>0.156</td>
</tr>
<tr>
<td>Change $R^2$</td>
<td>0.080 ***</td>
<td>0.054 ***</td>
<td>0.039 **</td>
<td>0.097 **</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>12.91 ***</td>
<td>16.63 ***</td>
<td>13.11 ***</td>
<td>10.04 ***</td>
<td>12.65 ***</td>
</tr>
</tbody>
</table>

**Notes:** Significant at: * $p < 0.05$, ** $p < 0.01$ and *** $p < 0.005$; table entries show standardized regression coefficients
The results in Table III support $H1a$ ($p < 0.005$), $H1b$ ($p < 0.05$) and $H1c$ ($p < 0.01$), when CQI, SSI or LMI is independently entered into a separate regression model. This demonstrates that CQI, SSI and LMI act as a mediator for patient safety results if each PI variable is considered alone. However, when entering CQI, SSI and LMI simultaneously into another model, we find that only CQI and LMI are significant in mediating hospital error sources for patient safety results.

Similarly, Table IV supports $H2a$ ($p < 0.005$), $H2b$ ($p < 0.005$) and $H2c$ ($p < 0.01$), when CQI, SSI or LMI is independently entered into a separate regression model. It signifies that CQI, SSI and LMI act as a mediator for organizational effectiveness results if each PI variable is considered alone. But, when entering CQI, SSI and LMI simultaneously into another model, we find that only CQI and SSI are significant in mediating hospital error sources for organizational effectiveness results.

Table V supports hypotheses $H3a$ ($p < 0.005$) and $H4b$ ($p < 0.005$), but not $H4c$, when CQI, SSI or LMI is independently entered into a separate regression model. This explains that CQI and SSI act as a mediator for sustainable competitive advantage if each PI variable is considered alone, whereas LMI does not independently mediate the impact of error sources for sustainable competitive advantage. However, when entering CQI, SSI and LMI simultaneously into another model, we find that only SSI is significant in mediating hospital error sources for sustainable competitive advantage.

Conclusions and pragmatic implications
As hospitals set priorities for desired areas of improvement and strive to meet shrinking budgets, administrators must be more selective about PI program implementation. Hospitals face increased pressure to enhance patient safety, operational effectiveness, and competitiveness. This is the first study to explore the mediating effects of CQI, SSI, and LMI on medical error sources for enhancing these three types of hospital outcomes. Although there may be some overlap of PI items in actual practice, our confirmatory factor analysis in Table II indicates that CQI, SSI, and LMI consist of three distinct constructs. Also, the regression analysis results demonstrate that each of the three types of PI programs mediates hospital error sources differently for each type of outcomes. Therefore, our findings can benefit healthcare practitioners as they select among PI techniques for desired hospital outcomes.

For hospital administrators trying to enhance patient safety results, our findings indicate that CQI is the most effective PI approach and that LMI offers some added benefits over and above CQI. It makes intuitive sense that CQI would enhance patient safety results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
<th>Model 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>HES</td>
<td>0.151 *</td>
<td>0.119</td>
<td>0.086</td>
<td>0.148 *</td>
<td>0.086</td>
</tr>
<tr>
<td>CQI</td>
<td>0.226 ***</td>
<td></td>
<td>0.140</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSI</td>
<td></td>
<td>0.276 ***</td>
<td></td>
<td>0.276 ***</td>
<td></td>
</tr>
<tr>
<td>LMI</td>
<td>0.023</td>
<td>0.073</td>
<td>0.095</td>
<td>0.031</td>
<td>0.002</td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.050 ***</td>
<td>0.072 ***</td>
<td>0.001</td>
<td>0.072 ***</td>
<td></td>
</tr>
<tr>
<td>Change $R^2$</td>
<td>4.83 *</td>
<td>8.10 ***</td>
<td>10.80 ***</td>
<td>2.51</td>
<td>10.80 ***</td>
</tr>
</tbody>
</table>

Notes: Significant at: * $p < 0.05$, ** $p < 0.01$ and *** $p < 0.005$; table entries show standardized regression coefficients
given that it emphasizes incremental improvement in quality of care with a focus on gradual long-term results. Our findings indicate that CQI is the most often used PI initiative (with an average use of 3.97 on a 0-5 scale). These results are consistent with previous research for CQI in resolving medical errors and providing a wide range of patient-centered benefits (Evans and Lindsay, 2011; Ryan, 2007; Ryan and Thompson, 1998).

It is a surprising finding that Six Sigma did not enhance patient safety beyond the gains for CQI and LMI, given that SSI focuses on accuracy. SSI tools such as statistical process control, fishbone diagrams, and the disciplined statistical approach to problem-solving of the DMAIC process, emphasize achieving 3.4 or fewer defects per million opportunities which equates to 99.99966 percent accuracy (Evans and Lindsay, 2011). It may be that the potential emphasis on bottom line results for Six Sigma can compete with patient safety goals. As stated previously, comprehensive literature reviews suggest that SSI implementation provides only a modest level of improvement for hospitals (DelliFranie et al., 2010; Glasgow et al., 2010). Our findings from Table I demonstrate similar mid-level gains for our measures of hospital outcomes (PSR, OER and SCA).

A second issue for enhanced patient safety from PI programs is the level of deployment of SSI. Some case studies report success only for those hospitals with high SSI implementation (Buell, 2010; Hilton et al., 2008). It seems that considerable patient safety results depend on the extensive use of SSI. For our study, hospitals report only a moderate level of SSI implementation (with an average use of 3.29 on a 0-5 scale) for our sample of hospitals. An extensive initial investment in resources is required for SSI, so few hospitals may have been able to implement it comprehensively in recent economic conditions.

A third novel contribution of this study for patient safety is the finding that LMI is effective for improving patient safety results, despite being the least commonly used PI initiatives among the hospitals we surveyed (with an average use of 1.10 on a 0-5 scale). The limited application and results in healthcare is consistent with previous research (Glasgow et al., 2010). We expect LMI is significant for patient safety results because lean tools are quickly learned, implemented, and produce immediate results (Graban, 2009; Protzman et al., 2010). The “5S”, process and value stream mapping, kaizen, and JIT tools measured for LMI seem to be exceptionally suited for improving patient safety. However, the internal and project-driven emphasis of LMI may reduce its impact on long-range organizational effectiveness and competitiveness.

For hospital practitioners seeking improvement in organizational effectiveness, we find that CQI and SSI are significant in mediating hospital error sources, but LMI is not significant over and above CQI and SSI. Organizational effectiveness refers to the ability to achieve quality improvements, enhance patient satisfaction, produce net cost savings, and reduce the severity of errors. It seems logical that CQI would be associated with improved organizational effectiveness. It has been deployed in most hospitals for the past two decades (Kazandjian, 1997), and has been reported to be successful in improving quality and customer satisfaction from the organizational perspective (Sollecito and Johnson, 2011). SSI may accordingly be linked to organizational effectiveness because it is designed to contain variation, so hospitals that use it tend to have more effective and consistent processes. Similarly, SSI has been demonstrated to be useful in containing costs, improving quality and enhancing patient satisfaction (Bisgaard, 2009; Kennedy and Fiss, 2009).

Finally, for hospital administrators desiring to gain a sustainable competitive advantage, SSI is significant in mediating hospital error sources; however, CQI and
LMI are not significant over and above SSI. Our findings suggest that SSI can be a distinctive strategic resource that contributes to hospital competitiveness. This result augments previous healthcare literature that emphasized CQI for achieving a competitive advantage in theory (Reed et al., 2000) and in practice (Douglas and Judge, 2001). The recent widespread use of CQI suggests that it may no longer provide a distinctive competence in terms of rareness and non-substitutability among hospitals. In contrast, LMI does not yield greater competitiveness possibly due to its limited deployment so far. Our study provides insight on greater competitiveness from SSI and potentially for LMI in the future, through more prevalent application in healthcare.

Limitations and future research
A major limitation of our findings is the dependence on perceptual indicators. However, dependent variables in healthcare management research are most frequently characterized by perceptual measures (Alexander et al., 2007; Caldwell et al., 2008; Goldstein and Iossifova, 2011; Halbesleben and Rathert, 2008; Khatri et al., 2007), with some exceptions in using third-party objective measures (Menachemi et al., 2008; Thouin et al., 2008). Potential sources of objective outcome data were considered for the current study, but they were not publicly available for all US hospitals at the time of this study. Common method bias was examined with Harman’s one-factor test (Podsakoff et al., 2003) above, suggesting that the single method of data collection appears to be an acceptable risk. Other limitations of this study include the use of a relatively small sample size, compared to the overall US hospital population, so expanding the survey to greater number of hospitals could be beneficial. Furthermore, including other potential alternate mediating or moderating constructs can enhance the sophistication of the relationships relevant to the outcome variables. Future studies with objective measures, such as patient satisfaction and quality of care data, could produce a broader view of the research findings.

As our study is exploratory, future research could enhance theoretical and practical implications of the study results shown here. Our findings can serve as an initial point of departure for a more sophisticated research model. This could include examining the PI initiatives in terms of their impact on outcomes other than patient safety, organizational effectiveness and sustainable competitive advantage. The different findings for each of the three PI initiatives suggest that additional mediating constructs, such as hospital executive leadership, could also prove fruitful for an expanded framework. Overall, examining an expanded framework with additional mediators and dependent measures might accentuate the significance of their interrelatedness and provide additional direction for healthcare practitioners designing superior PI interventions.

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Cottington, S. and Forst, S. (2010), Lean Healthcare: Get Your Facility into Shape, HCPro, Danvers, MA.


Evans, J.R. and Lindsay, W.M. (2011), Managing for Quality and Performance Excellence, 8th ed., South-Western Cengage Learning, Mason, OH.


Further reading

Appendix. Questionnaire construct items
Respondents provided a score for each item below on a scale of 0-5, where 0 was “none,” 1 was “very low,” 2 was “low,” 3 was “moderate,” 4 was “high” and 5 was “very high.”

Hospital error sources (HES)
To what extent does each of the following has contributed to errors at your hospital?
- Equipment failure/malfunction.
- Demand surge caused by factors internal to the hospital.
- Demand surge caused by factors external to the hospital.
- Infrastructure: public services and internal backup services.
- Unplanned circumstances and events.
- Computer issues.
- Employee willful misconduct.

Continuous quality improvement (CQI)
To what extent has your hospital implemented each of the following tools?
- Plan, do, check/study, and act (PDCA/PDSA) quality improvement method.
- Teams of employees for quality/process improvement.
- Employee recognition, rewards, and promotion opportunity for quality program success.
- Patient satisfaction measures (e.g. voice of the customer) by surveys, focus groups, etc.
- Competitive benchmarking of best-in-class processes.

Six Sigma initiatives (SSI)
To what extent has your hospital implemented each of the following tools?
- PI tools. Statistical process control chart, check sheet, histogram, Pareto chart, Fishbone diagram, etc.
- PI method, e.g. define, measure, analyze, improve, and control (DMAIC).
- Training in PI tools for employees, such as change agents, Green Belts, Black Belts, Champions, etc.
- PI projects, review, and closure.

Lean management initiatives (LMI)
To what extent has your hospital implemented each of the following tools?
- “5S” workplace organization: sort, set in order (straighten), shine, standardize, and sustain.
- Process mapping (flow chart, process map, etc.).
- Value stream mapping (VSM).
- Kaizen or Kaizen Blitzes (continuous improvement events).
- Just-in-time (JIT) process management or inventory management.

Patient safety results (PSR)
To what extent have results been realized?
- Reduction in the frequency of errors.
- Increased understanding of errors.
- Heightened awareness of errors.
- Reduction in the impact of errors.

Organizational effectiveness results (OER)
To what extent have results been realized?
• Quality improvement.
• Patient satisfaction increase.
• Net cost savings.
• Reduction in the severity of errors.

**Sustainable competitive advantage (SCA)**
To what extent does your quality program achieve sustainable competitive advantage in terms of:

• **Value added.** How well do your firm’s resources and capabilities enable your firm to respond to external threats and opportunities?

• **Rareness.** How much are your firm’s resources and capabilities not possessed by competitors?

• **Costly-to-imitate.** How much do firms without your resources and capabilities face a cost disadvantage to duplicate your program?

• **Non-substitutability.** How much is there no strategic equivalent for your program?

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