Six Sigma enters the healthcare mainstream

Six Sigma proves its staying power in a crowded field of performance improvement alternatives

by **Ian R Lazarus, FACHE and Wendy M. Novicoff, Ph.D.**

WHAT DO YOU do when you have exhausted all options for improving performance in an environment that is determined to protect the status quo? What do you do when your organization has reached the presumed limit of potential performance and has grown all too comfortable with its market lead? Is there a common set of methodologies to shake up both market laggards and leaders? How about subjecting your organization to the rigors of Six Sigma, the manufacturing-oriented methodology now sweeping through service industries? But take heed, warns John Desmarais, CEO of Commonwealth Health Corp. (Bowling Green, Ky.), when you start a Six Sigma initiative, "you learn some things about your organization you didn't necessarily want to know."

Commonwealth Health Corp. (CHC) was one of the first pioneering healthcare organizations to make a strong commitment to Six Sigma. The organization's stated "Six Sigma" vision (as it appears on their Web site) is that by the year 2004, "we will be proudly recognized by our employees, patients, clients, community, physicians and payers as the unquestioned leader in care and service, providing flawless quality never before achieved in the healthcare industry." Today, CHC is joined by several major medical centers and managed care organizations that have found Six Sigma a powerful program to invigorate an ambivalent workforce, to reduce medical errors, and to move toward a "world class performance" environment that will minimize waste, maximize satisfaction and boost company profits.

Six Sigma, defined

A systematic and statistically-based process to reveal defects in performance, driven by customer specifications. Six Sigma methodologies aim to reduce the variation in clinical and business processes which give rise to long cycle times, high cost and poor outcomes. A process that operates at true "six sigma" levels is producing acceptable quality over 99.99% of the time.

When Six Sigma first appeared in the healthcare industry several years ago, many were skeptical that a manufacturing-oriented approach to business improvement would be acceptable to the healthcare industry (Managed Health-

Ian R. Lazarus, FACHE is managing partner at Creative Healthcare USA (www.creative-healthcare.com) a consulting and training firm providing Six Sigma services to healthcare providers and suppliers. Wendy Novicoff, Ph.D. is an associate partner in Creative Healthcare and also on the faculty at the University of Virginia School of Medicine.

CARE EXECUTIVE first introduced Six Sigma to its readers in October 2001). Moreover, there were concerns that this amusing term represented nothing more than a redressing of existing performance improvement techniques that were already being utilized to the fullest degree within leading healthcare organizations. But a thoughtful examination of Six Sigma's potential in service industries such as healthcare has demonstrated that in many respects, the concept of achieving defect-free processes is even more compelling than in the automated world of manufacturing. "Six Sigma is here to stay," warns Don Redinius, a consultant that brought Six Sigma to Mount Carmel Medical Center in Columbus, Ohio. "And pretty soon, all hospital CEOs are going to have to decide what they are going to do about it."

Six Sigma benefits

- Reduce medical errors
- Achieve near defect-free processes
- Improve quality and profits
- Boost patient satisfaction
- Improve employee retention

FIX IT FOR THE LAST TIME

Many process improvement programs have come and gone over the years; Six Sigma is best applied to process improvement opportunities not satisfied by previous efforts. A pitfall of preceding performance improvement techniques is that any improvement gains are often lost over time as the process returns to its original baseline performance. Because the Six Sigma methodology is specifically aimed at redefining a process and in particular, removing the root cause of defects, it cannot regress to previous levels of performance. Six Sigma also aims to "do more with less," rather than relying on audits, additional staffing, punitive policies or similar initiatives to achieve desired levels of performance.

A "MAKE/BUY" DECISION

Hospital executives considering Six Sigma have a variety of choices regarding implementation, but it fundamentally comes down to a make/buy decision. Those not quite ready to subject their organization to the rigors of Six Sigma or unsure of the organization's resolve can simply 'buy" the time of Six Sigma practitioners to solve persistent process performance challenges. Over time, more projects may be undertaken until greater confidence exists to bring such capability inhouse. Those that want to truly "make" the institution a Six Sigma organization will "deploy" the program through training, coaching and certification of employees. The infrastructure of a Six Sigma organization will include "black belts" and "green belts" designating different levels of expertise in Six Sigma methodologies.

Implementation issues and challenges

- Resolve the "make-buy" decision
- Assemble implementation team
- Establish a change-agent mandate
- Define potential projects
- Establish milestone reviews
- Replenish projects when necessary

"IT'LL NEVER WORK"

When Palomar Pomerado Health Laboratory Services (Escondido, Calif.) called upon a Six Sigma consultant to assist with improving the turnaround time on a critical laboratory test, the immediate reaction of the existing staff was that layoffs would be followed by a new round of hiring, resulting in more people performing the same tasks. Many previous efforts at improvement took a similar turn, and various attempts at altering human behavior had done little to improve performance of the test. The specific test, Troponin, is an early indicator of myocardial infarction, and a brief delay in processing could result in a serious adverse event. The turnaround time for the test was nearly 78 minutes and trending upward, against an industry "best practice" benchmark of only 60 minutes.

"We were absolutely convinced that in order to increase throughput in the lab that we first had to increase staffing," recalls medical director Jerry Kolins, MD. "Six Sigma showed us not only that this was unnecessary, but that the throughput could be dramatically increased simply by improving the process itself."

The hospital's Six Sigma project team broke down the Troponin process into three basic steps: the order, the blood draw and the delivery of result. Although prevailing opinion was that the process of ordering the test was flawed, subsequent data analysis revealed this was only responsible for 17% of the total cycle time and that most of the processing time occurred after the blood was delivered to the hospital's internal lab. Six Sigma techniques were applied to construct a variety of hypothesis tests to determine the key drivers of process performance. In these types of studies, a "null hypothesis" is established, and compelling statistical evidence is needed to validate any alternative reality. The laboratory set forth the following null hypothesis:

- There is no impact on turnaround time by multiple blood draws
- It makes no difference whether the blood is delivered by tube or in person
- It takes no significant time from the completion of testing to the delivery of results

In each case the lab was able to establish compelling evidence to reject each hypothesis. They discovered multiple draws were significantly delaying the delivery of blood to the lab, and that although the pneumatic tube was perceived to be the most expedient delivery, it actually delayed the urgent tests as this blood would be placed in a queue in the accessioning department, further delaying de-

livery to the lab technician. Finally, because the instrument required about 20 minutes to process the blood and was out of sight of the technologists, results sat for an average of 7 minutes before being released to the physicians working in the emergency department.

Statistical analysis was used to determine the potential gains in making three significant adjustments to the existing process:

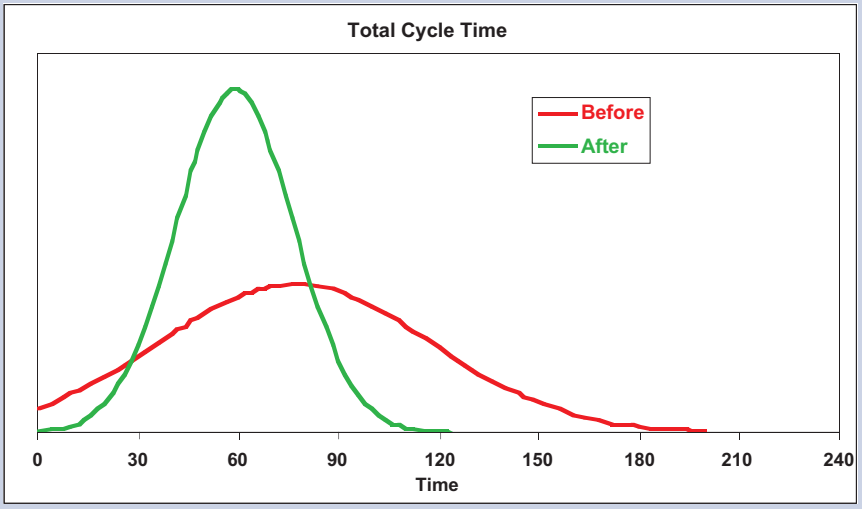
- Elimination of multiple draws when one or more Troponin was ordered
- Discontinuation of tubing for samples when Troponin test is ordered
- Use of audible alarm to indicate completion of instrument processing

The process changes were first implemented on a trial basis with a portion of the laboratory's staff and this was compared with a control group that was not asked to change their behavior in any way. The resulting performance matched the gains predicted by the statistical model (see chart, above). The hospital not only achieved a turnaround time of 60 minutes, they became "best in class" among their peer group for this particular test.

Among the other cultural barriers to testing Six Sigma was the notion that any gains made in the turnaround in one test would be at the expense of another. The laboratory performed a broad range of services for the hospital, and the cumulative average of all tests performed during 2002 was 50 minutes. By the end of the Six Sigma project, that rate fell to 45 minutes. By improving the efficiency of processes that ran in parallel to one another (as in a lab that performs multiple tests simultaneously), improvements were seen across the board.

"The benefit of this experience is not only the result, which was impressive, but that we could anticipate it long before we asked the laboratory staff to change behavior, because of the power of the statistical tests we ran in advance," notes Kolins. Kolins, who also serves as medical director for the San Diego Chapter of the American Red Cross, believes that blood banks and testing facilities are a new frontier for Six Sigma—he is probably right. Blood Systems Laboratories, the second largest blood testing company in the U.S. (second only to the Red Cross), launched a system-wide Six Sigma program earlier this year.

Turnaround time for Troponin: before and after Six Sigma project



Process Step	Before Six Sigma (in minutes)		After Six Sigma		Improvement	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Order Test	13.1	14.0	11.0	8.3	2.1	5.7
Draw Blood	12.4	9.2	7.9	6.7	4.5	2.5
Deliver Result	51.4	40.0	40.1	11.4	11.3	28.6
Total Cycle Time	**76.9**	**40.7**	**59.0**	**17.6**	**17.9**	**23.1**

WHERE NO MAN HAS GONE BEFORE

Six Sigma has succeeded in detecting and eliminating defects within many healthcare processes. But what happens when the process either doesn't exist or is so broken that no amount of fixing it will bring it to an acceptable level? The Institute of Medicine report on medical errors challenges healthcare providers to improve current processes. It further argues that the industry must take a fundamental look at the way it provides care across the continuum and face the reality that many of its systems are quite flawed. This stark reality calls for the need to design new processes from the ground up using Six Sigma techniques to ensure reliable and satisfactory performance.

Design For Six Sigma is an outgrowth of traditional Six Sigma methodology and there are many derivatives used in industry. For the purposes of this article, the focus will be on the DMADV model for DFSS: Define, Measure, Analyze, Design, and Verify. As applied to healthcare prod-

Design for Six Sigma, defined

A disciplined and statistically-based process to take customer requirements and translate them into process specifications and final design requirements. DFSS tools help to predict and improve quality and performance before a process or product is launched.

ucts and processes, this methodology can also allow for periodic updates to reflect the inevitable changes in healthcare delivery and technology.

DFSS: DMADV

DEFINE: Define the project opportunity and goals; get customer requirements
MEASURE: Assess needs and specifications
ANALYZE: Statistically examine options to meet specifications
DESIGN: Develop the process/product to meet specifications
VERIFY: Check the design to ensure specifications are being met

USING DMADV IN HEALTHCARE

The Joint Commission's new standards related to staffing effectiveness were implemented as part of their survey process in 2002. These standards were developed to acknowledge the relationship between clinical staffing patterns and patient outcomes and incorporated an evidence-based approach to address staffing variances. The University of Virginia Medical Center took this opportunity to build a measurement system that would allow management to assess the workload of caregivers, assess the current systems and structures in place that help or hinder workflow, and, most importantly, assess the impact of staffing levels on patient safety and medical outcomes. Dee San, a Six Sigma "black belt" on the project explains, "The goal of this DFSS project was to develop a valid and reliable measurement tool that could quantify direct and indirect patient care activities and staffing variances. This project was the first part of developing a comprehensive measure of staffing effectiveness."

During the Define stage of the project, the team gathered "voice of the customer" information (VOC) to help with designing the tool. Some of the critical success factors were:

- minimum end-user completion time
- no or few calculations needed
- inclusion of non-clinical variables
- acknowledgement of resource-intensive events.

Project teams were formed, and extensive time studies were undertaken in each of the four units to determine the time needed to perform specific patient care activities. A patient-specific factor was developed to account for routine and mandatory activities that were common for each patient regardless of diagnosis, and a staff-specific factor was calculated to allow for delays/interruptions/fatigue that are inherent in any working environment. Pilot tests of the tool on 7 units were very successful:

- 98% compliance with using the tool
- 94% inter-rater reliability
- 90% agreement between the care hours predicted by the tool and actual hours worked.

Plans are underway to take the tool institution-wide and improve the electronic capabilities of the systems that support it. Black belt Evie Nicholson acknowledges that there is still a long road ahead, but "the staff are really engaged and feel like they own this project, so it was all worth it in the end. We really epitomize the adage that sometimes the journey is more important the destination."

DESIGNING FOR PATIENT SAFETY: RETHINKING HOSPITAL DESIGN

St. Joseph Community Hospital, part of the SynergyHealth system in West Bend, Wis., is taking the unusual steps to plan and build a brand new hospital rather than remodel their current facility. Every step in the design process for the new hospital is being carefully considered from a quality and patient safety perspective. President and CEO John Reiling writes in a recent report, "We recognized that we had a unique opportunity to improve patient safety and promote a patient-safe culture through innovation in design of this new hospital. The design has received national and regional attention as a result of our focus on quality and safety."

Facility design principles: St. Joseph's Community Hospital of West Bend

- Visibility of patients to staff
- Standardization
- Automate where possible
- Scalability, adaptability, flexibility
- Immediate accessibility of information, close to point of service
- Noise reduction
- Patients involved with care
- Failure Modes and Effects Analysis (FMEA) at each stage of design
- Design for the vulnerable patient
- Human factors review
- Minimize fatigue
- Design around precarious events

One of the major initiatives for the new hospital involves pharmacy activities. Four of JCAHO's 2004 National Patient Safety Goals relate directly to medication ordering or administration, so these systems will be given careful scrutiny as they are designed for the new hospital. The pharmacy at St. Joseph's is currently open from 7:00 A.M. to 9:00 P.M. Monday through Friday and from 7:30 A.M. to 6:00 P.M. on weekends. The medication-ordering process is primarily manual: all prescriptions are transcribed from the physician's original script onto special medication ordering forms, which are then taken to the pharmacy for manual entry into a computerized system. Any orders written or received after hours must wait for the next day to be filled; in some cases, floor stock is used until the pharmacy can fill the order. All pharmacy orders are examined for potential errors: missing information, incorrect informa-

tion, potential drug interactions, and potential drug allergies.

A non-punitive, voluntary approach to error reporting has been extremely successful in pointing out areas of improvement, and several initiatives have been developed and implemented to reduce medication errors. But all involved acknowledge that catching errors after they have happened isn't the best way to move forward into a new hospital. Using Design for Six Sigma techniques, the project team has begun to scope out what a new system will look like, keeping the facility design principles in mind.

The first order of business will be to expand the current pharmacy hours to provide coverage on a 24/7 basis. Other work that will occur before moving into the new hospital will include activities specific to realizing the JCAHO National Patient Safety Goals. This will include improving the accuracy of patient identification, improving the effectiveness of communication among caregivers through "read-backs" of verbal orders, standardization of abbreviations and symbols used in medication ordering, and improving the safety of using high-alert medications such as heparin and narcotics.

Plans for the new hospital include computerized physician order entry (CPOE), bedside bar coding, and automated drug-dispensing devices.

The use of technology to provide more organized and easily accessible information across the care continuum is in keeping with the recommendations of several national groups looking at improving quality of care, including the Institute of Medicine, the Institute for Safe Medication Practices (ISMP), Leapfrog Group, the Joint Commission, and several others. The cost for all these activities will not be cheap, but the savings will be incalculable.

NOT FOR THE TIMID

Six Sigma may be compelling proof that, in the words of a famous explorer, "the expedient and the right thing are seldom the same thing." Successful implementation of a Six Sigma initiative requires commitment, focus and patience, but the rewards are substantial. Beyond the obvious practical benefits, organizations become leveraged to solve persistent problems while "raising the bar" in terms of the expectations they set for themselves. And in an industry where expectations are a moving target, applying the principles to set and reach the highest possible performance might be the best reason of all to consider this thing they call Six Sigma.