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## "SIX SIGMA" WHAT IT MEANS IN HEALTH CARE?

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Quality in healthcare has come to mean many things to many stakeholders, from satisfaction with service to the clinical outcome of the patient's treatment. The most widely accepted definition was stated by the Institute of Medicine as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".<sup>1</sup> The terminology is carefully chosen to include all points along the continuum of care.

Defects or errors in any business carry an associated expense, but medical errors also carry significant human costs. And the IOM report estimates that medical errors cost the nation (USA) approximately \$37.6 billion each year, with roughly \$17 billion of those costs associated with preventable errors.<sup>1</sup> In health care "errors" include administrative mistakes in admission, incorrect or untimely diagnosis, wrong medication, delays in management, departure from professional standards, wrong bills etc. Errors in healthcare result in part from poorly designed complex systems.

For a multitude of reasons, improving healthcare quality is paramount. Communities today are not only demanding access to the best technology and treatment available, but also assurances that medical encounters will be both safe and effective. In this competitive, quality-driven and cost-conscious environment, one of the most effective solutions healthcare professionals have found has been the adoption of Six Sigma methodology and related change management techniques. Mounting evidence illustrates that using Six Sigma to design and refine patient care processes eliminates the need to retrace steps, correct reporting errors, re-do examinations or re-schedule appointments. Such redundancies and waste are costly both in financial terms as well as discomfort and dissatisfaction to the patient.<sup>2</sup>

Since people feel variability more than averages, Six Sigma focuses first on reducing process variation and then on improving the capability of that process. A logical healthcare example can be found in patient wait time. If a patient waits to be seen by the doctor 5 minutes one time and 50 minutes the next, they won't base their satisfaction level on the average of the two wait times, but the impact of the wide variability and corollary unpredictability of the process.

Six Sigma is a systematic method for improving the output of the organization by improving the quality of the system and processes. This is done by preventing error, solving problems, managing change, and monitoring long-term performance in quantitative terms so that any incipient problems are detected before they become bothersome. It uses a collection of management practices to achieve its specified goal. Some of these practices are based on statistics, but

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many are not. <sup>3</sup> Why "Sigma" (s)? It's a statistical term that measures how far a given process deviates from perfection. The central idea behind Six Sigma is that if you can measure how many "defects" you have in a process, you can systematically figure out how to eliminate them and get as close to "zero defects" as possible.

Six Sigma is an error reduction methodology that has been successfully applied in industry, most notably at General Electric and Motorola. It represents both a management discipline and a standardized approach to problem solving and process optimization. When used as a metric (measure), Six Sigma technically means having no more than 3.4 defects per million opportunities in any process, product or service. Six Sigma is so named because its powerful tools provide a proven methodology of reducing error rates to the amount that would fall under a bell curve six standard deviations (or sigmas) from the mean. The goal is to redesign a given process to Six Sigma specifications to insure that the process is 99.99975% error free. The likelihood of an error occurring in a process with Six Sigma would be 3.4 per million opportunities. <sup>4</sup>

Using the Institute of Medicine report, the American healthcare system would rate a 2.8 process sigma over the short term and 1.8 sigma over the long term. A 2.8 sigma is more than 200,000 wrong drug prescriptions per year compared to six sigma of 68 wrong prescriptions per year. A 2.8 sigma means more than 5,000 incorrect surgical procedures each week compared to six sigma of 1.7 incorrect procedures per week. <sup>5</sup>

The case for adopting Six Sigma in healthcare organizations has more to do with managing the politics and power of quality improvement than applying advanced statistical problem solving tools. For example, in the few hospitals that have successfully deployed Six Sigma, the biggest benefit has been the adoption by the CEO of quality improvement as a strategy for institutional survival <sup>6</sup>. Presently the use of Six Sigma in healthcare is gradually taking off in many best healthcare organizations of the developed and the developing world. Some useful clinical improvement projects where Six Sigma can be successfully utilized are addressing chemotherapy medication errors, reducing blood stream infections in critical care areas, enhancing patient satisfaction, reducing surgical errors etc.

Sutter Health, one of the USA's leading nonprofit health care providers, sought to improve the quality of care for people with Congestive Heart Failure (CHF)<sup>7</sup>. Serving more than 100 communities in Northern California, Sutter Health is a family of nonprofit hospitals and physician organizations that share resources and expertise to advance health care quality. For the past six to eight years, Sutter Health has worked on roughly one new clinical initiative per year. Currently, Sutter Health tracks progress on the following initiatives:

- Breast cancer
- First pregnancy and delivery
- Childhood asthma
- Acute myocardial infarction
- Pressure ulcers
- Community-acquired pneumonia
- Congestive Heart Failure

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This work had its inception in 1998, when Gordon Hunt Jr., M.D., senior vice president and chief medical officer of Sutter Health, brought in one of the present authors (Bill Farrell) to provide statistical rigor to the quality improvement process. Dr. Hunt had just completed the Advanced Training Program at Intermountain Health Care and was anxious to apply techniques such as statistical process control to quantify the improvements he was seeing in the treatment of breast cancer.

Sutter Health's commitment to this paradigm can be seen in the Management and Clinical Excellence Program, an internal mini-version of Intermountain Health Care's Advanced Training Program. To date, more than 450 Sutter Health employees have been trained in Six Sigma and rapid cycle-improvement techniques by a faculty comprising both internal and nationally renowned external experts (including Brent James, M.D., M.Stat., the originator of the Intermountain Health Care Advanced Training Program).

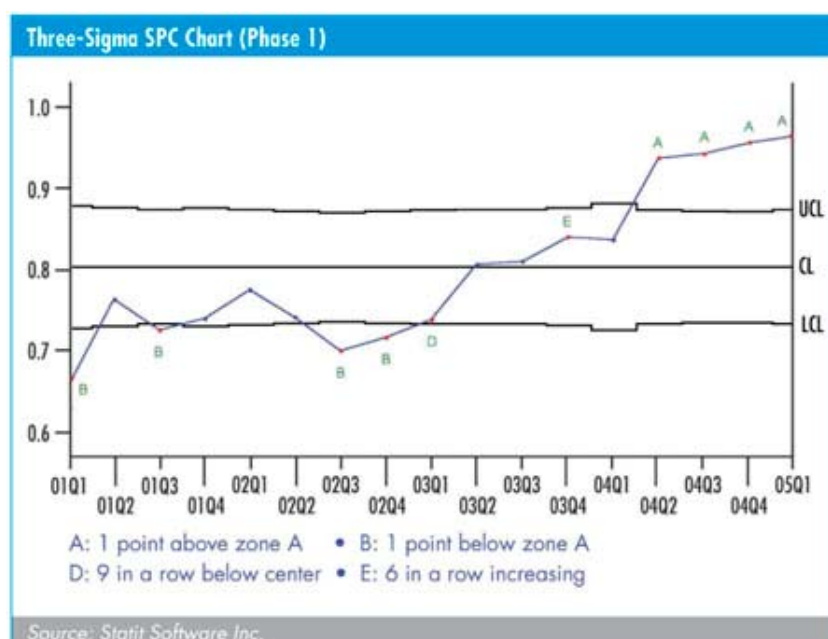
Using the Six Sigma DMAIC process, let's look at how Sutter Health approached CHF:

## DEFINE

CHF was chosen early on as one of Sutter Health's clinical initiatives, both because of the increasing burden the disease places on health care organizations and because of wide variations seen in the treatment of the disease. It's primarily a disease of the elderly, and as life spans increase, more people are being diagnosed with CHF. At the onset of the initiative, Sutter decided to focus on ACE inhibitors as the treatment of choice for CHF. Several random clinical trials had demonstrated the efficacy of this class of drugs in treating the disease, and other studies had shown wide variability in the extent to which CHF patients received these drugs. (Sutter is currently tracking nine measures for the inpatient CHF initiative but is focusing on ACE at discharge for this case study.)

## MEASURE

Sutter collects data quarterly for the initiative. Data collection initially was cumbersome, relying on manual chart review at each of the 20 Sutter Health hospitals that treat CHF patients. The process has been streamlined over time, with the data now available in a data warehouse. Sutter uses bar charts and spider (or radar) charts to compare hospitals for the current quarter's results. Statistical process control methodology (at the heart of Six Sigma) is used to track performance for individual affiliates over time, and confidence interval (CI) methodology is used to compare performance to a target.

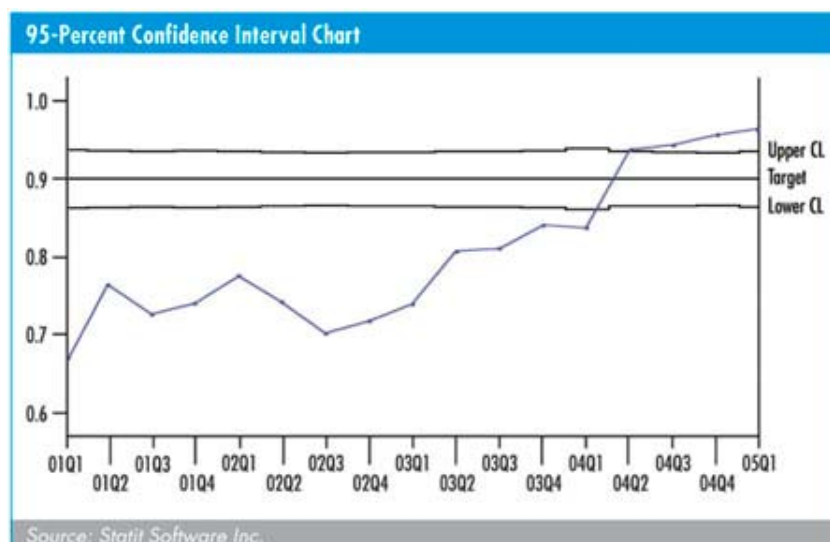


## ANALYZE

The figure above shows a standard three-sigma SPC chart for the fictitious Sutter St. Elsewhere Hospital, revealing the performance over time in getting ACE inhibitors to CHF patients as they are discharged from the hospital. Although the data are fictitious, they reflect real progress at Sutter Health in getting this important medication to people who have been hospitalized with CHF. Because numerator and denominator data are available for this measure, a p-chart is used. Statistical process control software plots the individual data points, draws the centerline as the average of the data points and draws the three-sigma control lines. The width of the control lines varies from quarter to quarter because the sigma measure depends (in part) on sample size, which in this case varies over time. Most important, the SPC software looks for and labels "rule violations," that is, cases where a particular data point shows unusual variability given the history of the process. In the figure, the last four data points are labeled "A," meaning that they are beyond three sigma on the high side. Several earlier data points are labeled "B," meaning that they are beyond three sigma on the low side.

## IMPROVE

This figure shows significant improvement. Seeing this, one might ask, "How much improvement is enough?" All of Sutter Health's clinical initiative measures have targets attached to them, so one answer to this question could be, "When everyone is at target." Statistical process control by itself cannot provide the answer, so Sutter turned to another technique, developed by Dr. James, which involves "tricking" SPC software into drawing a pseudo-confidence interval chart.



To implement this technique, Sutter fixes the center line at the target (i.e., 90 percent in the case of ACE inhibitors at discharge), rather than letting the software calculate the center line. In addition, the software draws two-sigma limits, rather than the standard three-sigma limits. Finally, the rule violation labels are turned off because they have no meaning in this context. The result, as shown in the figure above, is an unusual-looking but useful 95-percent confidence interval chart (three-sigma limits would produce a 99-percent CI chart).

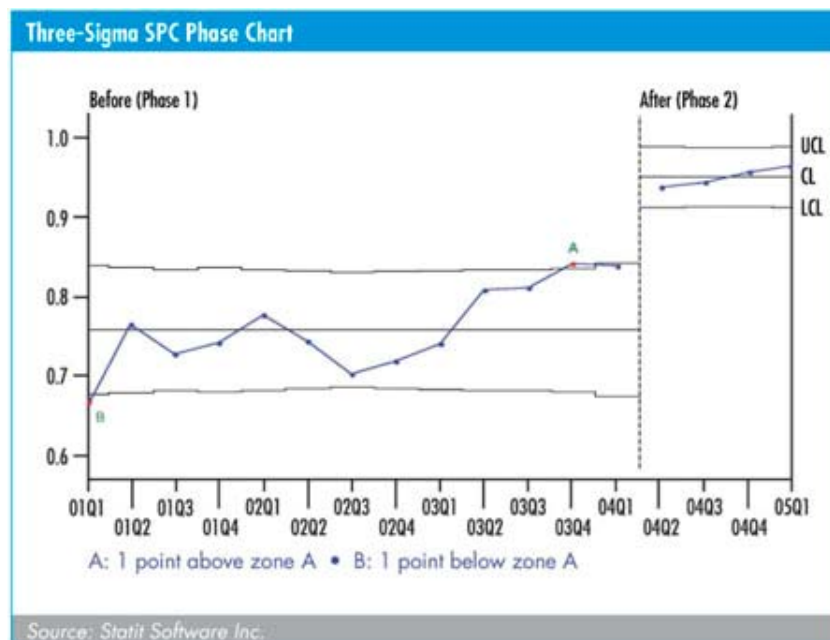
Interpreting the data is simple: If a data point lies outside the 95-percent "envelope," it is significantly different from (i.e., higher or lower than) the target. Points inside the envelope do not differ, in a statistical sense, from the target. In the present (fictitious) case, we see that although Sutter St. Elsewhere made significant positive progress from an SPC perspective, it took the hospital more than three years to move its ACE performance into (and beyond) the target zone.

Using these two methodologies in tandem provides a more complete picture of Sutter Health's improvement in getting ACE inhibitors to CHF patients. An affiliate may show no significant triggers on its SPC chart but have 18 consecutive quarters where its performance is significantly favorable to the target. Similarly, another affiliate may not reach the target zone but demonstrates several instances of significant upticks on the SPC chart; these are recognized and rewarded.

## CONTROL

In an industrial Six Sigma effort, control could mean keeping a process within a tight set of specification limits. This is less relevant in a health care setting--at least in the early stages of clinical improvement--where, in most instances, we want to see a process demonstrate significant upward movement. In other words, we want our processes to be out of control. However, as time goes on and clinical improvement processes start to mature, we hope to be in a position to utilize another tool in the SPC arsenal: the phase chart. This chart splits a process into "before" and "after" phases. It's commonly used in industry when a major change occurs--when a robot car painter replaces a human one, for example. Changes in health care delivery are not usually that abrupt, but the goal is to have most processes working at a relatively high level with relatively low variability.

For illustrative purposes, we will suggest that the ACE inhibitor process at Sutter St. Elsewhere moved to a steady-state phase 2 between the first and second quarters of 2004. The figure below presents the appropriate SPC chart for this process.



The phase chart shows a process with significant improvement over 12 quarters, followed by four quarters where the process is in control at a new, higher level.

At the moment, it is rare that a health-care delivery process shows this kind of abrupt shift and steady-state maturity. Sutter Health is committed to using Six Sigma tools for the long term, however, and looks forward to getting all of its quality processes in good control.

In Pakistan's health care context the use of Six Sigma is far from realization due to lack of process centeredness and application of simple statistical process control measures. There is no concept of treating health care core functions such as assessment of patients, care of patients, patient and family rights, facility management and safety, and infection control as a set of organizational processes that can be measured, controlled and continually improved. A process is defined as a set of interrelated activities that transforms inputs into outputs. The second problem is lack of data availability due to the prevailing anti-measurement culture. It is almost impossible to find research in the area of evaluating health care quality in the country. There is no national database of health care adverse events like medication errors. It is a well-established fact that if you can't measure you can't manage, and if you can't manage you cannot improve.

Rather than jumping on conclusions such as Six Sigma is a complex pure statistical tool not applicable to our work environment, it is better to understand it as a simple non-statistical philosophy or a paradigm for harvesting a culture of error prevention, problem detecting, problem solving, and managing change. One can start simple with realistic and attainable project goals using DMAIC Six Sigma approach.

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