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An Overview of Six Sigma

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Summary

We provide an introductory overview of the Six Sigma development and improvement processes. A historical perspective is provided. We also discuss the statistical methods frequently used within this framework and briefly comment on the impact of Six Sigma on the practice of statistics in industry.

Key words: Designed experimentation; measurement systems analysis; process capability; quality control; variability reduction.

1 Introduction

Improving quality has become an important business strategy for many organizations including manufacturers, distributors, transportation companies, financial services organizations, health care providers, and governmental agencies. Quality is a competitive tool that can result in considerable advantage to organizations that effectively employ its basic principles. A business that can delight customers by improving and controlling quality has the potential to dominate its competitors. Developing an effective quality strategy is a factor in long-term business success.

Six Sigma is a disciplined, project-oriented, statistically based approach for reducing variability, removing defects, and eliminating waste from products, processes, and transactions. The Six Sigma initiative is a major force in today's business world for quality and business improvement. Statistical methods and statisticians have a fundamentally critical role to play in this process.

We discuss the evolution of Six Sigma and describe its major components, including how it is usually implemented in business organizations, and the role of statistics and statisticians in the process. We also discuss the implications of Six Sigma for education and training of statisticians and the potential impact on the statistics profession. Some of these topics have also been discussed by Hahn *et al*. (1999), Snee (1999), and Hahn & Doganaksoy (2008). More detailed reviews and extensive Six Sigma bibliographies were provided by Brady & Allen (2006) and Nonthaleerak & Hendry (2006). A considerable amount of freely available information about Six Sigma can be found at www.isixsigma.com.

2 Historical Development of Six Sigma

2.1 The Quality Revolution and TQM

Folaron (2003) provided a comprehensive view of Six Sigma within the historical context of the development of industry and the associated impact on the quality of processes and products.

In particular, since 1980, there has been a profound growth in the use of statistical methods for quality and overall business improvement in the United States and throughout the world. This has been motivated, in part, by the widespread loss of business and markets suffered by many US companies that began during the 1970s. For example, the US automobile industry was nearly destroyed by international competition during this period. One US automobile company estimated its operating losses at nearly $1 million *per hour* in 1980. The adoption and use of statistical methods have played a central role in the renewed competitiveness of US industry with respect to quality.

Various management systems have also emerged as frameworks in which to implement quality improvement. One of these is total quality management (TQM), which is a strategy for implementing and managing quality improvement activities on an organization-wide basis. TQM began in the early 1980s, influenced by the philosophies of W. Edwards Deming, Joseph Juran, and others. It evolved into a broader spectrum of concepts and ideas, involving participative organizations and work culture, customer focus, supplier quality improvement, and many other activities to focus all elements of the organization around the quality improvement goal. Typically, organizations that have implemented TQM employ quality councils or high-level teams that deal with strategic quality initiatives, workforce-level teams that focus on routine production or business activities, and cross-functional teams that address specific quality improvement issues.

TQM achieved only moderate success for a variety of reasons. Frequently there was no real effective integration of the quality system with business goals, and too often insufficient effort was devoted to widespread utilization of the technical tools of variability reduction. Many organizations saw the mission of TQM as one of training. Some general reasons that are cited for the lack of conspicuous success of TQM include (i) lack of top-down, high-level management commitment and involvement; (ii) inadequate use of statistical methods and insufficient recognition of variability reduction as a prime objective; (iii) general, as opposed to specific, business-results-oriented objectives; and (iv) too much emphasis on widespread training as opposed to focused technical education. Another reason for the erratic success of TQM is that many managers and executives regarded it as just another “programme” to improve quality. During the 1950s and 1960s, programmes such as Zero Defects and Value Engineering were widely deployed, but they had little real impact on quality and productivity improvement.

Generally, Six Sigma has been far more successful than TQM was. There are several reasons for this, principal among them being the strong focus on projects that positively impact business financial performance. When quality improvement projects result in real savings, expanded sales opportunities, or documented improvements in customer satisfaction, upper management pays attention. Then business leaders are more likely to be fully involved, to commit the resources needed to train personnel, and to make Six Sigma positions full-time, using these positions as stepping stones to higher positions of responsibility in the organization. The level of technical training in Six Sigma is generally deeper and more extensive than in the typical TQM programmes of the 1980s. And, because the training is project-oriented, it is much more likely that the techniques will actually be used.

2.2 Origin of Six Sigma

Bill Smith, a Motorola engineer, developed the Six Sigma programme in 1986 as a response to the necessity for improving quality and reducing defects in their products. The CEO, Bob Galvin, was impressed by the early successes, and under his leadership, Motorola began to apply Six Sigma across the organization, focusing on manufacturing processes and systems. Godfrey (2002) interviewed Bob Galvin on these early days of Six Sigma.

Motorola established Six Sigma as both an objective for the corporation and as a focal point for process and product quality improvement efforts. The Six Sigma concept was tremendously successful at Motorola. It has been estimated that they reduced defects on semiconductor devices by 94% between 1987 and 1993. In recent years, Six Sigma has spread beyond Motorola and has become a programme for improving corporate business performance by both improving quality, reducing costs and expanding markets for products and services. Six Sigma, in some form, has been adopted by thousands of companies both large and small.

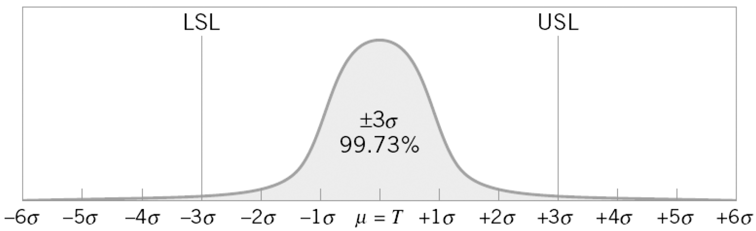
2.3 The Six Sigma Metric

The focus of Six Sigma is reducing variability in key product quality characteristics around specified target values to the level at which failure or defects are extremely unlikely. Figure 1a shows a normal probability distribution as a model for a quality characteristic with the specification limits at three standard deviations on either side of the target mean. The Motorola Six Sigma concept is to reduce the variability in the process, so that the specification limits are at least six standard deviations from the target. This is a Six Sigma quality level, and it results in about two parts per billion non-conforming to specifications. Under the Six Sigma concept, an assumption was made that when the process reached the Six Sigma quality level, the process mean was still subject to disturbances that could cause it to shift by as much as 1.5 standard deviations off target. This situation is shown in Figure 1b. Under this scenario, a Six Sigma process would produce up to 3.4 parts per million (ppm) non-conforming to specifications.

The drifting mean aspect of the Six Sigma metric has been a source of controversy. Some have argued that there is an inconsistency in that we can only make predictions about process performance when the process is stable, i.e. the mean and standard deviation are constant over time. If the mean is drifting, a prediction of up to 3.4 ppm non-conforming to specifications may not be very reliable, because the mean might shift by more than the "allowed" 1.5 standard deviations. Process performance is not predictable unless the process behaviour is stable. Advocates of Deming's philosophy have rejected Six Sigma in some cases on the grounds that the 3.4 ppm is a "numerical goal", the 1.5 sigma shift is arbitrary, and that Six Sigma is a "slogan", supposed violations of some of Deming's 14 points. (See Deming (1986).) However, no process or system is ever truly stable (this is the second law of thermodynamics at work), and even in the best of situations, disturbances and upsets occur. These disturbances can result in the process mean shifting off-target, an increase in the process standard deviation, or both. The Six Sigma process concept is one way to model this behaviour. Like all models, it is at best an approximation, but it can be a useful way to think about and quantify process performance. The 3.4-ppm metric, however, is increasingly recognized as primarily a distraction; it is the focus on reduction of variability about the target and the elimination of waste and defects that is the important feature of Six Sigma.

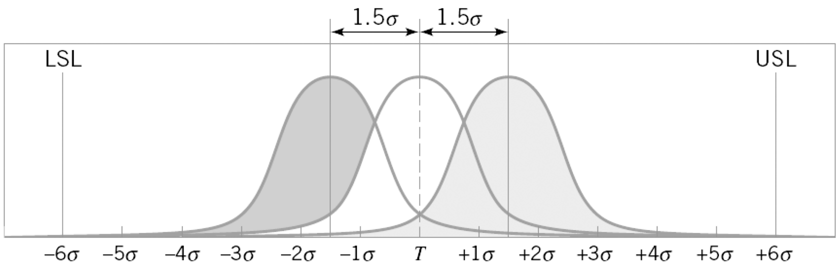
2.4 The Evolution of Six Sigma

Since its origins, there have been three generations of Six Sigma implementations. Generation I Six Sigma focused on defect elimination and basic variability reduction, primarily in manufacturing. Motorola is a classic exemplar of Generation I Six Sigma. In Generation II Six Sigma, the emphasis on variability reduction and defect elimination remained, but now there was a strong effort to tie these efforts to projects and activities that improved business performance through improved product design and cost reduction. General Electric is often cited as the leader of the Generation II phase of Six Sigma. In Generation III, Six Sigma has the additional focus of creating value throughout the organization and for its stakeholders (owners,



Spec. Limit	Percent Inside Specs	ppm Defective
±1 Sigma	68.27	317300
±2 Sigma	95.45	45500
±3 Sigma	99.73	2700
±4 Sigma	99.9937	63
±5 Sigma	99.999943	0.57
±6 Sigma	99.9999998	0.002

(*a*) Normal distribution centered at the target (*T*)



Spec. Limit	Percent inside specs	ppm Defective
±1 Sigma	30.23	697700
±2 Sigma	69.13	608700
±3 Sigma	93.32	66810
±4 Sigma	99.3790	6210
±5 Sigma	99.97670	233
±6 Sigma	99.999660	3.4

(*b*) Normal distribution with the mean shifted by $\pm 1.5\sigma$ from the target

Figure 1. *The Motorola Six Sigma Concept [From Montgomery (2008)].*

employees, customers, suppliers, and society at large). Creating value can take many forms, such as increasing stock prices and dividends, job retention or expansion, expanding markets for company products/services, developing new products/ services that reach new and broader markets, and increasing the levels of customer satisfaction (perhaps by reducing cycle time or increasing throughput) throughout the range of products and services offered. See Hahn *et al.* (2000) for a good discussion of the evolution of Six Sigma.

3 Six Sigma Deployment and Impact

3.1 The Belt System

Companies involved in a Six Sigma effort utilize specially trained individuals, called Green Belts (GBs), Black Belts (BBs), and Master Black Belts (MBBs). A project-oriented approach is used in Six Sigma deployment. BBs typically have a minimum of 4 weeks of specialized training, sometimes spread over a 4-month period and usually combined with concurrent work on a Six Sigma project. They lead teams that are focused on projects with both quality and business (economic) impact for the organization. In most organizations, BBs train GBs and work on other functions such as new project identification.

GBs typically have less training, often 1 or 2 weeks, and either assist on major project teams or lead teams engaged in smaller, more highly specific projects. MBBs are often engaged in training both BBs and other MBBs. They often write and develop training materials, are heavily involved in project definition and selection, and work closely with business leaders called Champions. The job of Champions is to ensure that the right projects are being identified and worked on, that teams are making good progress, and that the resources required for successful project completion are in place. Champions are project sponsors. MBBs also work closely with other members of the business leadership team. It is generally recognized that it is more effective to have BB and MBB positions be full-time.

The "belts", particularly BBs and MBBs, have specialized training and education on statistical methods and other quality and process improvement tools that equip them to function as team leaders, facilitators, and technical problem solvers. Hoerl (2001) described the components of one typical BB education programme. The American Society for Quality (ASQ) maintains a Six Sigma Black Belt body of knowledge on their web site (see http://www.asq.org/certification/six-sigma/bok.html). There is some variability in the content of Six Sigma training from one organization to another, reflecting differences in the businesses involved, and among the courses and training offered by consultants. Some universities have begun to offer Six Sigma training, both for credit as part of regular degree programmes and as non-credit or extension education. For example, see Montgomery *et al*. (2005). Various organizations, including ASQ and some companies, offer belt certification.

3.2 Six Sigma Projects

Six Sigma projects are typically 4–6 months in duration and are selected for their potential impact on the business. Six Sigma uses a specific five-step problem-solving approach: Define, Measure, Analyze, Improve, and Control (DMAIC). The DMAIC framework utilizes control charts, designed experiments, process capability analysis, measurement systems capability studies, and many other basic statistical tools. The DMAIC approach is an extremely effective framework for improving processes. We discuss project selection and the DMAIC process more fully in Section 4.

3.3 Deployment of Six Sigma

Snee & Hoerl (2003, 2005) provided excellent discussion of various detailed deployment strategies for Six Sigma. Most companies report a top-down strategy, driven by executive-level management, while some have used a bottom-up approach. The top-down strategy is much more effective in the long run, and it usually leads to greater immediate success. Some organizations have used a partial deployment strategy, starting in one or more specific divisions or operating units, and spreading the deployment to other units as successes are realized. Partial deployments and a bottom-up approach run the risk of being under-supported by top management. Regardless of the deployment strategy employed, there are three keys to success (see Snee & Hoerl, 2003, 2005):

(i) Top management commitment and involvement;
(ii) Use of top talent; and
(iii) Supporting infrastructure.

Top management commitment and involvement goes beyond just giving speeches at kick-off events. Executives must devote considerable personal energy to ensure success. Six Sigma must be on the personal score card of every manager. Using the best talent is also critical to success. If the members of the organization realize that the best people are becoming BBs and Champions, they will take the Six Sigma programme more seriously and want to be involved, if only to associate with the most talented people in the organization and the future business leaders. Supporting infrastructure means financial systems integration with project activity so that the benefits of completed projects can be accurately assessed, a system of defining and selecting projects can be developed, and that consistency and excellence of training can be maintained.

It is important that Six Sigma becomes part of the culture of doing business. Consider the following statement from Jim Owens, chairman of heavy equipment manufacturer Caterpillar, Inc., who wrote in the 2005 annual company report:

> "... I believe that our people and world-class Six Sigma deployment distinguish Caterpillar from the crowd. What an incredible success story Six Sigma has been for Caterpillar! It is the way we do business—how we manage quality, eliminate waste, reduce costs, create new products and services, develop future leaders, and help the company grow profitably. We continue to find new ways to apply the methodology to tackle business challenges. Our leadership team is committed to encoding Six Sigma into Caterpillar's "DNA" and extending its deployment to our dealers and suppliers—more than 500 of whom have already embraced the Six Sigma way of doing business".

At the annual meeting of Bank of America in 2004, chief executive officer Kenneth D. Lewis told the attendees that the company had record earnings in 2003, had significantly improved the customer experience, and had raised its community development funding target to $750 billion over 10 years. "Simply put, Bank of America has been making it happen," Lewis said. "And we've been doing it by following a disciplined, customer-focused and organic growth strategy". Citing the companywide use of Six Sigma for process improvement, he noted that in fewer than 3 years, Bank of America had "saved millions of dollars in expenses, cut cycle times in numerous areas of the company by half or more, and reduced the number of processing errors". These are strong endorsements of Six Sigma from two highly recognized business leaders that lead two very different types of organizations, manufacturing and financial services. (Jones (2004) discussed the Bank of America Six Sigma programme in more detail.)

Caterpillar and Bank of America are good examples of Generation III Six Sigma companies, because their implementations are focused on value creation for all stakeholders in the broad sense. Note Lewis's emphasis on reducing cycle times and reducing processing errors (items that will greatly improve customer satisfaction), and Owens's remarks on extending Six Sigma to suppliers and dealers – the entire supply chain. Six Sigma has spread well beyond its manufacturing origins into areas including health care, many types of service business, and governmental/public service (e.g. the US Navy has a strong and very successful Six Sigma programme).

4 The DMAIC Approach, Project Selection, and Statistical Methods

DMAIC, an acronym for Define, Measure, Analyze, Improve, and Control, is a structured problem-solving procedure widely used in quality and process improvement. Almost all

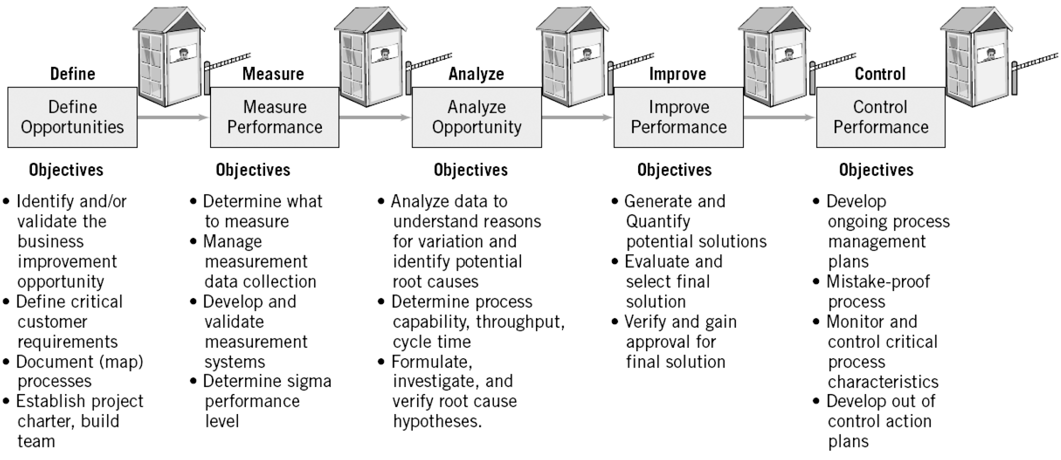


Figure 2. *The DMAIC Process [From Montgomery (2008)].*

implementations of Six Sigma employ DMAIC for project management and completion of process improvement projects. However, DMAIC is not necessarily formally tied to Six Sigma, and can be used regardless of an organization's use of Six Sigma. It is a general and very useful approach to management of change and improvement. DMAIC is a generalization of Walter Shewhart's Plan-Do-Check-Act cycle, which provides a roadmap to help people understand how to integrate the various tools into an overall approach to quality improvement.

The DMAIC steps are illustrated graphically in Figure 2. Notice that there are "tollgates" between each of the major steps in DMAIC. At a tollgate, a project team presents its work to managers and "owners" of the process. In a Six Sigma organization, the tollgate participants also would include the project Champion, MBBs, and other BBs not working directly on the project. Tollgates are where the project is reviewed to ensure that it is on track. They provide a continuing opportunity to evaluate whether the team can successfully complete the project on schedule. Tollgates also present an opportunity to provide guidance regarding the use of specific technical tools and other information about the problem. Organization problems and other barriers to success, as well as strategies for dealing with them, are often identified during tollgate reviews. Tollgates are critical to the overall problem-solving process. It is important that these reviews be conducted very soon after the team completes each step.

The DMAIC structure encourages creative thinking about the problem and its solution within the definition of the original product, process, or service. When the process is operating so poorly that it is necessary to abandon the original process and start over, or if it is determined that a new product or service is required, then the improved step of DMAIC actually becomes a process design or re-design step. In a Six Sigma organization, that means that a design for Six Sigma (DFSS) effort is required.

One of the reasons that DMAIC is so successful is that it focuses on the effective use of statistical tools. Table 1 shows the most prominent tools, along with the DMAIC steps where they are most likely to be used. Other tools, or variations of the ones shown here, are used occasionally in DMAIC. Some books on Six Sigma have given useful overviews of many of these other tools; for example see George (2002) and Snee & Hoerl (2005). Pande *et al*. (2002) provided a full discussion of the non-technical aspects of the DMAIC process, while Hahn (2002) provided valuable practical guidance.

Table 1
Some statistical tools used in DMAIC

Tool	Define	Measure	Analyze	Improve	Control
Project charter	X				
Process maps & flow charts	X	X			
Cause and effect analysis		X			
Process capability analysis		X			
Hypothesis tests, confidence intervals			X		
Regression analysis, other multivariate methods			X		
Gauge R&R		X			
Failure mode & effects analysis			X		
Designed experiments			X	X	
SPC and process control plans		X	X		X

4.1 Project Selection

Projects are an essential aspect of quality and process improvement. Projects are an integral component of Six Sigma, but quality and business improvement via projects traces its origins back to Joseph Juran, who always urged a project-by-project approach to improving quality (see Juran, 1988). Selecting, managing, and completing projects successfully is critical in deploying any systematic business improvement effort, not just Six Sigma. A project should represent a potential breakthrough in the sense that it could result in a major improvement in the product or service. Project impact should be evaluated in terms of its financial benefit to the business, as measured and evaluated by the finance or accounting unit. Obviously, projects with high potential impact are most desirable. This financial systems integration is standard practice in Six Sigma and should be a part of any DMAIC project, even if the organization as a whole is not currently using Six Sigma.

The value opportunity of projects must be clearly identified and projects must be well aligned with corporate business objectives at all levels. At the highest (corporate) level, the stockholders, top executives, members of the board of directors, and business analysts who guide investors typically are interested in return on equity, return on invested capital, stock price, dividends, earnings, earnings per share of stock, growth in operating income, sales growth, generation of new designs, products and patents, and development of future business leaders. At the business unit or operations level, managers and executives are interested in factory metrics such as yield, cycle time and throughput, profit and loss optimization, customer satisfaction, delivery and due-date performance, cost reduction, safety of employees and customers, efficient use of assets, new product introduction, sales and marketing effectiveness, development of people, and supply chain performance (cost, quality, service). Aligning projects with both business-unit goals and corporate-level metrics helps ensure that the best projects are considered for selection.

The first types of projects that companies usually undertake are designed to demonstrate the potential success of an overall improvement effort. These projects often focus on the areas of the business that are full of opportunities, but they also tend to be driven by current problems. Issues that are identified by customers or from customer satisfaction (or dissatisfaction) feedback, such as analysis of field failures and customer returns, sometimes are the source of these projects.

Such initial opportunistic projects often are successful, but they typically are not the basis for long-term success; most easy opportunities are soon exhausted. A different approach to project definition and selection needs to evolve. One widely used approach is basing projects on strategic business objectives. In this approach, defining the key set of critical business processes and the metrics that drive them is the first step towards successful project development. Linking those processes together to form an integrated view of the business then follows. Projects that focus on the key business metrics and strategic objectives, as well as the interfaces among critical business processes, are likely to have significant value to the company. The only risks here are that the projects may be very large, and still may focus only on some narrow aspect of the business. A good project selection and management system prevents such problems from occurring.

Many companies have set up formal project selection committees and conducted regular meetings between customers and the project selection committees to help select valuable projects. Ideally, projects are strategic and well aligned with corporate metrics, and are not local (tactical). If local projects are reduced to addressing crises, i.e. "firefighting", then their solutions are rarely broadly implemented in other parts of the business, and too often the solutions are not permanent. Some companies use a dashboard system – which graphically tracks trends and results – to effectively facilitate the project selection and management process.

Project selection is probably the most important part of any business improvement process. Projects should be able to be completed within a reasonable time frame and should have real impact on key business metrics. This means that a lot of thought must go into defining the organization's key business processes, understanding their interrelationships, and developing appropriate performance measures. Snee & Rodebaugh (2002) provided some very helpful advice on selecting good projects.

4.2 The Define Step

The objective of the Define step of DMAIC is to identify the project opportunity and to verify or validate that it represents legitimate breakthrough potential. It is desirable that a project be important to both customers (voice of the customer [VOC]) and the business. Stakeholders who work in the process and its downstream customers need to agree on the potential usefulness of the project.

One of the first items that must be completed in the Define step is a project charter. This is a short document (typically about up to about two pages) that contains a description of the project and its scope, the start and the anticipated completion dates, an initial description of both primary and secondary metrics that will be used to measure success and how those metrics align with business unit and corporate goals, the potential benefits to the customer, the potential financial benefits to the organization, milestones that should be accomplished during the project, the team members and their roles, and any additional resources that are likely to be needed to complete the project. Typically, the project Champion or sponsor plays a significant role in developing the project charter, and may use a draft charter as a basis for organizing the team and assigning responsibility for project completion.

Generally, a team should be able to complete a project charter in 2–4 working days; if it takes longer, the scope of the project may be too large. The charter should also identify the customer's critical-to-quality characteristics (CTQs) that are impacted by the project. Graphical aids are also useful in the define step; the most common ones used include process maps and flow charts, value stream maps, and Supplier/Input/Process/Output/Customer (SIPOC) diagrams. These tools provide much visual detail and facilitate understanding about what needs to be changed or improved in the process. These diagrams are especially useful in the non-manufacturing setting such as banks, financial institutions, hospitals, accounting firms, e-commerce, governmental agencies, and most transactional/service organizations, where the ideas of a process, system, and process thinking are often not well-understood.

The team also will need to prepare an action plan for moving forward to the other DMAIC steps. This will include individual work assignments and tentative completion dates. Particular attention should be paid to the Measure step, as it will be performed next. Finally, the team should prepare for the Define step tollgate review, which should focus on the following:

(i) Does the problem statement focus on symptoms, and not on possible causes or solutions?
(ii) Are all the key stakeholders identified?
(iii) Does the potential financial impact make the project worth doing?
(iv) Has the scope of the project been verified to ensure that it is neither too small nor too large?
(v) Has a high-level process map been completed?
(vi) Have any obvious barriers or obstacles to successful completion of the project been ignored?
(vii) Is the team's action plan for the Measure step of DMAIC reasonable?

4.3 The Measure Step

The purpose of the Measure step is to evaluate and understand the current state of the process. This involves collecting data on measures of quality, cost, and throughput/cycle time. It is important to develop a list of all of the key process input variables (sometimes abbreviated KPIV) and the key process output variables (KPOV). The KPIV and KPOV may have been identified at least tentatively during the Define step, but they must be carefully defined and measured during the Measure step. Important factors may be the time spent to perform various work activities and the time that work spends waiting for additional processing. Deciding what and how much data to collect are important tasks; there must be sufficient data to allow for a thorough analysis and understanding of current process performance with respect to the key metrics. The data collected during the Measure step may be displayed in various ways such as histograms, stem-and-leaf diagrams, run charts, scatter diagrams, and Pareto charts.

Data may be collected by examining historical records, but this may not always be satisfactory, as the history may be incomplete, the methods of record keeping may have changed over time, and, in many cases, the desired information may not have been retained. Consequently, it is often necessary to collect current data through an observational study, or it may be done by sampling from the relevant data streams. When there are many workers in the system, work sampling may be useful. In transactional and service businesses, it may be necessary to develop appropriate measurements and a measurement system for recording the information that are specific to the organization. This is a major difference between manufacturing and services. Measurement systems and data on system performance often already exist in manufacturing, since the necessity for the data is usually more obvious in manufacturing than in services. The data that are collected are used as the basis for determining the current state or baseline performance of the process. Additionally, the capability of the measurement system should be evaluated to make sure the team is not trying to solve an imaginary problem in which the process performance is fine, but the measurement system is flawed. Also, the team requires accurate data to solve the problem at hand. The measurement system analysis may be done using a formal gauge capability study, i.e. use of a designed experiment to quantify the accuracy and variation of the measurement process.

It is also a good idea to begin to divide the process cycle time into value-added and non-value-added activities and to calculate an estimate of process cycle efficiency where

$$\text{Process Cycle Efficiency} = \frac{\text{Value - Add Time}}{\text{Process Cycle Time}}.$$

The value-added time is the amount of time actually spent in the process that transforms the form, fit, or function of the product or service that results in something for which the customer is willing to pay. Process cycle efficiency is a direct measure of how efficiently the process is converting the work that is in-process into completed products or services. Process cycle time is also related to the amount of work that is in-process through Little's Law:

$$\text{Process Cycle Time} = \frac{\text{Work-in-Process}}{\text{Average Completion Rate}}.$$

The average completion rate is a measure of capacity; that is it is the output of the process over a defined time period.

At the end of the Measure step, the team should update the project charter (if necessary), re-examine the project goals and scope, and re-evaluate team makeup. The team may consider expanding to include members of downstream or upstream business units if the Measure activities indicate that these individuals will be valuable in subsequent DMAIC steps. Any issues or concerns that may impact project success need to be documented and shared with the process owner or project sponsor. In some cases, the team may be able to make quick, immediate recommendations for improvement, such as the elimination of an obvious non-value-added step or removing a source of unwanted variability.

Finally, it is necessary to prepare for the Measure step tollgate review. Issues and expectations that will be addressed during this tollgate include the following:

(i) There must be a comprehensive process flow chart or value stream map. All major process steps and activities must be identified, along with suppliers and customers. If appropriate, areas where queues grow and work-in-process accumulates should be identified and queue lengths, waiting times, and work-in-process levels reported.
(ii) A list of KPIVs and KPOVs must be provided, along with identification of how the KPOVs related to customer satisfaction or the customers' CTQs.
(iii) Measurement systems capability must be documented.
(iv) Any assumptions that were made during data collection must be noted.
(v) The team should be able to respond to requests such as, "Explain where that data came from" and questions such as, "How did you decide what data to collect?", "How valid is your measurement system?", and "Did you collect enough data to provide a reasonable estimate of process performance?"

4.4 The Analyze Step

In the Analyze step, the objective is to use the data from the Measure step to begin to determine the cause-and-effect relationships in the process and to understand the different sources of variability. That is, in the Analyze step the objective is to determine the potential causes of the defects, quality problems, customer issues, cycle time and throughput problems, or waste and inefficiency that motivated the project. It is important to separate the sources of variability into common causes and assignable causes. Removing a common cause of variability usually means changing the process, while removing an assignable cause usually involves eliminating a specific problem. A common cause of variability might be inadequate training of personnel processing insurance claims, while an assignable cause might be a tool failure on a machine.

There are many statistical tools that are potentially useful in the Analyze step. Among these are graphical data displays, control charts, hypothesis testing and confidence interval estimation, regression analysis, designed experiments, and failure modes and effects analysis. Discrete-event computer simulation is another powerful tool useful in the Analyze step. It is particularly useful in service and transactional businesses, although its use is not confined to those types of operations. For example, there have been many successful applications of discrete-event simulation in studying scheduling problems in factories to improve cycle time and throughput performance. In a discrete-event simulation model, a computer model is employed to simulate a process in an organization. For example, a computer model could simulate what happens when a home mortgage loan application enters a bank. Each loan application is a discrete event. The arrival rates, processing times, and even the routing of the applications through the bank's process are random variables. The specific realizations of these random variables influence the backlogs, applications that accumulate at the different processing steps. Other random variables can be defined to model the effect of incomplete applications, erroneous information and other types of errors and defects, and delays in obtaining information from outside sources, such as credit histories. By running the simulation model for many loans, reliable estimates of cycle time, throughput, and other quantities of interest can be obtained.

The Analyze tools are used with historical data or data that was collected in the Measure step. These data are often very useful in providing clues about potential causes of the problems that the process is experiencing. Sometimes these clues can lead to breakthroughs and actually identify specific improvements. In most cases, however, the purpose of the Analyze step is to explore and understand tentative relationships between and among process variables and to develop insight about potential process improvements. A list of specific opportunities and root causes that are targeted for action in the Improve step should be developed. Improvement strategies will be further developed and actually tested in the Improve step.

In preparing for the Analyze tollgate review, the team should consider the following issues and potential questions:

(i) What opportunities are going to be targeted for investigation in the Improve step?
(ii) What data and analysis supports that investigating the targeted opportunities and improving/eliminating them will have the desired outcome on the KPOVs and customer CTQs that were the original focus of the project?
(iii) Are there other opportunities that are not going to be further evaluated? If so, why?
(iv) Is the project still on track with respect to time and anticipated outcomes? Are any additional resources required?

4.5 The Improve Step

In the Measure and Analyze steps, the team decides which KPIVs and KPOVs to study, determines what data to collect and how to display and analyze them, identifies potential sources of variability, and determines how to interpret the data they obtained. In the Improve step, they turn to creative thinking about the specific changes that can be made in the process and other things that can be done to have the desired impact on process performance.

A broad range of tools can be used in the Improve step. Redesigning the process to improve work flow and reduce bottlenecks and work-in-process will make extensive use of flow charts and/or value stream maps. Sometimes mistake-proofing (designing an operation so that it can be done only the right way) an operation will be useful. Designed experiments are probably the most important statistical tool in the Improve step. Designed experiments can be applied either to an actual physical process or to a computer simulation model of that process, and can be used both for determining which factors influence the outcome of a process and for determining the optimal combination of factor settings.

The objectives of the Improve step are to develop a solution to the problem and to pilot test the solution. The pilot test is a form of confirmation experiment; it evaluates and documents the solution and confirms the solution attains the project goals. This may be an iterative activity, with the original solution being refined, revised, and improved several times as a result of the pilot test's outcome.

The tollgate review for the Improve step should involve the following:

(i) Adequate documentation of how the problem solution was obtained.
(ii) Documentation on alternative solutions that were considered.
(iii) Complete analysis results for the pilot test.
(iv) Plans to implement the pilot test results on a full-scale basis. This should include dealing with any regulatory requirements, legal issues, personnel concerns (such as additional training requirements), or the impact on other business standard practices.
(v) Analysis of any risks of implementing the solution, and appropriate risk-management plans.

4.6 The Control Step

The objectives of the Control step are to complete all remaining work on the project and to hand off the improved process to the process owner along with a process control plan and other necessary procedures to ensure that the gains from the project will be institutionalized. That is, the goal is to ensure that the gains are of help in the process and, if possible, the improvements will be implemented in other similar processes in the business.

The process owner should be provided with before-and-after data on key process metrics, operations and training documents, and updated current process maps. The financial benefits of the project should be quantified. The process control plan should be a system for monitoring the solution that has been implemented, including methods and metrics for periodic auditing. Control charts are an important statistical tool used in the control step of DMAIC; many process control plans involve control charts on critical process metrics.

The transition plan for the process owner should include a validation check several months after project completion. It is important to ensure that the original results are still in place and stable so that the positive financial impact will be sustained. It is not unusual to find that something has gone wrong in the transition to the improved process. The ability to respond rapidly to unanticipated failures should be factored into the plan.

The tollgate review for the Control step typically includes the following issues:

(i) Data illustrating that the before and after results are in line with the project charter should be available. (Were the original objectives accomplished?)
(ii) Is the process control plan complete? Are procedures to monitor the process, such as control charts, in place?
(iii) Is all essential documentation for the process owner complete?
(iv) A summary of lessons learned from the project should be available.
(v) A list of opportunities that were not pursued in the project should be prepared. This can be used to develop future projects; it is very important to maintain an inventory of good potential projects to keep the improvement process going.
(vi) A list of opportunities where the results of the project can be used in other parts of the business.

5 Other Elements of Six Sigma

In recent years, two other tool sets have become identified with Six Sigma, DFSS and lean systems. Many organizations regularly use one or both of these approaches as an integral part of their Six Sigma implementation.

5.1 Design for Six Sigma

DFSS is an approach for taking the variability reduction and process improvement philosophy of Six Sigma upstream from manufacturing or production into the design process, where new products (or services or service processes) are designed and developed. Broadly speaking, DFSS is a structured and disciplined methodology for the efficient commercialization of technology that results in new products, services, or processes. DFSS spans the entire development process from the identification of customer needs to the final launch of the new product or service. Customer input is obtained through VOC activities designed to determine what the customer really wants, to set priorities based on actual customer wants, and to determine if the business can meet those needs at a competitive price that will enable it to make a profit. VOC data is usually obtained by customer interviews, by a direct interaction with and observation of the customer, through focus groups, by surveys, and by analysis of customer satisfaction data. The purpose is to develop a set of critical to quality requirements for the product or service.

Traditionally, DMAIC is used to achieve operational excellence, while DFSS is focused on improving business results by increasing the sales revenue generated from new products and services and finding new application opportunities for existing ones. In many cases, an important gain from DFSS is the reduction of development lead time; that is, the cycle time to commercialize new technology and get the resulting new products to market. DFSS is directly focused on increasing value in the organization. Many of the statistical tools that are used in operational Six Sigma are also used in DFSS. Designed experiments are particularly helpful. Experimentation with prototypes and computer models is an area where statisticians can make useful contributions to DFSS.

Some organizations and practitioners use a variation of DMAIC, DMADV (Define, Measure, Analyze, Design, and Verify), for DFSS. In general, DFSS makes specific the recognition that every design decision is a business decision, and that the cost, manufacturability, and performance of the product are determined during design. Once a product is designed and released to manufacturing, it is almost impossible for the manufacturing organization to make it better. Furthermore, overall business improvement cannot be achieved by focusing on reducing variability in manufacturing alone (operational Six Sigma), and DFSS is required to focus on customer requirements while simultaneously keeping process capability in mind. Specifically, matching the capability of the production system and the requirements at each stage or level of the design process is essential. When mismatches between process capabilities and design requirements are discovered, either design changes or different production alternatives are considered to resolve the conflicts. Throughout the DFSS process, it is important that the following points be kept in mind:

(i) Is the product concept well identified?
(ii) Are customers real?
(iii) Will customers buy this product?
(iv) Can the company make this product at competitive cost?
(v) Are the financial returns acceptable?
(vi) Does this product fit with the overall business strategy?
(vii) Is the risk assessment acceptable?
(viii) Can the company make this product better than the competition?
(ix) Can product reliability and maintainability goals be met?
(x) Has a plan for transfer to manufacturing been developed and verified?

For additional information on DFSS, we recommend Perry & Bacon (2007).

5.2 Lean Manufacturing

Lean manufacturing systems are designed to eliminate waste (see Womack & Jones, 1996.) By waste, we mean unnecessarily long cycle times, or waiting times between value-added work activities. Waste can also include rework, scrap, and excess inventory. Rework and scrap are often the result of excess variability, so there is an obvious connection between Six Sigma and lean. George (2002) provided a good introduction to how lean and Six Sigma work together. Important metrics in lean are the process cycle efficiency, process cycle time, work-in-process, and throughput rate. Lean also makes use of many tools of industrial engineering and operations research. One of the most important of these is discrete-event simulation. Properly constructed and validated simulation models are often very good predictors of the performance of a new or redesigned system. Both manufacturing and service organizations can greatly benefit by using simulation models to study the performance of their processes.

We also find Six Sigma combined with lean principles and DFSS to be entirely consistent with Deming's system of profound knowledge. Six Sigma clearly adopts a systems perspective as it reaches into all aspects of a business. Knowledge about variation, what causes it, and how to reduce it by identifying cause and effect relationships is at the heart of almost all Six Sigma thinking. In addition, the theory of psychology as it relates to management involvement, teamwork, and leadership is essential to success with Six Sigma.

6 The Future of Six Sigma

6.1 Combining Six Sigma with Other Initiatives

Six Sigma has become a widely used implementation vehicle for quality and business improvement. It is logical to ask about its future. Some have speculated that Six Sigma is the "flavour of the month", as management looks for the quick fix to crucial operational problems. However, since Six Sigma is over 20 years old and implementations are growing worldwide, it is difficult to believe that it is simply a management fad. In an ideal implementation, Six-Sigma, DMAIC, DFSS, and lean tools are used simultaneously in an organization to achieve high levels of process performance and significant business improvement. Figure 3 highlights many of the important complementary aspects of these three sets of tools. In our view, this business improvement triad should be how most Six Sigma initiatives are structured in the future.

Six Sigma, often combined with DFSS and Lean, has been much more successful than its predecessors, notably TQM. The project-by-project approach is a key factor, and the focus on obtaining improvement in bottom-line business results has been instrumental in obtaining management commitment to Six Sigma. Another major component in obtaining success is driving the proper deployment of statistical methods into the right places in the organization. The DMAIC problem-solving framework is an important part of this. When combined with lean principles and DFSS, it is an end-to-end fully integrated approach that is:

(i) broad based,
(ii) reaches all parts of the organization,
(iii) achieves management involvement/commitment,
(iv) has high business impact,
(v) does not necessarily focus on just the "visible numbers", and
(vi) a "systemic" approach, consistent with Deming's philosophy.

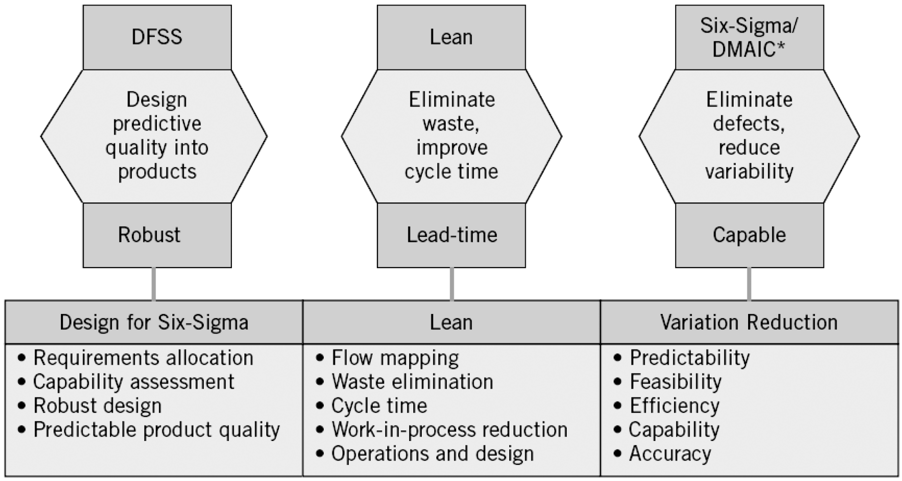


Figure 3. *The Business Improvement Triad [From Montgomery (2008)].*

6.2 Effect on Statisticians

Six Sigma has had a profound effect on practicing statisticians and on how future statisticians should be trained. Statisticians in industry have found themselves working more as active collaborators on projects and as MBB trainers, as opposed to the more passive consulting role of the past. Most statisticians are very well educated in the methodology of the field. However, many have a mathematical view of problem solving, as opposed to the more pragmatic approaches taught in many engineering disciplines. It is important to see how tools and methods fit together in a system for creative problem-solving. Few statistics programmes teach anything about the DMAIC process, and how it is deployed. Most engineering departments in US universities require a design course taken in the senior year that requires students to apply the principles and techniques that they have learned in several years of coursework to solve a comprehensive design problem. A similar course could be offered by statistics programmes based around the DMAIC process. Such a course would facilitate preparing statisticians for professional practice in business and industry.

6.3 Other Trends

We expect Six Sigma to become somewhat less outwardly visible, while remaining an important initiative within companies. Some companies, such as General Electric, gave heavy emphasis to Six Sigma some years ago. While they talk less about Six Sigma now, it has been retained as an important part of their operations.

We agree with Hoerl (2004), who expects further globalization of Six Sigma, more standardization of the DFSS process, and greater integration of the Six Sigma ideas and methods into the normal operations of companies. It is expected that healthcare applications will grow in importance. It has been documented that improvements in healthcare have the potential to save thousands of lives and billions of dollars. Some of the statistical tools used in Six Sigma need some modification before being applicable in healthcare. As reviewed by Woodall (2006), for example, control charts often have to be risk-adjusted to account for the variation in the health of patients. Improving healthcare may be more challenging than obtaining improvements in industry or financial services for a number of reasons, including the lack of electronic records, privacy issues, and, at least in the United States, a management structure where many of the key players act as independent contractors.

For continued success of Six Sigma, it is necessary to incorporate a broader array of statistical methods, particularly those that are more appropriate for the increasing amount of data available in applications. Nair *et al*. (2000), for example, pointed out the need for methods that allow the effective analysis of functional data and spatiotemporal data. The analysis of functional data in process monitoring was recently reviewed by Woodall *et al*. (2004). There are an increasing number of applications where somewhat more sophisticated statistical methods, such as these, are required in Six Sigma applications.

7 Conclusion

We wholeheartedly support the process design and improvement principles of Six Sigma, which have been used to great success in improving quality and productivity in applications around the world. The use of statistical methods is a key component of this metric-driven approach. We encourage readers to become involved in Six Sigma should the opportunity arise.

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Résumé

Nous offrons une vue d'ensemble d'introduction des processus de développement et d'amélioration de Six Sigma. Nous présentons également une perspective historique. Nous discutons aussi des méthodes statistiques fréquemment utilisées dans ce cadre et commentons brièvement l'impact de Six Sigma sur la pratique des statistiques dans l'industrie.

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