

Guiding Inpatient Quality Improvement: A Systematic Review of Lean and Six Sigma

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In the decade since the Institute of Medicine reported that as many as 98,000 people die each year in the United States as a result of medical errors,¹ the health care community has been focused on improving overall quality, efficiency, and safety. Despite this focus, the 2008 National Healthcare Quality Report (NHQR) shows only an average 1.4% annual increase in all measures of quality and an average annual decrease of 0.9% in patient safety measures.² The 2009 NHQR found that there is still considerable variability and that certain areas, such as patient safety and avoidance of health care-associated infections, still require urgent attention.³ With nearly all health care institutions participating in some form of quality improvement (QI) activities,⁴⁻⁶ the lack of substantial improvements in quality is disheartening.

Considering the NHQR's sobering analysis, it is important to evaluate the current state of QI in health care and begin to identify ways for improving health care quality and safety. An important step in this process is to understand the strength and weaknesses of the various QI approaches used in health care.⁷ The use of a variety of methods suggests that although these different QI approaches produce initially positive results, rarely are these results translated into sustained gains, making them ineffective.⁸⁻¹⁰ The noteworthy lack of sustainable success has led institutions frequently to discard their current QI approach in the hope that a new approach will produce more sustainable results.^{9,11} Reflecting on the history of QI in health care, it seems imperative to develop a review that examines the current QI approaches with a particular focus on determining whether improvements are sustained and on identifying any challenges involved in effectively adopting a QI approach.

Quality Improvement Approaches

On the basis of publication frequency,⁷ Lean and Six Sigma appear to be the most frequently used QI approaches for improving quality. Lean was developed and championed by the Toyota Motor Company as a philosophy and set of tools focused on the detection and elimination of waste. The end goal in a Lean company

Article-at-a-Glance

Background: Two popular quality improvement (QI) approaches in health care are Lean and Six Sigma. Hospitals continue to adopt these QI approaches—or the hybrid Lean Sigma approach—with little knowledge on how well they produce sustainable improvements. A systematic literature review was conducted to determine whether Lean, Six Sigma, or Lean Sigma have been effectively used to create and sustain improvements in the acute care setting.

Methods: Databases were searched for articles published in the health care, business, and engineering literatures. Study inclusion criteria required identification of a Six Sigma, Lean, or Lean Sigma project; QI efforts focused on hospitalized patients; descriptions of project improvements; and reported results. Depending on the quality of data reported, articles were classified as summary reports, prepost observational studies, or time-series reports.

Results: Database searches identified 539 potential articles. After review of titles, abstracts, and full text, 47 articles met inclusion criteria—10 articles summarized multiple projects, 12 reported Lean projects, 20 reported Six Sigma projects, and 5 reported Lean Sigma projects. Generally, the studies provided limited data, with only 15 articles providing any sort of follow-up data; of the 15, only 3 report a follow-up period greater than two years.

Conclusion: Lean, Six Sigma, and Lean Sigma as QI approaches can aid institutions in tackling a wide variety of problems encountered in acute care. However, the true impact of these approaches is difficult to judge, given that the lack of rigorous evaluation or clearly sustained improvements provides little evidence supporting broad adoption. There is still a need for future work that will improve the evidence base for understanding more about QI approaches and how to achieve sustainable improvement.

Table 1. References with Detailed Descriptions for the Lean and Six Sigma Approaches

Descriptions	Lean	Six Sigma
General Philosophy	12, 13	8, 14
Description of Tools	15-17	18, 19
Books	20, 21	22

is to ensure that actions that do not add value for the company's customers are minimized or eliminated. Six Sigma was developed at Motorola and popularly championed by General Electric. The focus in a Six Sigma project is to identify the customer's definition of quality and then develop a process that consistently produces a high-quality, error-free product. Detailed summaries of the general philosophy and techniques associated with each of these QI approaches are covered in many of the articles cited in this review. Rather than repeat this excellent work, we refer any reader who is unfamiliar with either approach to the sources listed in Table 1 (above).^{8, 12-22}

Although Lean and Six Sigma are two separate entities, there is a current effort to combine these two methodologies into a single approach, referred to in this article as *Lean Sigma*. Combining the approaches provides QI teams and the organization with processes focused on measuring and eliminating errors (Six Sigma) and on ensuring a work flow that is efficient and value-added (Lean). Furthermore, in combination these approaches suggest an environment that focuses on measuring and maintaining process performance (Six Sigma) while recognizing the importance of maintaining a culture that supports rapid continuous improvement (Lean). In addition, a combined approach may help employees at all levels of the organization to appreciate how active participation in QI improves both the staffs' and the patients' daily experiences. On the basis of the positive aspects of both approaches, there is some growing belief that Lean Sigma may be the QI approach that finally leads to sustained levels of high-quality care.^{23,24} However, it is critical to systematically review and evaluate for evidence that Lean, Six Sigma, and Lean Sigma lead to sustained improvements before advocating broad adoption.

Thus, the aim of this review was to analyze all publications related to the use of Lean, Six Sigma, or Lean Sigma for QI in the inpatient setting. Although these QI approaches have been applied throughout the

health care system, including improvement of administrative processes, this review focuses on acute care patient-related processes for three reasons. First, acute care is a multidisciplinary environment with many overlapping microsystems that present unique and life-threatening challenges for patients. Second, physicians are critical to improvements in the acute care setting and have been reported to be resistant to QI projects.²⁵ However, growth of the hospitalist model suggests that there are now physicians with new motivations and incentives to participate in inpatient QI projects.²⁶ Third, an acute care focus provides a manageable frame for a discussion that may provide direction for hospital leadership.

Methods

In a systematic literature review, we searched for published QI project reports that used Lean, Six Sigma, or Lean Sigma to improve quality in the acute care setting. Because these projects involve multidisciplinary teams, including direct care providers, managers, and engineers, the search used three databases: PubMed (health care), ABI/Inform (business and management), and Ei Engineering Village Compendex (engineering). The individual search strategies (Table 2, page 25) were developed in consultation with a clinical education librarian and executed on April 21, 2009, with a follow-up search on July 15, 2010. A broad keyword search was used because Lean and Six Sigma are not recognized keywords in any of these databases.

ARTICLE SELECTION

In an effort to best summarize and characterize the published literature, minimal standards were used to establish selection criteria. To be included in the study, the article was required to meet all of the following criteria:

- Self-identify as reporting on a Lean, Six Sigma, or Lean Sigma project
- Focus on acute care
- Describe the QI project
- Report end-of-project results

Acute care was defined as any activity associated with taking care of patients (including pediatric patients) on a hospital ward, including wound or other care of surgical patients but not surgical activities in an operating theater. It may also include hospital-based ancillary support services (for example, laboratory tests,

Table 2. Search Strategies Used to Determine Potential Articles

Database	Search String
PubMed	“Six Sigma”[All Fields] OR (Lean[tiab] AND sigma[tiab]) OR “Lean management”[All Fields] OR “Lean thinking”[All Fields] OR toyota[tiab] OR “Lean healthcare”[All Fields] OR “Lean manufacturing”[All Fields] OR “Lean principles”[All Fields]
ABI/Inform	LSU([SIX SIGMA]) OR LSU([LEAN MANUFACTURING]) AND (LSU([HEALTH CARE INDUSTRY]) OR LSU([HEALTH CARE SERVICES INDUSTRY]) OR LSU([HEALTHCARE INDUSTRY])) OR LSU([HOSPITALS]) OR (LSU([HEALTH CARE]) OR LSU([HEALTH CARE, HEALTH CARE]))
Ei Engineering Village Compendex	[Lean] wn ALL OR [Six Sigma] wn ALL OR [Lean sigma] wn ALL OR [toyota] wn ALL OR [Lean management] wn ALL Village Compendex OR [Lean manufacturing] wn ALL OR [Lean healthcare] wn ALL OR [Lean thinking] wn ALL OR [Lean principles] wn ALL AND [healthcare] wn ALL

equipment, radiology) when those projects are completed as a collaborative effort between patient care staff and support service staff.

For articles whose abstracts did not exclude them from the study, the full-text document was obtained for full review. The full-review process involved ensuring that each of the articles met the inclusion criteria and abstracting key information from the articles.

Abstraction, which was completed by the first author [J.M.G.], included information on the QI approach, methodologic quality of the study, QI goal, setting, team members, changes made, overall results, and length of reported follow-up.

METHODOLOGICAL CHARACTERIZATION

Because these publications were reporting QI results, the expectation was that most would report some variation of a quasi-experimental study design, as opposed to a randomized experimental design. To classify these studies, the following definitions were set a priori:

- A study would be classified as a *time series* if the article presented a minimum of two data points before and after the intervention period.
- A study that did not meet this criterion by reporting data both before and after the intervention, with one of these periods marked by a single time point, was classified as a *pre-post observational study*.
- Studies only presenting summary results amounting to a single time point were classified as *summary reports*.

Results

In total, the search strategies identified a total of 539 articles, 47 of which met final inclusion criteria. Figure 1 (available in online article) shows the number of articles returned by each database and how articles were excluded to reach the final selection.

STUDY CHARACTERISTICS

Of the final 47 articles meeting inclusion criteria, 10 involved articles that briefly discuss multiple QI projects. Because these summaries are typically very brief, these articles will be discussed but were not included in any analyses. Exclusion of these 10 articles leaves a final sample of 37 articles that use the Lean, Six Sigma, or Lean Sigma approach to improve the care of hospitalized patients. A summary organized by QI approach is available in the Appendix (available in online article), which lists the article title, overall project focus, setting of the project, description of QI team members, length of available post-implementation follow-up data (sustainability), and report classification (time-series, pre-post, or summary). The articles are ordered by QI approach, with 12 reporting a Lean focus, 20 reporting a Six Sigma focus, and 5 using Lean Sigma.

Most institutions only have a single publication in this review, although five settings generated multiple reports. For facilities implementing Lean, Virginia Mason has three articles included in this review,^{13,27,28} and the Pittsburgh Regional Healthcare Initiative has three articles, two from Allegheny General^{29,30} and one from the University of Pittsburgh.³¹ From the Six Sigma

arena, there are four projects from Virtua Health,^{14,32-34} two from Mount Sinai,^{18,35} and two from Saint Francis Health System.^{36,37} The articles are predominately from institutions in the United States, although there is one article from Australia³⁸ and one from the Netherlands.³⁹

The individuals participating in a QI project can be essential to its success or failure. Unfortunately, 12 of the articles do not report any details on their team members. In those reports that do mention team members, details are usually limited. Teams are typically multidisciplinary, including representatives from most groups that provide any direct patient care potentially impacted by the QI project. Only 8 reports make it clear that physicians directly participated in the project. Some projects did consult with physicians, particularly in a setting where recommended changes would have a direct impact on physician activities.⁴⁰

As is typical for QI projects, the reporting focused predominately on information dissemination (for example, what interventions were used) and less on program evaluation (For example, detailed reporting and rigorous statistical analysis). As such, 5 of the reports meet the definition of summary reports, 18 are pre-post studies, and 14 provide time-series data. Only 15 articles provide some follow-up data, with only 6 articles having a follow-up period of longer than two years.

Discussion

The first goal of this systematic review was to identify whether the existing body of evidence suggests that Lean and Six Sigma should be broadly adopted for improving acute care quality. There is a growing body of evidence suggesting a benefit; however, there are sufficient unknowns and challenges that make it difficult to recommend broad adoption.

In evaluating the evidence, a first consideration is whether the Lean and Six Sigma approaches are flexible enough to address the wide range of acute care quality issues. The collection of 10 articles that met inclusion criteria for this review but were too broad to include in the analysis are a good example of flexibility. For example, Lean has been used to improve financial services, inventory, and patient flow within the Avera McKennan health care system.⁴¹ Lean has also been used to tackle multiple projects in a rural 99-bed facility.⁴² New York-Presbyterian Hospital has 2 reports noting a substantial number of different projects using Six Sigma to improve quality.^{8,43} The remaining 6

reports provide summaries about the application of these QI approaches in a number of settings.^{9,44-48} Together, the articles in this review show that Lean and Six Sigma have been effectively applied to all components, from admission to discharge, of a patient's hospital experience. With the ability to help teams improve bed management⁴⁹ and glucose control,¹⁹ there is sufficient flexibility to improving quality in the acute care setting.

IMMEDIATE PROJECT RESULTS

Understanding that Lean and Six Sigma can be used to address a variety of projects, the next question becomes whether their application regularly leads to improvements in quality. Several recent reviews have examined the quality of project evaluation and reporting. The first review evaluated whether there is sufficient evidence to support the dissemination of computerized provider order entry (CPOE) systems.⁵⁰ The review concludes that current published reports are methodologically weak and that future studies need improved measurement and study design to determine true effects and generalizability of findings.

The other two reviews focus on Lean- and Six Sigma-based projects. The first of these reviews evaluated 9 Lean and 9 Six Sigma articles.⁵¹ The other review included 6 Lean, 26 Six Sigma, and 2 Lean Sigma articles.⁵² The articles contained in these reviews do overlap with the current review, but they were more focused on identifying high-quality reports rather than focusing on a specific clinical arena. As such, each review has different inclusion/exclusion criteria and different sampling frames. The overall conclusion from these previous reviews is that although the surveyed articles present some intriguing results, there are too many weaknesses in reporting and evaluation to provide a strong evidence base showing that Lean or Six Sigma improves quality.

On the basis of the published results in the 47 articles in the current systematic review, multiple institutions indicate that they have benefited from Lean-, Six Sigma-, or Lean Sigma-driven QI projects. However, the methodologic quality of these reports is no better than those discussed in the other reviews of QI projects. Given such limited methodological quality, it is impossible to conclude that these QI approaches definitively improve quality. Considering that the purpose of publishing QI articles is not always to provide a rigorous project evaluation but rather to disseminate information, it is not surprising that the

reported data and analyses do not meet stringent requirements. However, just as not all experiments must be double-blind randomized controlled trials, perhaps there is a level of evidence within these articles that meets a more practical or real-world threshold for adoption. A major component of this practical threshold is showing whether results from a QI project are sustained after project completion.

SUSTAINING QUALITY

For this discussion, we define *sustained improvements* as improvements that maintain the desired level of quality (within control limits if a control chart is presented) after project completion. For determining the sustainability of improvements, this discussion focuses on the six identified articles that report greater than two years of follow-up data. Results of the review suggest that when implemented improvements focus on care providers and not the underlying process, there is little likelihood of sustained quality. For example, the main changes made in an effort to reduce nosocomial urinary tract infections (UTIs) were to provide education and training to nursing staff.⁵³ These efforts resulted in a steady decrease in the number of UTIs for a year after the intervention, but then rates slowly began to increase, hitting the highest rate observed for a quarter in four years within two years of project completion. It is important to note that as a part of the improvement project the unit was monitoring UTI rates and was able to respond and bring the process back under control. However, because the response consisted of merely additional education for staff, the UTI rates may not remain as low as desired for long.

Another example of where improvements do not focus on the underlying process and changes have been questionably sustained comes from efforts to improve patient satisfaction with pain management.¹⁸ The interventions—staff education, patient education, and staff feedback—led to initial improvements, but follow-up data suggest a general downward trend. Once again, the group regularly monitored performance data so that each decrease in patients' ratings is followed by a staff response and a corresponding increase in satisfaction ratings. A potential critique of these two articles is that their focus on improving via personnel training may miss the intended objective of Lean and Six Sigma. Changes to personnel behavior may be critical to ensuring value and reducing errors in health

care, but projects that conclude with no greater process or system change than educating personnel have been unsuccessful.

When QI projects implement changes to how processes are performed, it appears that control is better maintained. One example is an effort to address catheter-related bloodstream infections (CRBIs). The project interventions included developing a system to monitor catheter dwell time and creating catheter insertion kits to ensure that all materials were immediately available in one area.⁵⁴ These changes resulted in a dramatic decrease in CRBIs, although continued monitoring showed that the infection rate increased during the first winter after implementation. Review of this increase in infections identified a specific subset of patients who were not evaluated in the original project. An additional change to the process—use of antibiotic-coated catheters in this subset of patients—brought the infection rate back under control, which was then maintained for a year. Another study reported on the use of five different process interventions to lower the rates of pressure ulcers.³⁶ As was the case with the CRBI report, the first intervention did not achieve the desired pressure ulcer rates, but this prompted the QI team to identify additional problems, which were addressed with subsequent interventions.

These four articles all used the Six Sigma approach to QI, yet differences in their approach to improving quality—education-based UTI⁵³ and pain management¹⁸ improvements as compared to continual monitoring and process improvement for CRBIs⁵⁴ and pressure ulcers³⁶—suggest a challenge in properly defining sustainability in the QI setting. Our definition of sustainability as the ability to maintain a desired level of quality may not be appropriate for evaluating certain projects, such as those using the Lean approach. In Lean, the focus is less on sustaining or maintaining control of the process as it is on creating a culture of continuous improvement. The two Lean articles presenting extended data focus not on when an intervention ends but rather on when the project begins and then on continuously monitoring and improving the process.^{38,55} Another three Lean projects continue this theme by only discussing how they have developed a culture of continuous improvement.^{28,30,56}

This discussion on sustained improvements raises two important points for consideration. First, the definition of sustainability used in this review may not be the most

appropriate definition for QI in health care. It is likely unrealistic to expect a single QI project to solve a quality problem permanently. Instead, the more appropriate metric may be the ability of a QI approach to create an environment where monitoring and continuous improvement are accepted. Very few articles discuss the environment or culture created in the process of implementing Lean or Six Sigma, which makes this sort of evaluation impossible with the available reports.

A second consideration is whether more stringent criteria are needed for determining which projects are Lean or Six Sigma projects. A common intervention in these projects was to educate or retrain staff. Although training and education may be important components of a project, especially when making significant process changes, those projects that rely solely on these interventions may not have represented the full Lean or Six Sigma philosophy.

After reviewing these articles and examining the short-term impact and then the ability to sustain that impact, we must conclude that there is not sufficient evidence to recommend broad adoption of Lean, Six Sigma, or Lean Sigma. The underlying approach to QI embodied in these approaches can be quite successful in improving quality, and those institutions that incorporate QI into larger efforts to measure care processes and create a patient safety culture may find them effective tools. However, an institution that hopes to only run occasional QI projects will be disappointed to find that in a few years any initial gains in quality will be lost. In the following section, we discuss some issues that may help institutions effectively to begin the process of adopting Lean, Six Sigma, or Lean Sigma to successfully improve the quality of care provided.

IMPORTANT CHALLENGES

Perhaps the key challenge in adopting QI and ensuring its success is making QI part of a broader institutional initiative to create a patient safety culture. Without this broader focus, it will be hard to overcome the initial resistance that QI initiatives often face. This resistance is seen from frontline staff, who may see Lean and Six Sigma as just another “management flavor of the month,”⁵⁷ and from managers who resist efforts to change and may not provide the needed employee time releases for participation in QI projects.⁴² When beginning planning how to implement Lean or Six Sigma into the organization, a common first step for successful organizations is to gather a group of leaders

(both by title and action) throughout the organization and have them observe the process in action at a highly successful organization. Most commonly, this has involved interacting with quality leaders in other industries, such as automobile manufacturing (for example, Toyota or GE). However, health care may now have its own quality leaders in places such as Virginia Mason, Mount Sinai, or the Pittsburgh Regional Health Initiative who can provide initial exposure and help hospitals develop an appropriate implementation and integration strategy.

The next step in successful QI program development is working to develop personnel with experience and expertise. Outside consultants will play an integral role during early adoption, but for a successful and sustainable program there will need to be full-time in-house talent (black belts) who can support the projects.⁵⁸ There will also need to be efforts to train a critical mass of employees with essential knowledge and experience.⁵⁷ Some recent articles address approaches and challenges to training medical professionals⁵⁹ and medical residents.⁶⁰

The development of a group of employees with knowledge and experience will improve chances for success, but there will need to be efforts to ensure acceptance by everyone in the organization. The change acceleration process (CAP) literature even uses the equation $E = Q \times A$, which says that the effectiveness (E) of a project is the product of the quality (Q) of the solution and the acceptability (A) of the solution.^{35,61} So even the most perfect solution will have no effect if it is not acceptable among the individuals affected by the solution. Reflecting the importance of ensuring acceptance, five of the articles in this review specifically noted use of CAP management tools to improve stakeholder acceptance of process changes. With up to 62% of change initiatives failing because key stakeholders do not accept the proposed changes,³³ tools such as CAP may be critical for ensuring QI project success.³⁵ Realistic evaluation theory has also been suggested as a tool that can help QI teams recognize the context in which they operate and how different approaches may lead to success or failure of the initiative.⁶²

LIMITATIONS

In any systematic review of QI, there is a particular concern about publication bias. Published results typically represent either early efforts or particularly successful projects. Yet, such projects may fail to appropriately address the difficulties and ambiguities that arise during QI.

Although the review of literature published in peer-reviewed journals was thorough, this systematic review did not include reports found in books, which are a significant source of case reports. However, such case reports are difficult to evaluate because discussion is typically limited and they are selected to best exemplify key points. Given that case reports are not typically intended to convey the full QI story, the decision made was not to include them in this analysis.

Recommendations for Future Directions

The articles in this review suggest that Lean, Six Sigma, and Lean Sigma do contribute to efforts to improve acute care quality. This review also suggests that process changes may lead to more sustainable improvements.

On the basis of our analysis of the reviewed articles, we propose three important steps necessary to establishing an evidence base for understanding how best to apply Lean and Six Sigma in health care. First, the quality of reported results needs to improve by increasing the contextual information provided, increasing the completeness of results over time, and providing more specific information about sustainability of improvements. It appears that at least two years of data are necessary to determine whether process changes are accepted and become part of the permanent culture.

Second, institutions with a long QI history should present multiyear analyses to examine sustainability. Evaluating sustainability should involve not only examining individual projects but also evaluating whether cultural change occurs and an interest in QI is sustained. Third, failed QI projects should also be published to provide insight into challenges and potential ways to avoid associated roadblocks in other institutions. With the context of the environment so critical to QI project success, reports on how different teams failed or fell apart may be quite informative in shaping a successful health care QI future.

Conclusion

This systematic review of the health care, business, and engineering literature collected 47 articles covering QI projects using Lean, Six Sigma, or Lean Sigma to improve inpatient care. This review suggests that these QI approaches can aid institutions in tackling a wide variety of problems encountered in acute care. However, the true impact of these approaches is difficult to judge because the lack of rigorous evaluation or clearly sustained improvements provides little evidence supporting broad adoption. Given this limitation, there is still a need for future work that will improve the evidence base for understanding more about these QI approaches and how to achieve sustainable improvement.

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Online-Only Content



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Appendix 1. Lean, Six Sigma, and Lean Sigma Articles
Figure 1. Article Selection Flowchart

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