A BIGGER PROBLEM THAN TERRORISM – HEALTHCARE ERRORS:

Using Total Six Sigma To Save Lives

by

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Abstract

Studies indicate that up to 100,000 people die each year in the United States from medical mistakes (Corrigan et al, 2000) – mistakes that are typically a result of quality and process problems. These are problems that Six Sigma is designed to diagnose, measure, analyze, improve and control. Six Sigma has the potential of saving more lives and money than any medicine or life-saving procedure that has been developed in the last 50 years and it isn't even approved by the FDA.

In the 80's Motorola credited a turn around in quality to Six Sigma, while GE in the 90's utilized Six Sigma to increase quality and reduce costs. Healthcare isn't Motorola or GE, and quality issues mean more than the loss of profits – they can mean a loss of life.

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"Knowledge is Power."

Francis Bacon (1561-1626)

❑ The Awful Truth

Did you know that you are safer traveling in Saudi Arabia than you are lying in bed at your local hospital? Yes, the chances of being killed by a terrorist in Saudi Arabia are less than being killed by medical errors in your community hospital. Throughout the world there were only 613 people killed by terrorists in 2003, but there were up to 100,000 deaths attributed to healthcare errors in the U.S. alone.

What two industries have the biggest opportunity for improvement?

- Hotels– No
- Computers– No
- Telecommunications– No
- Banking– No
- Transportation– No
- Construction– No
- Government–Yes
- Healthcare–Yes

It seems that the American public cares less about the number of people killed due to medical errors than they care about other industries' errors. Just look at the amount of attention that Firestone and Ford got when Firestones' manufacturing process produced some defective tires that caused a few dozen fatal car accidents. The problem was highlighted on TV, in newspapers and even the government was about to step in. It was the "talk of the town" and as a result of this bad publicity, Firestone stock fell. However, the truth of the matter is that you are safer driving in your car than lying in the hospital as the result of errors made by the product or service providers.

There is no other industry so in need of reinventing itself than the healthcare industry. Just look at some of the following healthcare facts:

- It has been estimated that globally some where between 1,500,000 to 2,200,000 people die as a result of healthcare errors every year. That number would be even higher except a large percentage of the world's population is not exposed to modern healthcare.
- Healthcare errors kill up to 100,000 people per year in the U.S. alone.
- One person in the U.S. dies every 8 minutes as a result of nosocomial infection and 95% are preventable. (Source: Center for Disease Control.)
- Hospitals with an atmosphere of distrust have a death rate of 58% higher than average.
- 2 million patients per year acquire an infection in the U.S. while hospitalized for other conditions and 88,000 die as a direct or indirect result. This adds an additional healthcare cost of $5 billion. (Source: Centers for Disease Control and Prevention.)
- In the U.S., healthcare accounts for 15% of the GNP and it will continue to rise to 18%. This compares to 8% and 10% in developing regions such as Japan, Europe and Canada.
- Health insurance premiums rose an average of 14% in 2003 and are projected to rise by 11 to 20% annually for the next three years.
- U.S. National healthcare spending is $1.7 trillion. (Centers for Medicare and Medicaid Services, Office of the Actuary, 2004).
- 43 million people in the U.S. are without any medical insurance.
- 77 million people will be retiring soon with reduced healthcare benefit, which will put more of a strain on the already-shaky medical system.
- U.S. healthcare consumers pay the highest prices in the world for drugs, therapists, and medical diagnostic and treatment technologies, effectively subsidizing both healthcare R&D and treatment in other industrialized nations as well as the developing countries.
- Patients are uninformed about the quality of service and acceptable standard that they will receive.
- Many studies have demonstrated that geographic location is a strong determinant of specialty care access and procedural decision making. (Wennberg et al, 2002) These

variations in regional patterns are principal determinants of differences in health status across rural and urban populations.

- Estimates are that, on average, it takes 17 years for evidence to be integrated into clinical practice. (Balas et al, 2000)
- Few healthcare entities are ISO 9000 certified.
- Healthcare costs run $1.7 trillion a year. Fraud and abuse run between $50 to $75 billion a year.
- Performance metrics are virtually non-existent.
- Research has shown that physicians incorporate the latest medical evidence into their treatment decisions 50% of the time. (McGlynn et al, 2003)
- Healthcare cost is contributing to the offshore movement of goods and services because the healthcare overhead cost is lower.
- 30-40% of the cost waste is caused by errors made by specialists
- The U.S. is the only developed nation whose healthcare is not run by the government.
- There is little standardization in treating patients.
- Total Quality Management (TQM) and Continuous Quality Improvement (CQI) were poorly implemented in most healthcare organizations.
- There is a critical shortage of nurses
- The U.S. government estimates that IT can save $140 billion per year through improved patient care and the elimination of redundant test ordered.
- 2% of hospital patients experience an adverse drug reaction, resulting in increased length of stay and $4,700 added needless expense. This accounts for 2.5% of the hospital's budget. (Source: Institute of Medicine.)
- Healthcare error rate is about 6,210 errors per million opportunities (3.8 sigma) and for same treatment activities run as high as one sigma. Compare this to the manufacturing Six Sigma standard of 3.4 errors per million opportunities for all processes.
- A patient improves faster at home by 10% to 60% than in a healthcare facility.
- Thirteen percent of hospitals in 2002 reported that they used EHRs. (HIMSS 2002). Physician office EHR use rates reported in 2002 ranged from 14% to a possible high of 28% practices. (Loomis et al, 2002; HIMSS, AstraZenca, 2002)

- About 20% of U.S. products' and services' extra cost is caused by our legal system
- Canada
  - Medical errors account for 9,000 to 24,000 deaths per year
  - One in 11 babies born vaginally suffers injury.
  - One hip is fractured out of every 1,124 hospitalized seniors
  - Adverse events accused in 7.5% of medical or surgical admissions. 37% of these are preventable (Source: CBC New Online Staff, June 9, 2004)
- Australia's adverse event rate is 16.6%. (The Quality in Australian Healthcare Study report)
- United Kingdom's adverse event rate is about 10%. (UK Department of Health)
- Europe's adverse event rate is about 10%. (European Working Party on Healthcare)
- In the UK, the average waiting time to get into a hospital is 9 months after the doctor recommends an operation. (The government is trying to improve this to 18 weeks. Why not two days?)

More Details

- **"Fixing Hospital Billings Errors,"** *CBS MarketWatch.com,* January 16, 2004, by Kirsten Gerencher. As many as nine out of ten hospital bills are in some way inaccurate, and many patients cannot check their bills because they cannot decode charges and do not ask the right question. In *Consumer Reports* January issue 2004 five percent of 11,000 readers said they found major errors upon reviewing their itemized hospital bills. Those with at least $2,000 in out-of-pocket expenses were twice as likely to have found inaccuracies.
- **"The Biggest Mistake of Their Lives,"** *The New York Times,* March 16, 2003, by Susan Burton. Each year an estimated 1,500 surgical patients have foreign objects (sponges etc.) left in them during surgery, leaving many to face crippling health problems. However, there is no mandatory system for reporting errors, leaving the actual number of medical errors in question. It is often only through malpractice lawsuits that these errors become public knowledge. The article goes on to report that five percent of doctors are found responsible for over 50% of successful malpractice

suits. One caution – most malpractice cases don't make it to court. Only one in 6 victims even file and about half of those abandoned cases before trial.

- **"Hospital Apologizes for Surgical Mistake,"** *The New York Times,* January 19, 2003, by the Associated Press. Linda McDougal, 46, underwent a double mastectomy after being advised by her surgeon that she had an aggressive form of cancer. Two days after the surgery she was informed that the lab at United Hospital in St. Paul, MN, had switched her lab results with another patient and that Ms. McDougal in fact had never had cancer. Ms. McDougal has been fighting several infections and will undergo reconstructive surgery before she decides whether to sue for malpractice.
- **"Survey: 40 percent of public experienced medical errors,"** *Asbury Park Press,* December 15, 2002, by Robert Davis (*USA TODAY*). A new survey, which appeared in the *New England Journal of Medicine*, reports that more than 1/3 of practicing physicians and 40 percent of the public have experienced a medical error in the care that they or a family member received as patients. One of the findings of the survey is that "physicians disagree with national experts on the effectiveness of many of the proposed solutions to the problem of medical errors."
- **"Government Declares Man Very Much Alive, Dead,"** *Associated Press,* February 19, 2002. Ramon Cruz, 81, had not even been hospitalized when Good Samaritan Hospital Medical Center in Islip, NY, forwarded the incorrect information that he died to government agencies. Apparently, a hospital worked called up the wrong "Ramon Cruz" in the database. Cruz's monthly Social Security checks were halted, his bank accounts emptied and Medicare benefits terminated. A spokesman said all Cruz's lost money will be returned, adding that it can take a couple of months.
- **"The Wrong Foot, And Other Tales of Surgical Error,"** *The New York Times*, December 11, 2001 by Lawrence K. Altman, MD. At least 150 times since 1996, surgeons in hospitals in this country have operated on the wrong arm, leg, eye, kidney or other body part, or even on the wrong patient. The figure does not include near misses, i.e. when doctors have started to operate on the wrong part of the patient or even the wrong patient, but stopped before the operation was completed because the error was detected. No one collects such information.

A Personal Look at the Problem

By now, you should be convinced that we have a problem worldwide, but let's take a little closer and more personal look at the problem by reviewing some individual incidences.

- Patricia Ann Hottois, age 53 of Phoenix, died last year of septic shock after the abdominal pad was left in her surgical wound. She had her surgery on June 8, 2003 at Maricopa Medical Center. About 2 weeks after the surgery, she was still complaining about the pain when her doctors discovered that the pad was left inside her. She died on July 1, 2003. This medical malpractice case was settled for $320,000. These types of error should be eliminated by just doing a sponge count. According to a 2003 study in the *New England Journal of Medicine*, this type of surgical error occurs in above one out of every 1,000 to 1,500 abdominal operations, a lot more than the six sigma goal of 3.4 per million.
- March 19, 2004, two patients died at Foothill Medical Centre because they got an incorrect solution during dialysis treatment. They were given a potassium chloride solution instead of sodium chloride. The mix up took place in the hospital's pharmacy. Dr. Bob Johnston the CHR's Chief Medical Officer stated "Despite our best efforts, errors do occur." Barry Cavanaugh, Chief Executive of the Pharmacists Associate of Alberta stated, "An adverse event could happen because they are overworked."
- In September 2003, Tawnya Brown underwent surgery at Inova Fairfax hospital. Although the surgery went well, the patient ultimately died. Brown was given two pints of A-negative blood and her blood type was O-positive. To make the condition worse, her doctor called for more blood when he discovered that she was not doing well in recovery. In the following 3 hours, she received six more pints of the wrong type of blood. (A person her size can hold a volume of about eight pints of blood only.) The day before the surgery a technician drew a blood sample so that the correct type would be available if needed. The problem was that the technician took the sample from the wrong patient. This should have been discovered by the phlebotomist, but he failed to perform two required identification screens: checking the patient's hospital bracelet and asking the patient to state her name. The financial

settlement for this error was about $1.7 million. But not even $1.7 million can make up the loss of a mother to an 8-year old girl.

- Brian Bachman, two years of age, died after undergoing a liver transplant at the Fairview University Medical Center in Minnesota. The surgery was uncomplicated and Brian was doing well initially. However, two days after the surgery things, Brian's condition worsened. At 7:00 AM, a nurse misread the table on a log of Heparin she was replacing. The new bag contained a much higher concentration of blood thinner than the one she was replacing and the machine delivering the medication was not reprogrammed. Brian began receiving 10 times the amount ordered by the physician. The staff failed to notice the mistake throughout the day even though the medication drip was checked every 15 minutes. The error was finally discovered by the evening nurse, but Brian had already experienced internal bleeding and a blood clot in the artery leading to Brian's liver. A blood clot can trigger liver damage, which can cause swelling of the brain and brain death. Doctors determined that Brian "will most likely remain in a vegetative state." As a result, Brian was taken off life support and died soon thereafter. Mike Sertz, Fairview's Vice President for Risk Management stated, "It was more a system error than an individual error."

These are just four typical examples of healthcare errors. There were 99,996 similar stories that could be told about healthcare in 2003. They resulted in more than 100,000 healthcare workers that have restless night thinking about what they should have done differently and 100,000 families that despair because they lost a loved one before his or her time.

The Awakening

Medical errors became a national issue in 1999, when the Institute of Medicine issued a highly published report that stated medical errors contribute to more than one million injuries and up to 98,000 deaths annually.

The most common medical errors are:

- Sepsis infections – they result in a 22% higher risk of death and add an additional cost of $57,727 to the stay in the hospital and 11 extra days of hospitalization

- Surgical wounds – they result in a 10% higher risk of death and add an average additional cost of $40,323 plus more extra days of hospitalization
- Medical objects accidentally left in the patients
- Adverse drug reaction (wrong or incorrect quantity of drug given to the patient).

In a study published in the October 2002 issue of the *Journal of American Medical Association*, it indicated that medical injuries in U.S. hospitals in 2000 led to about 32,600 deaths and at least 2.4 million extra days of patient hospitalization and an additional cost of the U.S. healthcare system of about $9.3 billion. This is considerably lower than the 1999 study on medical errors reported by the Institute of Medicine that stated up to 98,000 deaths were caused by medical errors.

In the July 27 2004 issue of *The Boston Globe,* Scott Allen reported on a study conducted by Health Grades of Denver. In this report they stated that the actual death toll from medical mistakes in the U.S. is actually closer to 200,000 per year (the equivalent of 390 fully loaded jumbo jets).

It does not matter what the correct number actually is – 200,000 or 32,000 – 32,000 deaths is 32,000 too many.

Although much of the information presented so far relates to the U.S. healthcare system, it is one of the best healthcare systems in the world and its error rate is far below average. In some of the developed countries, their healthcare error rate is more than twice as bad as in the U.S. The developing countries error rate is even much higher.

❑ What Is the Answer?

We hope by now we have presented you with enough information about healthcare systems around the world that you will agree that they need to be reformed. We need to start measuring our healthcare failures in deaths per million, not deaths per 100's or even deaths per 1,000's. Even deaths per million is not good enough in the healthcare system. The required standard should be measured in the deaths per billion and errors per million. This is where proven,

preventive approaches, like Total Improvement Management and Total Six Sigma, can provide real benefit to the healthcare system. Both of these two approaches have been refined as they were used in other industries and they are now ready to advance the healthcare industry into a new, higher level of performance.

Studies indicate that the services industries have an error rate of 159,000 to 308,000 per million opportunities. In mathematical terms that turns out to be 2.0 to 2.5 six sigma level. For example, the process for treating depression is estimated to be running at 308,538 errors per million opportunities or at the 2.0 sigma level. Sigma (σ) is a Greek letter. It is commonly used as a measure of the variation around the average of any process. Also known as the standard deviation, 1σ represents 34.134% of the data points. (Note: we provide a detailed explanation of how sigma is used to analyze healthcare later on in this paper.)

Although process capability techniques have been used extensively in manufacturing for over fifty years, a major breakthrough occurred when Motorola applied them to its business support functions as a logical extension of its manufacturing quality initiatives. The results were improvements of ten times to a hundred times in Motorola's business processes in as short a period as two years. When Motorola won the Malcolm Baldrige Award in the late 1980s, it credited the Six Sigma program as the primary driver of its improvement. During the first part of the 1990s, the Six-Sigma Program continued at Motorola and spread slowly into other organizations. But in the mid-1990s GE latched onto the concepts and committed millions of dollars to implementing the program throughout the entire organization. GE's program expanded from 200 projects in 1995 to 6,000 projects in 1997, which resulted in more than $320 million in savings, all directly attributed to this Six-Sigma Program. In 1998, GE estimated that its savings were about $750 million.

Six Sigma projects are defined as projects designed to reduce error rates to a maximum of 3.44 errors per million exposures (or "opportunities") through the use of statistical analysis techniques, problem solving, and quality principles. The typical healthcare organization has error rates in excess of between 67,000 and 309,000 (3 and 2 sigma) errors per million opportunities.

Individuals, departments, projects, functions, plants, or entire organizations can use this approach.

More important than the specific measurement of error rates (because healthcare is about people as well as process), is the methodology behind Six Sigma. The Six Sigma process forces hospitals to measure those things that are important to the business of healthcare, things like quality, mortality, customer satisfaction and employee satisfaction. If a hospital says that it is a patient-focused organization, what does that mean? And if the organization claims to be patient-centered (or focused), then how does it measure "patient focused"? If the hospital says they can't measure it, then it is it really important to them? Most organizations limit their measurement mechanisms to traditional accounting measurements, such as income and expenses, but medical mistakes are typically not measured and generally underreported due to malpractice and the practice of penalizing and terminating individuals who report errors. (After all, one critical error can lead to the revocation of a practitioner's license). Under a Six Sigma methodology, the hospital will find ways to measure what is important to them by tracing and analyzing the things they value the most as they relate to the internal or external customer's needs. Organizations that can't measure what they say they value don't really value what they profess to value. And if they can't measure it, they can't improve it!

While many healthcare organizations have attempted process improvement over the last 20 years, most have ended in disappointment. The discipline of the Six Sigma approach to quality through process improvement (as opposed to isolated quality attempts – such as inspection and post-mortem review of errors) is potentially the industry's best opportunity to address lingering issues of quality and the resultant real costs that are added to any system when poor quality is the rule, rather than the exception.

"When you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you can not express it in numbers, your knowledge is of a meager and

unsatisfactory kind. It may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science."

William Thomson, Lord Kelvin, (1824 – 1907)

❑ Six Sigma

An ever-growing number of healthcare organizations are using Six Sigma to improve processes from admitting to discharge and all the administrative and clinical processes in between. This adoption is driven by several factors including – the need to improve the organization's bottom line, eliminate medical errors and position themselves for an imminent global consumer-centered healthcare revolution. Healthcare providers once enjoyed a respect by their customers that few institutions in the world enjoy. Then came continuous years of double-digit cost increases capped off by the Institute of Health report indicating that medical errors kill approximately 98,000 people per year in the United States. These mistakes can range from prescription errors to a failure to wash hands. Many healthcare consumers began to question why increasing costs did not equate to improved quality. Accordingly, the healthcare industry finds itself at a crossroad – to continue on the current path, which would lead to disaster, and while the other, leads to potential redemption. Many organizations have chosen a path of redemption – Six Sigma.

A brief history of Six Sigma yields is helpful to a healthcare entity considering a Six Sigma initiative. The earliest quality initiatives were based on 100% inspection, a concept that would be impossible in a service-oriented\environment, such as healthcare. Because this was expensive and time-consuming sampling plans were developed to define acceptable defect levels, then in the 1970s quality guru Phil Crosby established a program called *zero defects*. This program was an inspirational way of explaining to employees the notion that everything should be done right the first time, that there should be no failures or defects in the work output. In the healthcare world, a defect can be as little as an unpaid bill or as serious as a medication error causing the death of a patient. Probably more critical than in any other industry, zero defects should be the order of the day in a patient encounter.

The zero defects concept was somewhat controversial because some quality experts felt it mainly focused on meeting internal design specifications. It did not focus on customer requirements or on continuous improvement. Many quality professionals disagreed with the concept because they believed that it was impossible to have zero defects all the time. These process-oriented professionals felt that process capability requirements were a better way of defining acceptable performance. But the U.S. government quickly embraced this concept and it became the "in" thing to do for a number of years.

In the 1970s and early 1980s organizations, like IBM, released requirements that their process capabilities (C_{pk}) must reach a 1.40 level, or an acceptable corrective action plan needed to be in place before products could be shipped to their customers. IBM's technical report entitled "Process Qualification—Manufacturing Insurance Policy," by Dr. H. James Harrington, published September 15, 1980, required that a process' plus or minus four-sigma limit must fall within the specification limit when the following are considered:

- Accuracy
- Precision
- Repeatability/reproducibility
- Variation/stability
- Linearity, resolution
- Sensitivity
- Variation between similar pieces of equipment used for the same purpose.

C_{pk} is a concept as well as a measure of how well a process' output (product or service) meets the requirements of the customer over time. To put it very simply, it is the 3 sigma value of the process' output divided into the requirements range, or in mathematical terms, $C_{pk} = Zmin/3$. For example, if the requirements were ± .003 and the calculated 3 sigma limits over time was ± .0022, the C_{pk} would be:

$$C_{pk} = \frac{.003 \text{ X } 2}{.0022 \text{ X } 2} = 1.36$$

In the beginning of the 1980s, Motorola's president directed that all processes should have a tenfold improvement within a five-year period. They turned to Total Quality Management (TQM) to accomplish this. In the mid 1980s Motorola's president called for a second 10-fold improvement. This called for radical changes in the way processes within Motorola functioned. To bring about this drastic change, Motorola implemented a program they called "Six-Sigma Program." This program set an objective for all processes to statistically perform at an error rate no greater than 3.4 errors per million opportunities. The real breakthrough in Motorola's Six Sigma approach was that the Six Sigma concept was applied to all processes, not just the manufacturing processes. (Obviously, in hindsight, was the fact that general systems theory creates a relationship between nearly all the processes in an organization.)

To calculate the process performance, samples of the output were plotted on a histogram and the standard deviation was calculated. Once the standard deviation and mean were calculated, it was easy to compare the Six Sigma calculated performance limit to the specifications and/or requirements, if the organization has defined its requirements for each process and each activity within the process. Of course, this was not the case for most non-production activities. As a result, organizations that undertake a Six-Sigma Program are forced into a major upgrading of their internal requirements and measurement system.

Once the process variation and mean performance are compared to the requirements, most processes fail to meet the Six Sigma requirements. Many non-production processes fail to even meet a ±3 sigma performance level (3 defects per 1000, or 3,000 per million). To place this in context, a routine appendectomy might consist of two to three hundred opportunities for error (hand and room washing, instrument sterilization, scheduling, pharmaceuticals, skills of surgeon, etc.), most non-critical, but many fatal. The non-critical are the most common and result in "nickel and diming" up the cost of care, while the well-publicized critical errors might result in malpractice or expensive corrective action, such as repeat procedures or infection, or death of the patient, each of which is extremely expensive to organizations in reputation and in dollars. In a fast paced and variable environment, such as a hospital emergency room, one might expect dramatic fluctuations in the sigma performance level, but typically the deviations from the mean

are not much greater than that found in an accounting office. This is true because the defects built into the system are generally consistent across time.

Another major change was initiated at Motorola; the company assigned some people to be full-time problem solvers. These individuals, called *Black Belts*, were subjected to very extensive problem-solving training that emphasized statistical techniques.

Six Sigma quality became popular immediately following Motorola winning the Malcolm Baldridge National Quality Award in 1988. The information package that Motorola distributed to explain their winning stated:

"To accomplish its quality and total customer satisfaction goals, Motorola concentrates on several key operational initiatives. At the top of the list is Six-Sigma Quality, a statistical measure of variation from a desired result. In concrete terms, Six-Sigma translates into a target of no more than 3.4 defects per million products, customer services included. At the manufacturing end, this requires designs that accommodate reasonable variation in component parts but production processes that yield consistently uniform final products. Motorola employees record the defects found in every function of the business, and statistical technologies are increasingly made part of each and every employee's job."

Although Motorola called its program *Six-Sigma*, Motorola only required that Six Sigma be applied to one point in time ($C_p = 2$) and allowed the process to perform at lower levels when the process drift is considered (C_{pk}). Motorola's assumption is that all processes have a ± 1.5 sigma shift over time, which is not always the case. Figure 1 relates the various levels of sigma to defects per thousand and per million.

QUALITY LEVELS AND CORRESPONDING NUMBER OF DEFECTS		
Quality Level	**Defects Per 1,000 Opportunities**	**Defects Per Million Opportunities**
1 sigma	317	317,310
2 sigma	45	45,500
3 sigma	2.7	2,700
3.5 sigma	0.465	465
4 sigma	0.063	63
4.5 sigma	0.0068	6.8
5 sigma	0.00057	0.57
6 sigma	0.000002	0.002

Figure 1. Quality Levels and Corresponding Number of Defects

Note that our calculation differs from the 3.4 per million as defined by Motorola because we take into account the shift of process average.

❑ Standard Histogram

Figure 2 is a histogram depicting the same information that is shown in Figure 1. By studying Figure 1, it is easy to see that six sigma is two defects per billion units processed, not the 3.4 defects per million that Motorola accepts for its Six Sigma quality level. There is a difference between the two because Motorola considers a 1.5 sigma shift of the process average over time of their total specification. For example, consider a manufacturing process whose spec limit is equal to six sigma (Cp = 2). If the process average is off-center by 1.5 sigma, the maximum number of defects is 3.4 per million based upon the standard normal distribution table. Figure 3 shows the effect on the process' capability to meet specification when the center point drifts over time.

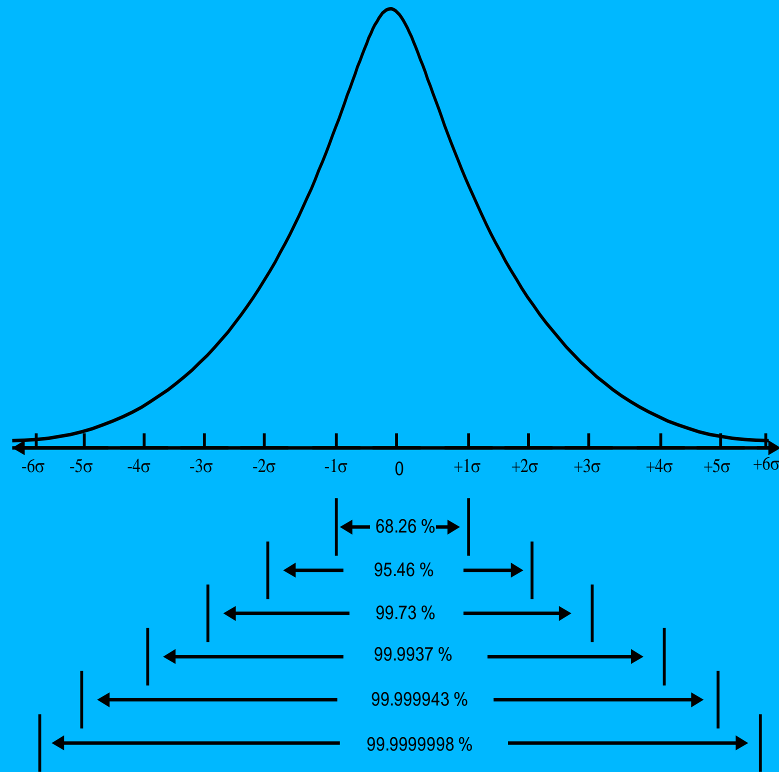

Figure 2. Frequency Distribution Chart

Short-Term vs. Long-Term Standard Deviation

For n=5 parts sampled consecutively across N=6 subgroups, σ ST may be estimated by:

$$\hat{\sigma} = \frac{\bar{R}}{d_2^*}$$

If short term capability of the process is 6 σ which degrades to 3 σ in the long term, then robustness =

$$\frac{3\sigma}{6\sigma} = 50\%$$

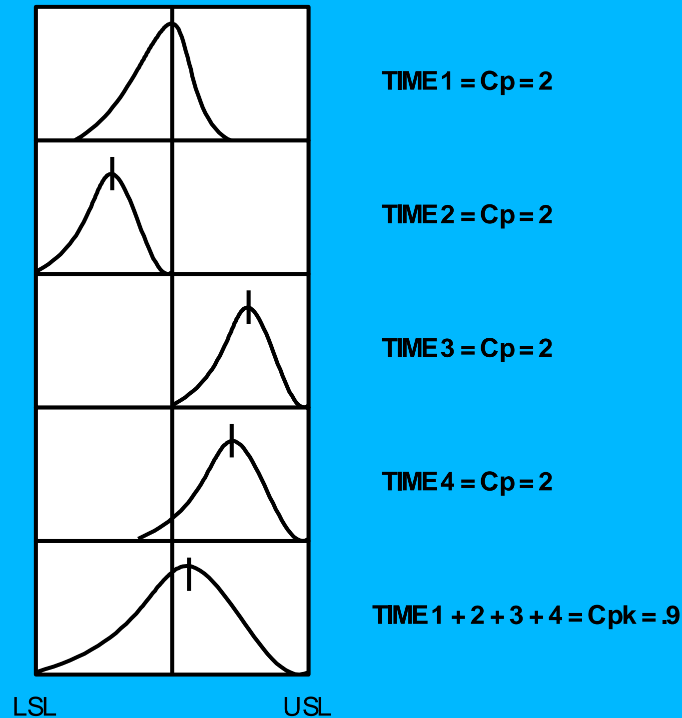

Figure 3. The Effect of Center Point (Mean) Variation Over Time on Process Capability.

(Source: Six-Sigma Productivity Analysis and Characterization, by Mikel J. Harry and J. Ronald Lowson. Reading, MA: Addison-Wesley Publishing Co., 1992)

It is important to note that this same effect can occur as operators are changed and between different sets of equipment used in the same process to do the same activity. Equipment presents an additional problem because both the mean and the distribution can be different between equipment and fixtures built to the same specification. Figure 4 shows how quality levels vary based on off-center drifts expressed in sigmas.

THE NUMBER OF DEFECTIVES (PARTS PER MILLION) FOR SPECIFIED OFF-CENTERING OF THE PROCESS AND QUALITY LEVELS							
Off-Centering Quality Level	**3 Sigma**	**3.5 Sigma**	**4 Sigma**	**4.5 Sigma**	**5 Sigma**	**5.5 Sigma**	**6 Sigma**
0	2,700	465	63	6.8	0.57	0.034	0.002
0.25 Sigma	3,577	666	99	12.8	1.02	0.1056	0.0063
0.5 Sigma	6,440	1,382	236	32	3.4	0.71	0.019
0.75 Sigma	12,288	3,011	665	88.5	11	1.02	0.1
1 Sigma	22,832	6,433	1,350	233	32	3.4	0.39
1.25 Sigma	40,111	12,201	3,000	577	88.5	10.7	1
1.50 Sigma	66.803	22,800	6,200	1,350	233	32	3.4
1.75 Sigma	105,601	40,100	12,200	3,000	577	88.4	11
2 Sigma	158,700	66,800	22,800	6,200	1,300	233	32

Figure 4. The Effect of Off-Center Drifts on Quality Level, as Expressed in Sigmas

You can readily see that there are a number of ways to have a quality level of 3.4 defects million parts or less. The following are four typical examples:

- With 0 sigma off-centering with 4.5 sigma quality
- With 0.5 sigma off-centering with 5 sigma quality
- With 1 sigma off-centering with 5.5 sigma quality
- With 1.5 sigma off-centering with 6 sigma quality

From our standpoint, it is much easier to center the mean than it is to reduce variation significantly. Pandu R. Tadikamalla, a professor at the University of Pittsburgh, pointed out in his article published in the November 1994 issue of *Quality Progress*:

"When companies embark on Six Sigma quality programs, what is their objective? Is it to reduce the process variance so that the half-tolerance of the product characteristic is equal to six times the standard deviation? Or is it to have very few defects, say in the neighborhood of 50 to 100 per million? From the technical viewpoint, it might make sense to talk in terms of the process variance. From the managerial or customer viewpoint, the quality standards can be

described in terms of defects per million. In addition, in many situations, adjusting the process to move the process average closer to the target value is relatively easier than improving the process to reduce the variance. Thus, if the goal is to reduce the number of defects, it does not make much sense to improve the process to Six-Sigma levels and not center the process. Planning or allowing for the process average to drift 1.5 standard deviations from the target value just in case is similar to building up inventories when implementing just-in-time inventory management."

We do not believe that a debate on Six Sigma or allowable off-center drift is time well-spent. The important thing is the output quality level, expressed in parts per million or parts per billion. Figure 5 is a chart prepared by Fred McFadden, Professor at the University of Colorado. It was published in an article entitled "Six-Sigma Quality Programs" in the June 1993 issue of *Quality Progress*. It provides an excellent example of defect rate decrease as the sigma specification level ratio increases.

DEFECT RATE VS. SIGMA LEVEL (CENTERED PROCESS)			
Sigma level	**Defect rate (ppm)**	**Duration of power outages per month**	**No. of misspelled words**
1	317,400	228.5 hours	159 per page
2	45,600	32.8 hours	23 per page
3	2,700	1.94 hours	1.35 per page
4	63	2.72 minutes	1 per 31 pages
5	0.57	1.48 seconds	1 per several books
6	0.002	0.005 seconds	1 per small library
7	0.000003	0.00001 seconds	1 per large library

Figure 5. Defect Rate Vs. Sigma Level for Power Outages and Misspelled Words

Although .002 errors per million fuses, bolts, screws, nuts, garden hoses, or brooms may not be an aggressive target, when you start to apply the same requirements to management decisions, drawings, books, letters, sales contracts, meals served, auto repairs, medical operations, sales calls, or lines of codes, it turns out to be a very aggressive target. This is particularly true in any type of service activity where quality cannot be inspected or tested in.

The Six-Sigma program is not just a new performance standard because the new performance standard cannot be met if the organization does the same old thing the same old way. It is for this reason that Motorola calls its program "Six-Sigma Quality Program." It drove a major improvement effort that radiated through the organization. Motorola's Six-Sigma Quality Program is pictorially presented in Figure 6.

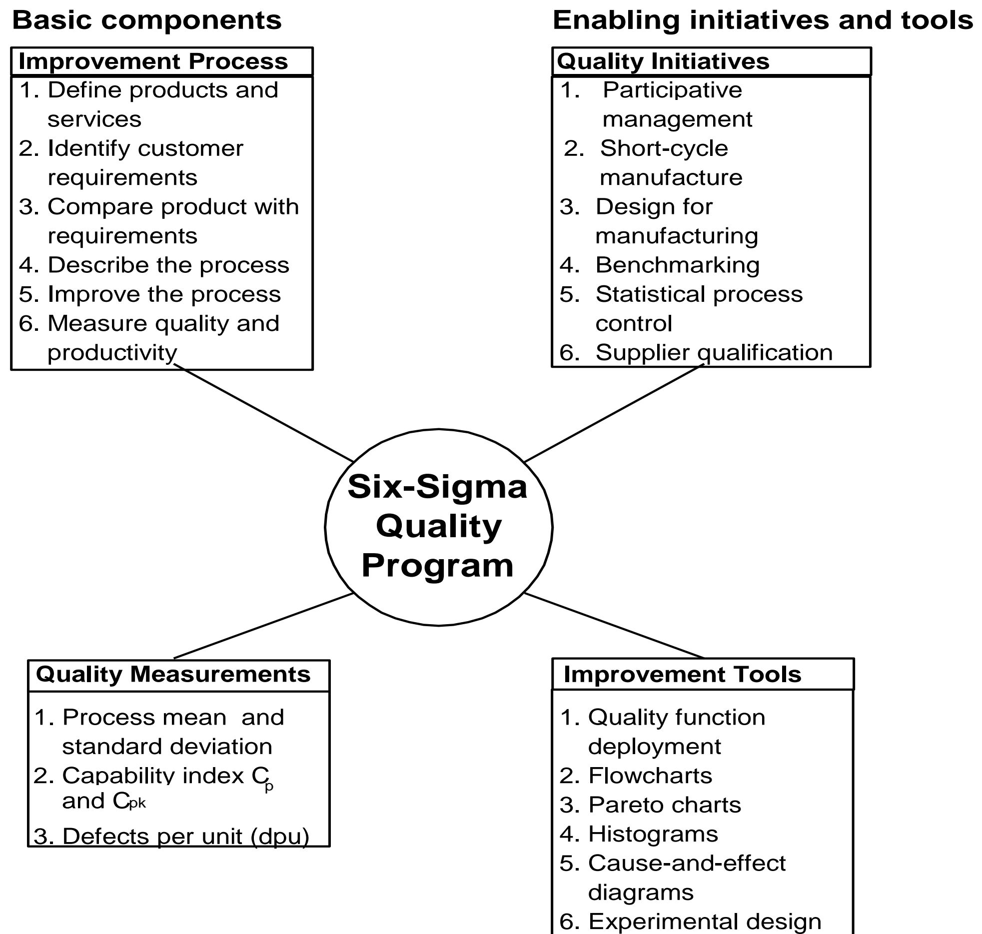

Figure 6. Six Sigma

You will note that the Six-Sigma Quality Program is divided into four major quadrants:

- Improvement process
- Quality initiatives
- Quality measurements
- Improvement tools

To help with the implementation of the Six-Sigma Quality Program, Motorola formed the Six-Sigma Research Center to develop a set of reference books known as the *Encyclopedia of Six-Sigma*. This encyclopedia consists of three main parts:

- A collection of statistical tools
- Application case studies
- Descriptive, specific optimization methods.

Motorola established an innovative recognition system, called the "Black Belt program," to support the Six-Sigma Quality Program. Individuals progress through various levels that were designated as:

- *Green Belts*— Individuals that have completed the training.
- *Black Belts*—Individuals highly competent to serve as the on-site consultants for applications of Six-Sigma methodologies.
- *Master Black Belts*—Individuals who have mastered the Six-Sigma process and are capable of teaching the process to others.

It is very important to understand that Six Sigma is not just solving problems. It must result in a complete culture change and the most important Total Six Sigma tool is organizational change management. Organizations that just focus upon problem-solving usually get poor results from their Six Sigma projects.

To meet the very challenging quality requirements associated with Six Sigma, an organization has only three options:

- Reduce the process variability
- Center the mean of the population
- Open the acceptable performance limit

The first approach should always be to focus on centering the process mean and reducing the process breadth. Motorola's research institute recommends the following six steps:

- Step 1. Identify the product characteristics that are critical to satisfying both the physical and functional requirements of the customer and the requirements of relevant regulatory agencies. This might mean that patients who come into your facility for a series of tests will have all of them performed on a single day rather than over an extended period.
- Step 2. Determine the specific product elements that contribute to achieving these critical characteristics. What does your organization do to streamline the process for the patient or coordinate appointments?
- Step 3. According to product elements, determine the process step or process choice that controls each critical characteristic. Is your organization designed to serve the staff, the equipment, the patient or none of the above?
- Step 4. Determine a nominal design value and the maximum (real) allowable tolerance for each critical characteristic, which still guarantees successful required performance. How would you have to change the scheduling process to achieve the Six Sigma goals?
- Step 5. Determine the capability for parts and process elements that control critical characteristics. In the example of scheduling appointments in the same visit, is the limitation in IT systems, in physical layout of the plant or is it rooted in outmoded processes?
- Step 6. If C_p is not = 2 (C_{pk} = 1.5), then change the design of the process to achieve C_p = 2 (or institute process control measures which will narrow process capability sufficiently to achieve C_p = 2).

General Electric has embraced the Six Sigma concept in order to drive its future quality improvement activities. GE's Six-Sigma Program is the largest quality initiative ever mounted in the U.S. They call their design for Six Sigma *DMADV,* which stands for:

- Define—Define the process, product or service that will be improved. Define customer's view of error-free performance.
- Measure—Evaluate the current item's performance.
- Analyze—Define best practices, benchmarks and enablers.
- Design—Develop a best-value future-state solution.
- Verify—Measure the new item to ensure it meets the requirements documented in the define stage and the Six Sigma requirements.

The Six Sigma approach to quality improvement is being adopted throughout all the divisions of General Electric. Jack Welch, past chairman and CEO of GE, embraced the Six-Sigma Program. Welch believed that the Six-Sigma Program would add $5 billion to GE's net earnings through the year 2000.

As different organizations use the Six Sigma concept, its structure grew to include many other tools. Today we are using what is called "Total Six Sigma" because it has developed far beyond the concept as defined by Motorola. Total Six Sigma includes concepts like:

- Reengineering
- Project Management
- Organizational Change Management
- Risk Analysis
- Knowledge Management
- Benchmarking
- Taguchi Robustness
- Just-In-Time
- Lean
- Total Production Maintenance

As an example, the following are a few of the tools and techniques used by GE in support of Six Sigma:

1. Quality Function Deployment	2. Cost/Benefit Analysis	3. Pareto Charts
4. Organizational Change Management	5. Business Process Improvement	6. Process Capability
7. Value-Added Analysis	8. Shareholder Analysis	9. Scatter Diagrams
10. Charting (Pie, Bar, etc.)	11. Prioritization Matrix	12. Histogram
13. Root Cause Analysis	14. Problem Cycle	15. The 5 W's
16. Critical Source Factors	17. Surveys	18. Benchmarking

19. Classification of Solution Criteria	20. Focus Groups	21. Gap Analysis
22. Activity-Based Costing	23. Process Frame (boxing)	24. SPC
25. Regression Analysis	26. Visioning	27. Affinity Diagrams
28. Design of Experiments	29. Gantt Chart	30. Process Analysis
31. Cause-and-Effect Analysis	32. Project Management	33. Stratification
34. Force-Field Analysis	35. Common/Special Causes	36. Work-Out
37. Cycle Time/Work Flow analysis	38. Moments of Truth	39. Value Analysis
40. Quantifying Opportunities	41. Resistance Analysis	42. Brainstorming
43. "Should Be" Process Maps	44. Behavior Conditioning	45. Mind Mapping
46. Work Breakdown Structure	47. Risk Assessment	48. Charters
49. Continuous Improvement	50. Standardization	51. Measurement Plan

It is very important to point out that one of the most used tools in Total Six Sigma is Business Process Improvement (BPI). The 3 major methodologies that are included in BPI are:

- Process Redesign
- Process Reengineering
- Process Benchmarking

All three of these require that a very effective change management project be used in conjunction or the possibility of failure runs very high.

Hammer and Champy in their book, "Reengineering the Corporation," reported, "Some 50 to 70% of reengineering attempts fail to deliver the intended dramatic results."

Training is a key part of preparing the organization for Six Sigma. The following is the minimum Six Sigma training required by job assignment based upon ASQ recommendations:

- Executive – one day overview
- Upper Management Champions – 5 days
- Six Sigma Green Belt – 10 days on Six Sigma concepts

- Six Sigma Black Belt – 20 days over a 4-month period. They will go to class for one week each month and then spend the next three weeks applying what they have learned.

Examples:

GE - Jack Welch launched the Six-Sigma Program at GE with 200 projects in 1995. In 1996 it was increased to 3,000 projects. It expanded to 6,000 projects in 1997. The target for the Six-Sigma Program was to save $150 million in productivity gains and profits. The actual 1997 savings was $320 million, more than double the goal. In 1998, net savings were estimated to be about $750 million.

Some of the people within GE were concerned because they believed Six Sigma would cause bureaucracy to increase. Welch's reply to this concern was, "I don't give a damn if we get a little bureaucracy as long as we get the results."

William Woodburn, head of GE's industrial diamonds business, reports that in four years the operation's returns on investment increased fourfold and at the same time, the cost structure was cut in half. He gives the Six-Sigma Program credit for much of the improvement. To get the improvements, he had to cut over a third of the workforce, which included more than 50% of the salaried staff. (Source: Business Week, June 9, 1998 page 47).

Allied Signal - Lawrence A. Bossidy, former GE Vice-Chairman, started the Six-Sigma Program at Allied Signal Inc. when he was CEO in 1991. The increased productivity and profit got Jack Welch's attention. At this time GE was running at a three to four sigma level. The gap between four sigma and Six Sigma at GE was costing GE between $8 and $12 billion a year.

Will Six Sigma Work in Healthcare?

To make Six Sigma more personal, consider the case of a physician who performs over 1,000 surgical procedures (1,000 opportunities for error per case) with no more than 1 mistake. Certainly, this is very challenging based upon normal performance levels. It requires a radical

new design to the way the operating room functions. There are a number of points that need to be considered when you are using the Six Sigma process; they are:

- Six Sigma works well where there are high production rates of the same or very similar parts. In other words, many organizations have tackled CABG since it fits the above requirement well.
- Six Sigma is very difficult to obtain in areas like administration, sales, personnel, etc. where results, while not difficult to measure, are unique from one incident to another.
- It is extremely difficult for management to perform at the Six Sigma level due to the high degree of variation in the "process" of managing.
- It works well when variables data can be collected, not so well when attributes data are used.
- It is based upon the use of normal distribution, not abnormal or skewed distributions.

Total Six Sigma tools are grouped into three categories: design, process, and material. These are easily adaptable to healthcare if you consider them from a slightly different perspective. These tools are:

- **Design Tools (or "Design of Care")**
  - Design to standard parts/materials
  - Design to standard processes
  - Design to known capabilities
  - Design for assembly
  - Design for simplicity
  - Design for robustness
- **Process Tools (or "See Process in Healthcare")**
  - Short cycle manufacturing
  - Process characterization
  - Process standardization
  - Process optimization
  - Statistical process control
- **Material Tools (or "Central/Sterile Supply Optimization")**
  - Parts standardization

- Supplier SPC
- Supplier certification
- Material requirements planning

Why do you need Six Sigma?

Assume that a typical surgical procedure contains 1,200 processing steps (not unusual since the typical healthcare organization has approximately 20,000 individual processes). If each step has a short-term 4 sigma capability, the throughout yield would be:

$Y_{RT} = 0.999968^{(1200)} = 96.24\%$

If you consider over a period of time, the process drifts away from the nominal as much as 1.5 sigma, the yield at each step would be degraded to .9938 and the throughput yield would be:

$Y_{RT} = 0.9938^{(1200)} = 0.05\%$

In other words, you have near zero possibility of completing a surgical procedure without committing an error. This is assuming that all the steps are in series with each other. Figure 7 provides you with a breakdown of this concept based upon the number of steps in the process, and various sigma limits, assuming a 1.5 sigma shift.

Process Sigma Level (Assume 1.5 Shift)				
No. Process Steps	**3**	**4**	**5**	**6**
1	93.32%	99.379%	99.9767%	99.99966%
2	87.09	98.76	99.95	99.99932
5	70.77	96.93	99.88	99.9983
10	50.09	93.96	99.77	99.9966
50	3.15	73.24	98.84	99.98
100	0.10	53.64	97.70	99.966
500	0	4.44	89.02	99.83
1000	0	0.2	79.24	99.66
2000	0	0	62.75	99.32

Figure 7. Throughput Yield Vs. Number of Process Steps and Process Quality

Note however, that by applying Six Sigma principles, it is relatively easy to reduce current error rates and a 50% reduction in errors in a 3 sigma healthcare organization can not only lead to greater customer satisfaction, but large reductions in claims related to mistakes.

"I'm surprised we didn't come up with this a few decades ago. For a hospital like ours, questioning and second-guessing is common."

Dr. George Kerlakean

Good Samaritan Hospital

Six Sigma Applied to Healthcare

The Six Sigma approach is in its infancy in the healthcare industry. It has been applied to some extent to refine some hospitals' business processes using reengineering or process redesign methodologies. Monica Berry, President of American Society for Healthcare Risk Management,

stated, "If we look at quality as it has been implemented in the past, we won't be successful in reducing patient errors."

Most healthcare providers have put in place some type of Total Quality Management (TQM) or Continuous Quality Improvement (CQI) program. A Six Sigma project does not endanger this program. In fact, it will enhance them as it builds on their strengths and puts additional focus on the measurement system.

The TQM programs focuses on defining the voice of both internal and external customers, Process Control, Process Redesign, Problem Solving (PDCA), teams and the need for objective data, total organizational involvement and reporting in order to improve the processes.

The Continuous Quality Improvement model was defined in 1987 in the American Society for Quality book, *The Improvement Process*. It defines the continuous improvement process in the following 10 building blocks.

1. Obtain top management's commitment.
2. Establish an improvement steering council.
3. Obtain total management participation.
4. Secure team participation.
5. Obtain individual involvement.
6. Establish system improvement teams (process control teams).
7. Develop supplier involvement activities.
8. Establish a systems assurance audit activity.
9. Develop and implement short-range and long-range improvement plans and implement short-range strategy that will eliminate and prevent errors.
10. Establish recognition and reward system that reinforces desired behaviors.

The following is a ten-step process to achieve Six Sigma in a clinically intensive process.

1. Identify Your Products—What is the service or product that you are producing? In the case of an operating suite it might be technically superior procedures.

2. Identify Customer Requirements—The patient's perception of error-free performance is based upon all the little things that go on around them. Is the right food brought to them on time? Does the nurse show up as quickly as the patient wants them to when they ring for them. (Remember the patient sets the performance standard.) When more than one doctor is involved, do they all provide the same advice. The patient uses these simple measurements to define the quality of service. If the hospital can not do these simple things right, how can the patient have confidence that they can exercise a complex activity like performing an operation correctly. Thanks to the Internet, patients are much more savvy about their healthcare today than past generations. These “wired customers” understand quality in healthcare and demand it more often.
3. Diagnose the Frequency and Source of Errors—What is the source of errors? In an Emergency Department errors could come from any number of places including supply carts or ineffective ambulance routing leading to overcrowded waiting rooms.
4. Design the Process—How can the process enablers be put together to provide a best-value solution? In said emergency room, perhaps there are mechanisms that can avoid the overcrowding.
5. Develop a Simulation Model—This is used to project the process’ performance characteristics and determine if the process will meet the customer’s error-free needs. Try a new scheduling system.
6. Error-proof the Process—How can the process be changed to eliminate potential errors? While there are many processes in the practice of medicine that are difficult to “error proof,” there are thousands more that would be considered “simple” if the right approach were used. For example, wristbands indicating allergies could be routinely audited by pharmacy staff who “checked” patients who have known allergies once a day. While to some this may seem excessive, the savings from the cost of poor quality would more than pay for the added minutes needed per day. Error-proofing applies to any process. First you need to understand the process. Then you need to ask the question, "If I wanted the outcome to be bad, what would I do?" This leads to making a list of how the process could fail and defining what needs to be done to eliminate

the possibility of an error occurring. If you can't prevent it, document what you need to do to recover if the error occurs.

7. Install Internal and External Control Points and Measurements—How can you detect trends before they become errors? In the case of the billing department, one might institute reporting of missing information or unsigned discharge orders before they reach final billing. In the case of the emergency room, correctly stocked supply carts might eliminate trips to and from Central Supply.
8. Install New Process—How do you get the users to embrace the new process? (A pilot installation often is required. In any case an early change management intervention is advised as is input by those effected)
    - Certify each step or activity in the process
    - Qualify the total process as a single item
9. Measure Performance – Does the process meet the Six Sigma requirements? If not, how does the process need to be adjusted to do so?
10. Continuously Improve – How can the process' effectiveness, efficiency, and adaptability be improved?

The system approach required cross-functional teams to be formed to work on process problems. For example, to reduce medication errors in a hospital required a team made up of delivering nurses, ordering physicians, dispensing pharmacists and medication suppliers, all working together. At Stanford Hospital they formed eleven cross-departmental teams. For example, the Cardiac Surgery team was made up of:

- Physician Champion / Co-Leader
- Department Manager / Co-Leader
- Clinical Specialists
- Pharmacists
- Social Workers
- Case Managers
- Respiratory Therapists
- Managers from all the Process Departments
- Clinical Financial Analysts

- Consultant

Natural Work Teams (NWT) also play key roles in a Total Six Sigma project. Some typical Natural Work Teams and project teams in a healthcare provider organization are:

- Finance and budget team
- Nutrition team
- PHC Nursing team
- Infection Control team
- Pediatrics team
- Administrative Affairs team
- PHC Coordination and follow-up team
- Quality Assurance team
- Legal affairs team
- Human resources team
- Planning and strategy team
- Engineering team
- External Customer Suggestion team
- External Customer Complaints team
- Records and Document Control team
- Risk Analysis team

The measurement system for the CQI approach was called "Poor-Quality Cost." Poor-quality cost is divided into two major categories – direct poor-quality cost and indirect poor-quality cost. Direct poor-quality cost is the cost reflected in the healthcare provider's accounting books. Indirect poor-quality cost is the cost that the other stakeholders incur over and above what they are billed and the impact stakeholder dissatisfaction has on the income of the healthcare provider.

- Direct Poor-Quality Cost
    - Prevention cost
    - Appraisal cost
    - Internal error cost
    - External error cost

  - Test Equipment cost
- Indirect Poor-Quality Cost
  - Customer – incurred cost (resulting from errors)
  - Customer – dissatisfaction cost
  - Loss-of-reputation cost
  - Last opportunity cost

You will note that in the 1980's, the CQI approach was directed at reducing cost caused by errors. This changed in the 1990's as cycle time became as important in many cases, sometimes more important than cost.

The problem-analysis cycle was called "The Opportunity Cycle" and consisted of 5 phases:

- Phase 1- Problem Selection
- Phase 2- Root cause Analysis
- Phase 3- Correction
- Phase 4- Measurement
- Phase 5- Prevention

Many organizations just stayed with the old, proven Shewhart approach as it was simpler. It was

- Plan
- Do
- Check
- Act

Another quality model sometimes used in healthcare was developed by a well-known physician, Dr. Donabedian. The Donabedian model developed in the 1980's focused on three domains:

- Structure
- Process
- Outcome

You will note that all three approaches have a focus on processes like:

- Pharmaceutical Care
- Diagnostic Testing
- Accurate Drug Administration
- Registration
- Billing
- Appointment Scheduling

It is easy to see that the Six Sigma approach should blend easily with your present quality system and improve upon it. It is a normal addition to your current system to help update it with the best and latest proven technology.

Six Sigma At Work in Healthcare

Some healthcare units are running pilot Six Sigma projects and the results are very encouraging. Typical improvements are:

- Reduced length of stay
- Improved customer satisfaction
- Reduce time to enter the healthcare unit
- Reduce inventory
- Increased efficiency in the billing system

“We do this project so that our staff learns and achieves results by proactively participating in the six sigma process. The result (decline) in registered nurse overtime alone was 65% over one year.”

Douglas Sears

Bon Secours Health Systems

Typical Six Sigma activities are:

- Charleston Area Medical Center applied Six Sigma to their supply chain management for surgical supplies saving $1,000,000.

- Virtual Health focused on their congestive heart failure patients and reduced variation leading to shorter length of time to recover.
- Scottsdale Healthcare applied Six Sigma approaches to the emergency room process and reduced the time required to transfer a patient to in-patient hospital bed, increasing profits by $1,600,000 per year.
- One of the Stanford Hospital and Clinics' Six Sigma teams directed the Coronary Artery Bypass Graft (CABG) Surgery process. The results were outstanding:
  - Annual savings $15 million (U.S.)
  - Mortality rate dropped from 7.1% to 3.7& for all CABG procedures
  - Cost was reduced 40%
  - Intensive care time was reduced by 8 hours
  - Intubation time was reduced from 12 to 16 hours to 4 to 6 hours
- Theresa Garrison reports that at St. Louis Hospital, they were able to reduce infections by 65%.
- Hospital with good team spirit and nurses with authority to act on their own in case of sudden problems had 59% lower than average death rates.
- Stanford Hospital and Clinic saved $25 million per year from standardized purchasing and other process improvements.

"The results were a reduced average ventilators length of stay of 25% and reduction of defects per million opportunities by 12% for annualized savings of $450,000."

Sarah Davis

Director of Nursing

Sentara

The following is a list of some of the healthcare organizations that are using Six Sigma:

- Northshore Jewish Health System
- Memorial Hospital and Health of Marlton N.J.
- McLeod Regional Medical center

- Froedtest Memorial
- New York Presbyterlas
- Vytra Health Plans
- Several Blue Cross and Blue Shield Plans
- MD Anderson Cancer Center
- Thebodaux Regional Hospital
- University of New Hampshire
- Commonwealth Health Corporation
- Charleston Area Medical Center
- Mount Carmel Health System
- Bon Secours National Health System
- Stanford Research Center

(Note: This is not meant to be complete list as other healthcare organizations may already be doing Six Sigma).

Six Sigma will help in many ways. It is not just a problem-solving tool; it is also an information gathering and analysis tool. There is a huge information gap between what should and could be available and what is available.. The present data systems in most hospitals are poor at best.

Gregg from Blue Cross Blue Shield of Tennessee, when he was discussing the quality and quality of outcome information that was available to the customers stated, “If you think about it as the equivalent of a manufacturer not having the system and information flow to understand and measure quality, that’s pretty scary.” The Six Sigma approach to data collection analysis can help with this problem along with electronic record keeping.

Six Sigma also attacks the basic problem that all hospitals have, which is the variation in the way things are done. For example, a simple urinary tract infection without any complications can be treated in 135 different ways. Which process provides the best overall value? No one knows or everyone would be using it.

Different Views of Healthcare Quality

One of the problems that slow down quality in healthcare is the many different views of what quality is. For example,

- The paying organization views quality as a measure of the value associated with the delivered care.
- The Physician/Nurse views quality as making the right diagnosis, prescribing the right medicine and employing the right procedure to make the patient better. It's doing the right job from a scientific point of view.
- The patients view quality as the perceived services, such as: Are the employees gracious? Do they appear to be competent? Are they receiving timely care? Is the hospital a good environment?
- The Healthcare Managers view quality as the appropriateness of care. Quality in healthcare is the evaluation of the appropriateness of treatment.

When we develop the healthcare system, all four views of quality must be designed into the system.

Conclusions:

Many other non-healthcare organizations have embraced the Six Sigma concepts. Among them are IBM, Texas Instruments, Defense System Electronics Group (DSEG) and General Electric. While the implementation of Six Sigma in a healthcare-provider setting is in its early stages, some of the top healthcare organizations in the world are interested in the possibilities. Most quality-focused organizations performed at the four-sigma level at the beginning of the 1990s. As of this date, we know of no organization that is performing all of its measurements to the Six Sigma requirements. Our experience indicates that Six Sigma and the related methodologies are not implemented without difficulties. G. Don Taylor and John R. English, in their paper entitled "A Benchmarking Framework for Quality Improvement," published by Marcel Dekker, Inc. 1993, point out the five following problems related to the Six Sigma methodology:

- The problem of determining how to measure defects,
- The problem of applying Six Sigma in non-traditional settings,

- The problem of determining whether to relax specifications or to reduce the normal variability of the product,
- The use of restrictive assumptions; and
- The determination of appropriate tools to use to achieve Six Sigma goals.

Motorola, on the other hand, reports the following results (in a manufacturing environment):

- Improved yields - lower than expected fallout during manufacturing (This could equate to less use of supplies or less errors.)
- Better productivity
- Higher performance
- Improved MTTF (Mean Time to Failure)
- Lower manufacturing cost (or lower costs per procedure, patient etc.)
- Improved customer satisfaction

Potential in Healthcare

Billing Department - Imagine a billing department that reduced errors in processing patient bills to a five-sigma process level. While the department might be producing claims at a very efficient and effective rate, it is common knowledge in the industry that many claims are rejected due to errors by personnel at the payer organization. As of autumn 2003, Cigna, Anthem and many of the Blues are implementing Six Sigma in their organizations. Should a provider and payer agree to implement Six Sigma in tandem, tremendous savings could be achieved solely on the potential to reduce or eliminate claims adjudication in favor of a "trusted" claims chain.

Emergency Department – Imagine an emergency department with a phone-in triage function aimed at "pre-processing" patients for the appropriateness of care. Diverting potential ER department patients to more appropriate venues of care or sister facilities for load balancing – a not unheard of application when most patients could use their cell phones to call on-route.

Floor Procedures – Imagine a system where patients gain control of their stay via meal delivery as a "menu with room service." This psychological "control" leads to faster recovery times, increased patient satisfaction and potential reduced costs by the food services department through

better balancing food preparation throughout the day instead of centered on breakfast, lunch and dinner.

What would work in one facility wouldn't necessarily work in another and this is the beauty of the Six Sigma approach. Instead of following the cookie-cutter approach of the healthcare provider down the street, the hospital is able to evaluate its own opportunities and work to improve its unique opportunities. Just as facilities specialize, so too are they empowered by the Total Six Sigma process to individually identify and improve processes tailored to their individual patient population, payer mix and staffing situation. Six Sigma truly offers an opportunity for a breakthrough in healthcare.

In the past we have believed that the healthcare system was too complex with too many players – companies, insurers, medical device makers, pharmaceutical companies, doctors, nurses, hospitals, special interest group and others – to bring about major cultural changes. These players all have different interests and objectives, making it difficult, if not impossible, to correct most of the problems facing the healthcare providers. But if we, the business community, do not step-up to the challenge, the government will have to and we believe we can find a better answer. Total Six Sigma is not the total answer to the problems we are facing in our healthcare system, but it can be a key part of the solution. It is time to start making some major changes in the way we provide healthcare services.

Additional Reading

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