The Statistical point of view of Quality: the Lean Six Sigma methodology

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Abstract: Six Sigma and Lean are two quality improvement methodologies. The Lean Six Sigma methodology is applicable to repetitive procedures. Therefore, the use of this methodology in the health-care arena has focused mainly on areas of business operations, throughput, and case management and has focused on efficiency outcomes. After the revision of methodology, the paper presents a brief clinical example of the use of Lean Six Sigma as a quality improvement method in the reduction of the complications during and after lobectomies. Using Lean Six Sigma methodology, the multidisciplinary teams could identify multiple modifiable points across the surgical process. These process improvements could be applied to different surgical specialties and could result in a measurement, from statistical point of view, of the surgical quality.

Keywords: Medical statistics; statistical analysis; thoracic surgery; Six Sigma methodology

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Introduction

Six Sigma and Lean are two prominent quality improvement methodologies that have been validated across several areas of healthcare. Despite a slow initial uptake within surgical unit, the use of Lean and Six Sigma has increased markedly (1).

The Six Sigma methodology

Six Sigma was developed by the Motorola Corporation in 1986 and aims to improve the quality by identifying and correcting the causes of errors (1). The Six Sigma approach attempts to drive production failures to six standard deviations (sigma) from the mean or 3.4 defects per 1,000,000 products. The term *Six Sigma* reflects the statistical objective of the approach, namely striving to achieve a negligible number of defects, corresponding to the probability associated with a *corrected* Six Sigma value for the normal curve. Applying the normal curve, Six Sigma attempts to relegate defects and quality problems to the very tails of the distribution, making such problems literally rare exceptions in a process that operates almost without defects. The Six Sigma level of performance is not possible in biological systems, but its methodology is applicable to repetitive procedures. The roots of Six Sigma as a measurement standard can be traced back to Carl Frederick Gauss [1777-1855], who introduced the concept of the normal curve. Six Sigma as a measurement standard in product variation can be traced back to the 1920 when Walter Shewhart showed that three sigma from the mean is the point where a process requires correction. The Six Sigma methodology has gained wide popularity because it has proven to be successful not only at improving quality but also at producing large cost savings along with those improvements. As mentioned earlier, to achieve the Six Sigma objective, a process must not produce more than 3.4 defects per million opportunities to produce such *defects*, where a defect is defined as any kind of unacceptable outcome produced by the process under scrutiny (2) Note that the 3.4 defects per million criterion actually corresponds to a normal z value of 4.5 because the Six Sigma approach allows for a 1.5 times sigma value of so

called 'drift' or process 'slop', termed by Motorola the 'long-term dynamic mean variation'.

The lean strategy

The Lean process strategy is attributed to Taiichi Ohno, from Toyota. In the Toyota Production System, specific types of manufacturing "waste," which absorb personnel, resources, or time but do not add value to the overall process or to the end user of the service or product are eliminated. Lean is a process that continually reduces waste and improves workflow to efficiently produce a product or service that is perceived to be of high value to those who use it. The successful application of Lean and Six Sigma management tool is not limited to manufacturing, but has been applied in the customer and financial service industries and the government. Increasingly, Lean and Six Sigma are being used in the health care industry. Similar to other industries, the use of these tools can be applied to several aspects of health care, including finance, inventory management, information processing, outpatient clinics, and inpatient setting (3). Lean focuses on reducing wasteful or non value-added steps in a process, and Six Sigma reduces process variation through the application of statistical methods. In many quality improvement projects, these different tools are complementary, which has led to merging them into a single strategy, the Lean Six Sigma methodology (3).

The Lean Six Sigma methodology

Recently, in health care Lean Six Sigma was used to improve the organization and quality of care and to reduce costs. Lean Six Sigma offers the roadmap of DMAIC (define, measure, analyze, improve, control) as an improvement methodology and a conceptual organizational framework with specific roles for project leaders and project owners to improve processes. The DMAIC phases are milestones for the improvement project and integrate statistical quality tools and techniques like failure mode and effect analysis and statistical process control. Process and outcome measurements are combined with project metrics into a systematic review process, so that management can deal with the progress of the projects. Following, we describe the five DMAIC phases (2).

(I) *Define.* The Define phase of the DMAIC roadmap concerns the definition of the problem to be solved. The project charter determined the project leader, process owners, scope, timeline, and auxiliary members of the project team. To put the problem in perspective, a Supplier, Input, Process, Output, and Customer (SIPOC) analyses were made, leading to a detailed flowchart of the process at micro level. The process leader did a stakeholder analysis, to chart the stakes and the influence of the people involved.

(II) *Measure.* To quantify the current process performance, we need appropriate measurements, the so-called critical to quality indicators in Lean Six Sigma terms. A critical to quality flow down was used to translate the rationale underlying the project into performance indicators and strategic focal points. The critical to quality flow down resulted in a measurement plan to determine the current performance, the number of clinical intakes and throughput time of the (main) process.

(III) *Analyze.* The aim of the Analyze phase was to arrive to a data based diagnosis of the current process performance.

(IV) *Improve.* After the process was diagnosed, the project team determined objectives for interventions to eliminate waste and to reduce waiting times.

(V) *Control.* The new process is actively monitored, to assure that better results are retained (4).

The power of Lean Six Sigma lies in its *empirical* data-driven approach (and its focus on using quantitative measures of how the system is performing) to achieve the goal of process improvement and variation reduction. The distribution of a characteristic in Six Sigma is usually assumed Normal (or Gaussian) for continuous variables and Poissonian for discrete variables. To date, the use of Lean Six Sigma methodology in the health-care arena has focused mainly on areas of business operations (nurse recruitment), throughput (emergency department and diagnostic radiology wait times), and case management (improvement of test scheduling) (5). The clinical use of Lean Six Sigma methodology has focused on efficiency outcomes, such as reducing the length of hospital stay in stroke patients, but application of the Lean Six Sigma corporate improvement method was successfully used to improve clinical outcomes and also to reduce surgical complication in repetitive procedures (2).

A clinical example of the use of Lean Six Sigma as a quality improvement method, developed from previous experience in other specialties (6), can be employed in order to reduce the complications resulted during and after lobectomies. A surgical team was assembled and trained

in the Lean Six Sigma methodology. Committed and consistent leadership to overcome the complications was assured by this team. The surgical team firstly generated a SIPOC table for surgery process. To achieve the performance objective, the surgical team first determined by brainstorming the critical to quality factors, i.e., the factors that may have an influence on the objective. The surgical team determined the metrics to measure existing process. The metrics to be chosen for a Six Sigma study were:

(I) Total number of performed in the unit;

(II) Number of complications.

Data were collected for a period of x years. In this period, s lobectomies were performed on n patients. Complications had been noted as they occurred. The surgical team identified c types of complications and classified them as when (e.g., intraoperatively and/or postoperatively), and how soon they occur (e.g., acute, sub-acute and/or chronic). Then, sources and root-causes of these complications are tabulated by type. To measure the current sigma level of a complication, the surgical team calculated the current defects per million opportunities and sigma levels for each complication type:

$$Defects\ per\ Million\ Opportunities = \frac{10^6 c}{s}$$

where s is the total number of surgeries performed and c is the total number of complications occurred. Normal distribution underlies Six Sigma's statistical assumptions.

Conclusions

Using Lean Six Sigma methodology, the multidisciplinary teams consisting of thoracic surgeons, anesthesiologists, nurses, hospital administrators could identify multiple modifiable points across the surgical process. Process improvements based on these findings could be applied to different surgical specialties and could result in a measurement, from a statistical point of view, of surgical quality.

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