Lean Six Sigma for the Healthcare Practice

A Pocket Guide
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Lean Six Sigma for the Healthcare Practice
A Pocket Guide

Roderick A. Munro, PhD

ASQ Quality Press
Milwaukee, Wisconsin
This book is dedicated to the Quality Improvement Coaches (QICs) and Primary Care Providers (PCPs) in Michigan who have embarked on the Improving Performance in Practice (IPIP) process.

The State of Michigan has combined the reporting requirements of the Patient-Centered Medical Home and the national IPIP into one reporting process to reduce redundancy and to focus more on improvements in healthcare quality.

Most especially to the many overloaded, stressed-out healthcare professionals who may feel that they can not take on one more task or new patient. The methodologies and tools found in this book will help you.
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Acronym List

7S—sort, set-in-order, shine, standardize, sustain, safety, oversight

8D—eight disciplines to problem solving

APQP—healthcare advanced practice quality planning

BOS—business operating system

C&E—cause-and-effect diagram

CI—continual improvement

COPQ—cost of poor quality

COQ—cost of quality

CPHQ—Certified Professional in Healthcare Quality

CQIA—Certified Quality Improvement Associate

DMAIC—define, measure, analyze, improve, control

FMEA—failure mode and effects analysis
**Acronym List**

**IPIP**—improving performance in practice

**IPO**—input, process, output

**ISO**—International Organization for Standardization

**LCL**—lower control limit (see “Process Behavior Chart”)

**MPCC**—Michigan Primary Care Consortium

**MSA**—measurement systems analysis

**PCMH**—patient-centered medical home

**PCP**—Primary Care Provider

**PDCA**—plan–do–check–act

**PDSA**—plan–do–study–act

**PI**—process improvement

**QIC**—Quality Improvement Coach

**ROI**—return on investment

**RPN**—risk priority number (see “FMEA”)

**SDCA**—standardize–do–check–adjust

**SIPOC**—supplier, input, process, output, customer

**SOP**—standard operating procedure

**SPC**—statistical process control

**UCL**—upper control limit (see “Process Behavior Chart”)

**VSM**—value stream map
This book is a continuation of a series of works started by the author, referred to as QUIT—“Quality in Training.” It is hoped that through this ongoing series people will be helped in finding joy in the work that they do, leading to healthier, happier lives.

A Zen Buddhist text on *The Art of Living* states:

*The Master in the art of living makes little distinction between his work and his play, his labor and his leisure, his mind and his body, his education and his recreation, his love and his religion. He hardly knows which is which. He simply pursues his vision of excellence in whatever he does, leaving others to decide whether he is working or playing. To him he is always doing both.*

It will be left to the reader to decide at what point the author is/was doing each in this text.
We are discussing the concept of healthcare quality sometimes called “quality of care and services.” In this book, our focus is on how well the organization performs the many activities and functions involved in patient care. The term “quality of care and services” is not limited to the technical quality of care provided to patients; “quality of care and services” is a broader, more general category that includes not only the technical quality of care, but also includes how well patient service needs are met.

If you would like to make comments to the author about this book, please contact him at authors@asq.org.
As in any work, a lot of people were involved in developing this book. I would like to thank all the class participants, suppliers, and peers that I have worked with in the past 30 years. I continue to learn from all your input.

I especially would like to thank Dr. Dean H. Stamatis and Dr. Elizabeth J. Rice for their years of friendship and their encouragement and support of this work.

Thanks also go to the staff at ASQ Quality Press and the reviewers for their time, efforts, and support in making this book a reality. Thanks especially to Paul O’Mara and Matt Meinholz for their ongoing support of this series.

Special thanks goes to the Michigan IPIP team of professionals. The Healthcare Improvement Model on page xvi is a summary of some of the early work that has been accomplished in assisting Practices toward healthcare improvements.
Facilitate the project using best processes

“Lean” the practice

Solve problems/breakthrough improvement

Health system professionals

Community

Quality and lean professionals

Patient-Centered Medical Home

Acknowledgments
I would like to especially acknowledge the following individuals:

Dr. Walt Talamonti, MD, Chair, Michigan IPIP Steering Committee

Dr. Ernest Yoder, MD, Vice Chair, Michigan IPIP Steering Committee

Dr. Joseph Fortuna, MD, Medical Champion

Rose Steiner, RN, Director, Michigan IPIP

Dr. Kevin Piggott, MD, Chair, IPIP Learning Collaborative

Quality Improvement Coach team volunteers:

Lou Ann Lathrop (General Motors), Chair

John Casey (Whitehall Group)

John Katona (Delphi)

Dave Lalain (AIAG)

Victor Lloyd (St. John Health)

Rebecca Snyder (Ford Motor Company)

Advisor to Michigan MPCC/AIAG IPIP process:

Barry Klein (GlaxoSmithKline Pharmaceuticals)
This book is for those in the Practice or staff activities of your organization whose customers/payers may be encouraging or requiring you to use Lean Six Sigma in your workplace or to simply improve the way healthcare is being provided. The book is intended to be a basic, easy-to-read, quick and handy reference to the process improvement topics that are so important in healthcare (page xx shows a Venn diagram of tools found in this book). The first seven sections of the book cover the basics of Lean Six Sigma (“What Is Lean Six Sigma?” through “Lean Six Sigma Road Map for the Practice”) and how it can be applied and implemented in the Practice. The tool matrix guide beginning on page 2 has been arranged alphabetically for ease of finding tools as needed. The remainder of the pocket guide gives a brief description of the various tools and methodologies used in Lean Six Sigma. Each discussion has purposefully
been kept short and simple to allow for a basic understanding and includes some tips on how or when to use the tool. If more detail is needed, other references can be consulted to realize the full impact of the tool.

Everyone in the organization, from the janitor to the senior executive or Practice oversight committee, should know the basic information found in this book. Some have felt in the past that this type of information belonged only on the manufacturing floor. Today we have learned that there is probably more opportunity within the Practice than ever thought before (Berwick and Leape
Especially since many healthcare practitioners have received a large amount of scientific training, the use of statistical tools to improve processes in healthcare and quality of care and services should be a natural combination.

Persons who can pass a designated test, either internally created or one of many offered by various organizations, can be designated as Lean Six Sigma Green Belts. Green Belts work with teams to gather data and to analyze, improve, and control the processes in the Practice. People who become exceptionally expert in the use of the Lean Six Sigma methods and processes and who pass advanced testing are called Lean Six Sigma Black Belts. Black Belts use experiments and other advanced tools to help solve especially difficult problems.

Your Practice may or may not have a Black Belt (a full-time or part-time person dedicated to doing Lean Six Sigma in your Practice). However, everyone should become involved in continual improvement efforts to help ensure your organization’s survival and the improved care and health of patients. Some process improvements can be very simple to identify and implement while others may take some time for the staff to fully understand the dynamics of the issues involved. These improvement efforts can be accomplished by using this book and the tools within it to guide your improvement projects.
In addition, you may deal with customer audit personnel, government auditors, people designated as “rent a Black Belts,” or other coaches or consultants to help with the advanced aspects of Lean Six Sigma. By using all the resources that are available, you can help your Practice stay competitive in today’s global marketplace.

One of the biggest challenges in the Practice is to allow time to understand the use of these tools and to start collecting the data and information that will be needed to make continual improvement efforts a reality. Everything can be defined as a process, and processes can be measured so that they can be monitored for improvement. In the past, you may not have thought about how to measure work that is done in the Practice. Keeping an open mind will be paramount to the success of Lean Six Sigma in your Practice and to making your work easier and more fulfilling. Experience has shown that the journey can be fun and rewarding for those who get honestly involved in using the improvement tools and methods. This effort is the “how to” of learning to “work smarter, not harder!”
The DMAIC Matrix Guide

The DMAIC model (shown in Figure 1) is referred to throughout this book. The acronym stands for define, measure, analyze, improve, and control. The reader will find the

Figure 1  The DMAIC model.
The following matrix helpful as he or she matches particular tools and approaches to particular phases in the DMAIC process.

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Lean Six Sigma is a term describing the overall concept of continual improvement of everyday processes (Deming 1993). Continual improvement can be defined as the use of problem-solving techniques and quick deployment to implement improvements, and then the use of process behavior charts (Wheeler and Poling 1998) to maintain the gains. Lean Six Sigma is about strategic alignment, applied learning, and culture or belief system transformation that uses four distinct but interrelated characteristics: a strategy deployment approach, a belief system, a statistical calculation, and a suite of project improvement methods (Caldwell, Brexler, and Gillem 2005). Lean Six Sigma is being used in many organizations today in a variety of applications (for example, schools, hospitals, and private practices). Basically, Lean Six Sigma is about collecting data on a process and using that data to analyze and interpret what
What Is Lean Six Sigma?

is happening in that process so that the process can be improved to better satisfy the customer. A basic process can be defined as an input, transformation, and output (see Figure 2).

Lean Practice is simply the banishment of waste. It is the elimination of waste by better organizing and managing customer relations, the supply chain, product development, and service activities. Many service organizations, especially the larger ones, have been designed with the idea of creating large service runs over short periods of time (sometimes resulting in repetitive checking of work done)—typically called mass production. In Lean Practice, the organization develops a process for processing/producing just what is needed, as it is needed, by the patients/customers that eliminates waste in time, energy, effort, rechecking/verifying, inventories, material handling, storage, and so on. This process is also called the pull concept because the patient/customer “pulls” what is needed from the suppliers or Practice instead of the supplier making and stockpiling large quantities until the customer decides it wants some, as in mass production.

![Figure 2](image-url) The process model.
So, bringing these two concepts together we get Lean Six Sigma for Healthcare. This is a process that uses continual improvement techniques/methodologies to eliminate waste in the Practice. Waste is defined as anything that stifles healthcare staff personnel or patients, or results in lost time, productivity, or simply sitting around an office waiting for something to happen. But is this really important in the way healthcare is delivered today?

Dr. Donald Berwick has stated, “With the rising complexity and reach of modern medicine have come startling levels of risk and harm to patients” (Berwick and Leape 1999). Many people who work in healthcare may not recognize the things that they do as being part of a process. Since they do not work repetitively as a person in a factory running a machine, the Practice employee might be tempted to say, “I do not have a process.” A process does not have to be a repetitive task done exactly the same each and every time. When we come into work each day, we have general tasks that we do every day. The specific items may change or be done in different sequences; however, we do have procedures that we follow to get our work done. This is what we will be looking at and studying throughout this guidebook.

Lean Six Sigma started at Motorola in the late 1980s as Six Sigma on the shop floor (process) and
What Is Lean Six Sigma?

then moved into the front office (transactional). What we know today as Lean Six Sigma for Healthcare has been honed with the addition of lean methodologies at General Electric and a growing number of other organizations. Following a prescribed process, an entire organization starts to look at everything that it does in the light of reducing variation and waste—with the result of increasing customer satisfaction. Customers are defined as anyone from the next person who uses the work we do (internal customer) to the ultimate customer who uses the products or services that our organization produces (external customer). To assist in this process, sometimes the supplier and customer are added to the basic process flow (input, transformation, output), creating the SIPOC (supplier, input, process, output, customer) identification. This is especially useful in helping to define the boundaries of what is to be studied (see Figure 3).

Figure 3  The SIPOC model.
For some, the idea of improving a process is a waste of time and should not be bothered with (“we are already working the hardest that we can”). Lean Six Sigma is *not* about working harder, it is about working smarter! Juran (1964) points out that the work we do is a result of the fact that “changes creep up on us week by week, a little bit at a time. Over a year or two, there are 50 or 100 of these bits, which amounts to quite a bit. The skills of the staff or managers have not necessarily kept pace, and we wake up to the existence of a wide gap.” This is one explanation for why accidents and procedural errors happen in healthcare today. If the root cause is found for an accident or rejection of a product or service, it usually can be traced back to either many small changes that occurred in our organization or something having been omitted accidentally between healthcare units.

Using Lean Six Sigma methodologies, we can find those bits of change and decide which ones should be fixed/modified and which ones need to be improved. This process is not meant to be a quick-fix (silver bullet) approach to the healthcare industry or individual patient care. The methodical use of the tools over time will save resources and effort (and lives) in doing our daily jobs. This book provides an overview of the tools and processes used in Lean Six Sigma. Detailed explanations of the use of each tool or process can
be accessed readily in other references or on the Internet. For many readers, this book will serve as a quick reference to what you may already have in your Practice that can be used by individuals and teams to improve overall processes.
Your Role in Lean Six Sigma

In the Lean Six Sigma problem-solving process, you may find a number of tools and methods that you are already familiar with and a few that are new to you. You may very well ask, “How is this any different from what we have done before?” The direct answer will need to be given by your organization, and it depends on the various programs that have already been used. For many Practices, the Lean Six Sigma effort is part of an ongoing evolution of how they do their work to improve patient care. One of the main things that you should notice is that everyone will be more involved with problem-solving efforts and with the everyday problems found in patient care.

As we prepare for this exciting journey, first look at Figure 4. What would you predict as the golfer’s next score if you were looking only at the top box of numbers? Maybe a golf score within the range 100 to 105 would be a good
Which provides more insight?

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or

**Golf Scores**

What is your prediction for game number 205?

![Figure 4](image)

**Figure 4** More insight.

guess. Could you say anything about the golfer in general? Now take a look at the graph of the same numbers (this is called a run chart), and a lot of information becomes very clear. Your new estimated score for game number 205 might be within the range of 92 to 97. You could also say that up through game 180 the golfer was relatively consistent, scoring around 120. But then something happened—maybe lessons were taken, new clubs bought, or a new grip started to be used—and things began to improve. The
golfer still has not stabilized from whatever happened and may improve even more. The graph should be continued to monitor the golfer’s progress. Thus, as the saying goes, this one picture (a run chart) is worth a thousand words. Now think about the large number of “scores”—patient tests or numerical values—that we have in healthcare for a patient. The human body is also a system, and by using some simple graphs we can work with patients to help improve an individual’s system (process) of health. One quick note here: if we record a patient’s vitals in an electronic system (that is, registry, spreadsheet, database), then the computer can give us these graphics with a couple of simple clicks.

During the change process, and while using this book, you will be able to use the Lean Six Sigma model for improvement. It has been shown that by following a model or road map we can usually accomplish something much quicker than we can without a guide. Some organizations today use a model called MAIC (measure, analyze, improve, control) as a road map. They refer to this process as being able to do “magic” without the G (garbage) that we find in many activities. Many organizations have added a D (define) stage at the beginning of the model to identify the customer process, resulting in the DMAIC model (see Figure 5), which is commonly used in the Lean Six Sigma approach.
You may already use run charts, checklists, process sheets, standard operating procedures, or any number of other such techniques in your daily work. The use of the Lean Six Sigma model for improvement should not replace anything you’re currently doing. It should, however, help you to review your daily work and look for areas or methods to improve the process that customers/patients want and need. Just because we are doing the same things we have done before, do our customers/patients still want the same things from us? How many handwritten or typed letters, memos, scripts, and so on, do you
see in a typical Practice today? Most work is now done on computers and sent electronically.

We are beginning a journey of continual improvement that can be used in our work and our daily lives. Some of us have been on this journey for some time while others may just be starting. The process involves using what Deming (1993) refers to as profound knowledge: appreciation for a system, knowledge about variation, theory of knowledge, and psychology. By following the Lean Six Sigma methodology for improvement you should see things around you work better, be safer, and satisfy your customers more.
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What Is Variation?

Variation is the basic principle that no two things are exactly alike. There are usually many reasons for things not being constant. Have you ever noticed while driving that your vehicle does not stay exactly the same distance between the white and yellow lines? What causes this variation? Of course most of us drive well, and the lines are on the road to help us get to where we want to go without running into other vehicles or the ditch. But if we could measure our vehicle’s distance between the lines, we would find that minor drifts do occur on a regular basis (common cause variation). If a police officer pulls us over, however, some of the reasons for drifting too far (special cause variation) might include these: wind velocity with a high-profile vehicle, alcohol or drug involvement, cell phone usage, inexperienced driver, poor weather conditions, worn or damaged tires, or other factors. The author was once pulled over by
the police because he was driving too close to the white line. It seems that in that area, this could only mean that the driver had been drinking at the local casino! However, on dark, foggy nights, the author prefers staying close to the white line to give oncoming drivers more room on two-lane country roads.

Similar things happen in healthcare. We have procedures for how to do the work, but small variations or personal preferences can and will cause differences in the output of the process. A common way to describe this is with the formula $Y = f(x)$, or $Y$ equals the function of the $x$’s. Graphically, this is most easily seen when using the cause-and-effect (fishbone) diagram. The effect (the head of the fish) is the “$Y$” of the formula, and the causes (the bones of the fish) are the $x$’s. Note that this process will actually help improve creativity in your Practice as the inputs will become less varied and the activities can become more robust for the customer outputs, or patient care.

The traditional view of quality (sometimes called the goalpost mentality—see Figure 6) depicts the way many people regard variation when dealing with processes (for example, blood pressure, HDL, LDL). It shows that some processes (or items that are used) are clearly performed within specifications or tolerances while others are outside of specifications. There is no
What Is Variation?

relationship called out for $Y = f(x)$, but the question that should be asked is “What is the ‘real’ difference within the process or between a service that is just inside the specification (a) and another that is just outside the specification (b)?” (See Figure 7.) Two competing services (say two overnight delivery services) may be very similar and probably will function equally well when used by your Practice. That is one of the reasons companies who use this traditional model continue to provide services even if they are just outside the spec limits (that is, time of the actual delivery)—because they think they can get a few more sales to the customer and the deficiency will not be noticed. This usually happens during heavy office workload times when temporaries are brought in and not trained very well.

Figure 6  Traditional view of quality.
A different perspective on variation can be seen in the Taguchi loss function model (see Figure 8). This updated view of quality states that all services (or processes), measured by the $x$’s, should aim for a target value that is located
at the middle of the specification limits (which reflect customer expectations or healthcare specifications). In this case, services that are not centered but similar to each other (for example how well a report is written or the variation from the expected wait time for a service) have nearly the same “loss” to the customer (who may be a manager or patient) and will not be accepted very well if at the outer boundaries of the graph. As the services offered move away from the target value, the cost to the patient/customer (which includes internal customers within the healthcare process), and thus society, increases as issues or problems within the patient or with the use of that service increase. The goal today is to reduce variation (both common cause and special cause—to be discussed later) so that the patient feels better or the customer will see more service delivery that is closer to the target value of what they want versus what we can provide.

Recently, in ordering business cards from a national office supply chain store, the author experienced a good example of poor service. The first order was taken by a very knowledgeable salesperson and was processed quickly and efficiently. Then a couple of weeks later at the same store a second order for a different card was placed. The logistics manager for the store took the order the second time and was totally unfamiliar with the order process. Instead of a pleasant and
quick experience in ordering a simple item, the experience was a long, drawn out, grueling effort that left the author very frustrated and ready to walk out of the store!

Another service example of the Taguchi loss function is when people pay money to attend a public seminar. The seminar is advertised to last eight hours. If the seminar ends before the eight hours, people may feel that they did not get their money’s worth. If the seminar drags on beyond the eight hours, people become upset because they could miss their airplane, car pool, kids waiting to be picked up, and so on. Thus, the seminar leader must ensure that the attendees’ expectations are met within the boundaries advertised and within the attendees’ wants and needs.

A patient may have been coming to a Practice for a long period of time, and annual blood work has shown that their HDL and LDL have been within acceptable limits. Then, all of a sudden, the numbers are not acceptable and a script is written to help improve the numbers. However, the cause of the just-out-of-specification numbers may be due to any number of variables ranging from what the patient may have consumed, contamination of the sample process, reading of the blood work, or the instruments used to make the measurements. However, if the annual values of the HDL and LDL were available to the
doctor and patient in run chart format, then the patient’s body process could be reviewed first to see if there is something going on in the patient’s life that actually requires medication, or to point to a potential faulty reading and the need for retesting.

Note: Be aware of the difference between variation and variability. Variability comprises three components: variation (discussed earlier), instability (when a process has high amounts of unknown [special cause] variation), and off-target conditions (which happen when a process is not centered between the engineering specifications) (Bajaria and Copp 1991).
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Your Practice may be using Six Sigma or another quality methodology: lean office, business operating system (BOS), continuous improvement (CI), total quality management (TQM), or a system known by some other name. As a staff worker or supervisor of a process, you will be asked by your Practice management to help implement improvement of the activities or procedures that you work with. Your challenge will be to look at the process with an eye toward both simple improvements, which you may already know need to be made (cleanliness, too many signature requirements, information just sitting around, recording data into a registry, and so on), and how you can measure certain factors to investigate better ways of performing the process.

You will be asked to use the tools in this book, and maybe others, to study your work area and activities or procedures to look for improvement
ideas and ways to implement those ideas. You may already be familiar with some of these tools; the challenge will be in learning how to use them in new ways to help your Practice to meet upcoming rule changes by payers, insurance programs, and state or national programs or regulations.

Many of us find that by using a model or framework we can do things more simply—“a picture is worth a thousand words.” This is also true when trying to improve processes. Dr. Kaoru Ishikawa (the man who created the fishbone diagram—see Figure 13, page 80) gave us a road map to follow when first looking at a process that needs to be improved. The words may not make much sense right now, but as you work with process improvement, you will come to understand the importance of what is said here.

POINTERS IN EXPRESSING QUALITY

1. Determine the assurance unit. (What is to be measured?)

2. Determine the measuring method. (How will we measure it?)

3. Determine the relative importance of quality characteristics. (Is this key to our process?)
4. Arrive at a consensus on defects and flaws. (Does everyone agree on what is good and bad?)

5. Expose latent deficiencies. (Look at the process over time.)

6. Observe quality statistically. (Use process behavior charting.)

7. Distinguish between “quality of design” and “quality of conformance.” (Ishikawa 1976)

After we know what we can change (quality of conformance) versus what we can not change right now (quality of design—this is left to the Design for Six Sigma [DFSS] process), we can start working on our processes. Many Practice personnel start out viewing this effort as only more work, but many find that doing these studies actually saves them a lot of time and grief in the future as things start to improve, work flows better, and patients actually see results and feel better. One question to ask yourself right now is “How often does my process slow down or stop because something is not working the way it should?” Or “Is the output ever significantly changed or even disregarded by someone down the line (including my external customer/patient) because something did not happen right at my activity?” Note that this last question does not
ask if the business needs changed, which may have caused the instance of variation. Working on things that no one uses happens a lot for staff, and dealing with this and the changing business needs is also part of DFSS.

The next section discusses the DMAIC model, where you will learn when to most appropriately use the methods and tools presented in this book to improve your or the patient’s processes. As we proceed, please continue to keep an open mind and be willing to experiment with the tools. Be willing to look for ways to apply them in your activities and procedures to learn as much as you can about how a process operates. Also, you may be expected to show patients, by use of the graphical tools, how their health is being affected, given the measurements that have been taken over time. You will then be able to modify your work or instruct the patient as appropriate and give your organization and your patients/customers the best possible outcome.
Throughout this book, you’ll find a number of approaches and/or steps to assist you in applying the tools or methods being discussed. For the implementation of Lean Six Sigma, a model has emerged that is well recognized and which you’ll need to use in your Practice to show customers that Lean Six Sigma is being used. The DMAIC model (see Figure 9) stands for define, measure, analyze, improve, and control, and is very similar to the PDSA (plan, do, study, act) or PDCA (plan, do, check, act) models that you may have heard of or are already using.

A key factor in each step of DMAIC is keeping the focus of the Practice strategy in mind so that all of the healthcare staff can work with the methodology and focus the time and resources to accomplish each of the phases and strive for continual improvement. This is one of several driving forces that make Lean Six Sigma different from other quality improvement programs.
Other driving forces include getting everyone in the healthcare system involved (patients, payers, employers, and so on), getting the information technology group to assist in supplying data more quickly to everyone, and getting financial data in the form of cost-of-quality analysis. Research (Stamatis 1996) is showing that many organizations are finding more opportunity for improvement to the bottom line in the office than currently exists on many plant production floors.
Staff personnel at all levels will be asked to get involved with the Lean Six Sigma model and look for continual improvement opportunities in work areas. Basically, you will do the following:

**Define**  Identify the issue causing decreased customer satisfaction.

**Measure**  Collect data from the process.

**Analyze**  Study the process and data for clues to what is going on.

**Improve**  Act on the data to change the process for the better.

**Control**  Monitor the system to sustain the gains.

An example:

1. Select one important problem that you have in the Practice.

2. Draw a flow diagram, or similar tool, of the issue—how does it currently work?

3. Get concurrence from everyone who is involved in that process that the flow diagram is accurate. This in itself can be a painful process of getting concurrence and may actually solve some of the issues as this process gets people aligned.
4. Look over the flow diagram and ask “Given what we know today, is this the most effective way to do this?"

5. Make changes to the process as necessary and update the process flow diagram (note: this tool now becomes a simple job aid, reminder, or training tool on how that process works). Caution: be careful about throwing technology at problems. The process must work well first before you computerize it. Otherwise, you will only get the same problems as before—only faster.

6. Now review the process and ask “What could this process be?” or “How could this process be more effective?”

7. Seek management approval and funding for future changes.

8. Update the process flow diagram to match the new flow. Train everyone in the new/updated process flow using the flow diagram/chart.

See Figure 10.

A number of tools and methods can be used in the steps of the DMAIC model. This book gives a quick overview of many of these items as they relate to potential areas for improvement. More
detailed information can be found in quality control/assurance books, on the Internet, or in quality improvement magazines or journals. The DMAIC model uses the following tools:

**Define**

7S

Advanced practice quality planning (healthcare APQP)

Auditing (sampling, sampling plans)

Brainstorming

Business operating system (BOS)

Cause-and-effect diagram (fishbone diagram, Ishikawa diagram)
Cost–benefit analysis (cost of quality, quality cost, cost of poor quality, return on investment)

Cycle time analysis

Failure mode and effects analysis (FMEA)

Flowcharts

Lessons learned—review

Practice strategy

Process behavior charts

Process identification—storyboards

SDCA (standardize, do, check, adjust)

SIPOC (supplier, input, process, output, customer) diagram

Systems thinking

Team development

Team meetings (huddles)

Value stream mapping

Voice of the customer (patient feedback)

Walkaround/walkthrough/waste walk

Measure

7S
Auditing (sampling, sampling plans)

Benchmarking—start by setting the current baseline for the process

Business operating system (BOS)

Cause-and-effect diagram (fishbone diagram, Ishikawa diagram)

Cost–benefit analysis—start collecting information

Cycle time analysis

Data collection—check sheets, histograms, Pareto charts, run charts, scatter diagrams

Identifying a data collection plan

Identifying variability—instability, variation, off-target, cause-and-effect diagram, process capability

Measurement systems analysis (MSA)

PDSA (plan–do–study/check–act)

Practice strategy

SIPOC (supplier, input, process, output, customer) diagram

Stratification

Team meetings (huddles)
Value analysis
Walkaround/walkthrough/waste walk

**Analyze**

7S
Auditing (sampling, sampling plans)
Benchmarking—how others do things
Brainstorming
Business operating system (BOS)
Cause-and-effect diagram (fishbone diagram, Ishikawa diagram)
Check sheets
Continual improvement
Cost–benefit analysis (cost of quality, quality cost, cost of poor quality, return on investment)
Flowcharts
Practice strategy
Scatter diagrams
Stratification
Team meetings (huddles)
Value analysis
Walkaround/walkthrough/waste walk

**Improve**

7S
Auditing (sampling, sampling plans)
Brainstorming alternatives
Business operating system (BOS)
Continual improvement
Cost–benefit analysis (cost of quality, quality cost, cost of poor quality, return on investment)
Cycle time analysis
Flowcharts
Failure mode and effects analysis (FMEA)
Kanban (wait time, patient pull-through)
Lessons learned
Mistake-proofing
PDSA (plan–do–study/check–act)
Practice strategy
Problem solving
Process improvement
Scatter diagrams
Standard operating procedures (SOPs)
Stratification
Systems thinking
Team meetings (huddles)
Variation reduction
Visual controls, aids
Walkaround/walkthrough/waste walk

Control

7S
Auditing (sampling, sampling plans)
Business operating system (BOS)
Continual improvement
Cost–benefit analysis (cost of quality, quality cost, cost of poor quality, return on investment)
Cycle time analysis
FMEA—update
Kanban
Lessons learned—update
Measurement systems analysis (MSA)
Mistake-proofing
PDSA (plan–do–study/check–act)
Practice strategy
Process behavior charts
Run charts
Standard operating procedures (SOPs)—update
Standardization (SDCA—standardize, do, check, adjust)
Team meetings (huddles)
Value analysis
Variation reduction
Visual controls, aids
Voice of the customer (patient feedback)
Walkaround/walkthrough/waste walk

Most Practice staff members will find this process very exciting as they will have the tools and methods to demonstrate the improvements that they are helping the organization to achieve. There are times when a staff worker tries to tell
a supervisor that something is wrong with a process. Now we have the means to not only tell but also show and demonstrate what needs to be done. Following this process creates a road map for continual improvement and, once started, it is a never-ending journey. These tools and methods have proven themselves useful everywhere: from shop floors to office settings, from schools to hospitals, and even from churches to the home. Also, if your Practice is currently planning on achieving ISO 9001 registration, Patient-Centered Medical Home status, the Malcolm Baldrige National Quality Award (or related state-level award), or any number of other quality improvement–based awards or recognitions, one of the baseline requirements is the ability to demonstrate that continual improvement is actually being achieved.
The first thing we need to look at with respect to teams is the difference between a team and a group. A group (as in a natural work group or department within the Practice) is a collection of individuals who may be working toward a common goal but who are not necessarily interdependent. A team is a group of people who have come together for a specific common purpose—often to be accomplished within a specific time frame—and has established a common definition of what the members will be doing. Each person understands and can discuss the common objective. Many philosophies and books are available on teams, team building, and how to create effective teams. For example, the American Society for Quality’s Team and Workplace Excellence Forum has a lot of material.

An important problem many managers (those who direct or run the Practice) face with respect to teams is failing to ask individuals in the group
what they want from their experience on the team! Lack of communication within the team and between it and management thus causes a vast number of failures. Finding a solution to this should be the manager’s number one concern any time groups of people come together. Just saying the words one time is not enough for effective communication to take place.

The second-most-important issue has to do with the team itself. The members must be able to answer three basic questions before they can start and continue the process of teaming. These questions are summed up in the acronym MCG. M stands for “Who will be the members on the team and why?” C stands for “Who will handle what roles and responsibilities, and who is in control?” G represents “What are the goals of the team?” and ensuring that those goals are communicated to everyone who interacts with the team. Each team needs to ask these three questions and ensure that its members share a common purpose.

MCG can be expanded by using another acronym, SGRPI: systems, goals, roles, procedures, and interpersonal relationships. The term systems refers to thinking about how the team fits into the structure of your Practice. Goals, as in MCG, refers to what the team wants to accomplish and communicating that to others. Roles, as in the C of MCG, refers to the various roles involved
in a well-operating team and who will fill each. *Procedures* refers to agreed-to and communicated ground rules and logistical agreements that the team has made with itself. *Interpersonal relationships* refers to the relationships that any team must work out in advance, as this becomes a major issue if things are not resolved early. People need to know how to relate to each other and agree that they are all working for a common purpose.

The following are some rationales for team building from the National Training Laboratories Institute (1984):

<table>
<thead>
<tr>
<th>The Obvious</th>
<th>The Less Obvious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal clarity and commitment</td>
<td>Identifying wants and needs</td>
</tr>
<tr>
<td>Surfacing control or influence issues</td>
<td>Support needs</td>
</tr>
<tr>
<td>Inclusion/cohesion needs</td>
<td>Creative interdependence (synergy)</td>
</tr>
<tr>
<td>Exploration of working norms</td>
<td>Discovery of intrinsic needs</td>
</tr>
<tr>
<td>Control/management of destructive competition</td>
<td></td>
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</table>
Every team must go through a series of stages toward group actualization. Five states commonly involved are: forming, storming, norming, performing (producing), and ending. This process usually takes a lot of time, and if at any point something changes (for example, new managers, new team members, economic conditions, a significant emotional event experienced by one of the existing members, and so on), the team as a whole may need to go back to some prior stage and repeat their efforts in order to become a top-performing unit. Failure to follow these basic stages is the most common reason why some teams never achieve their full potential.

You should keep in mind several points at each stage. Forming involves the people on the team getting to know and trust each other. There can be many frustrations here (for example, lack of action, no clear assignment, poor communication, and so on), and there is a lot for the team to work through leading to the ultimate goal of acceptance and commitment of the group to becoming a team. In storming, team members need to work out their differences with each other. Because of the forming activities, team members should feel they are able to talk things out with each other without hurting feelings or risking rejection just because they see things differently. The primary outcome of this stage should be to clarify the team's major activities and develop members’
sense of belonging to the team. Norming occurs when the team sets its boundaries and members become more sensitive to each other and to the goal or goals of the team. The team is now ready to work on projects and enjoy a level of internal support. In the performing stage the team can work to full capacity to achieve its goals with the pride that develops from performing well. The last phase is ending. We all at various times in our lives must deal with something coming to an end. At the end of a team, or on losing a team member, we want to be able to have satisfaction with, and recognition of, a job well done.

Many managers want teams to immediately jump into the performing stage of teamwork, but this usually causes friction and a disconnect within the group, which has not been given the opportunity to form into a team. Each team, ideally during its formation phase, will identify what its goal or purpose is for existing. There are a number of team structures or types of teams:

- **Cross-functional team.** Members come from various functional areas of the organization and/or customers and suppliers to achieve the goals of the team.

- **Improvement team.** Has a specific assigned task of making one or more operational improvements (cost, cycle time, quality) in the Practice.
- **Self-directed team.** Operates with virtually no management or supervisor involvement. Its members have been given the time and resources to accomplish the tasks assigned to them.

- **Quality circle.** A team with the specific assigned task of improving the quality of an operation, service, or product. These groups are commonly called improvement teams today.

- **Project team.** A project-focused team that has a specific goal to accomplish. It could be a start-up of new activities, the launch of a new product or service, a preventive maintenance or cleaning program, or other goal that may not involve a continual improvement issue.

A team is far more than just a group of people who happen to work in a given area. Well-functioning teams take time to form and arrive at their level of functionality, but once that has taken place such teams have a lot of fun and take pride in what they accomplish. Your overall goal should be to develop well-functioning teams in your Practice to achieve customer satisfaction and continual improvement.
The Lean Six Sigma Road Map for the Practice

As you prepare for the Lean Six Sigma journey, you’ll do well to take a look at the following suggested road map:

1. Develop a flowchart (or similar tool) of a current significant process—“as is”—in your Practice.

2. Recognize that variation exists in everything you do—standardize the process throughout the Practice.

3. Develop/refine measures of work for customer satisfaction in the process.

4. Identify what the patient/customer wants and needs—reduce variation around this target.

5. Develop a “should be” or “preferred state” process flow map.
6. Use a problem-solving methodology to plan improvements.

7. Follow the PDSA model to deploy the improvement.

8. Monitor the process using run charts or process behavior charts.

9. Incorporate new technology where appropriate.

10. Update standard operating procedures or policies and lessons learned.

11. Celebrate successes.

12. Repeat the road map for continual improvement—PDSA/SDCA.
We are starting a journey of continual improvement in your Practice. The way may be familiar to a lot of you as you have been using the tools and methods for some time. Others of you may be new to this path, and through this book the author hopes to assist you along the way. This book is designed to be a guide rather than a detailed description of each tool used. Follow the process, and use what seems to be appropriate at each step. Every tool and method will not be used each time a new study starts. You may even find uses for these tools and methods in different phases of the DMAIC model, and that is encouraged. The goal of all this work is to continually improve your procedures and activities to satisfy your patients and customers (both internally and externally) and increase the effectiveness of your total Practice.
Here are some other points that healthcare professionals should remember when using this process:

1. If the method seems to be getting too complicated, it probably is, and you should step back to see if you can simplify what you’re trying to study!

2. Asking patients to wait for long periods of time is waste! Find a better way.

3. Most problems can be solved without using designed experiments. If the process is an old, established one and it used to work okay, then keep asking why it isn’t now until you find the problem!

4. Remember the KISS principle: keep it simple (keep it simple staff, keep it simple statistician, or keep it statistically simple)!

5. Sometimes all you need is an updated histogram or flowchart to see the problem!

6. Never give up!

7. Have fun!

At times, your Practice might run into problems that seemingly can not be solved, or you just don’t have enough time and resources to handle everything. It will be during those times that consultants or other specialists may be called in to
assist with the issues at hand. Many times such people will have advanced training in the tools and methodologies discussed in this book. We usually call these people “Lean Six Sigma Black Belts,” and they may ask your team to start a “Green Belt project.” Since that is what you are doing with this book—Lean Six Sigma Green Belt projects—you will be able to call yourself a Lean Six Sigma Green Belt.

If you would like to earn a formal title in this arena, check with a local quality practitioner or contact the American Society for Quality (ASQ) about the Certified Quality Improvement Associate (CQIA) or other certification processes or examinations for healthcare professionals. ASQ can be reached at 800-248-1946 or http://www.asq.org for more information.
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Tools

An old Japanese quality auditing technique, after the initial greetings in the front office, is to visit a rest room in the hourly working area before conducting the rest of the audit. The purpose of this detour, rather than to use the facility, is to check for the cleanliness of the rest room. The belief is that if management can not
provide clean facilities for staff, then a number of other processes may be at issue in the organization. Have you ever used a dirty restroom at a gas station or a restaurant? What did you think about how that organization handled other activities on the property?

How organized is your Practice and work area? Is there dust, grease, food scraps, eye irritants, trash, or other unclean issues in the work space? An unclean office setting hides safety hazards, health risks, and equipment problems, shows a lack of pride in work, and signals a host of other issues. If your office does look clean on the surface, how about the way paperwork is stored in your Practice? Does the doctor have all of the correct files available at a single glance, or is everything stored in patient files so that each packet is different? How much time do patients have to wait in the various waiting rooms in your Practice? How about other personnel that work in the Practice? Is everything available in a timely, orderly manner, or is information typically missing or hard to find when needed to accomplish the tasks at hand?

It has been researched and proven that cleanliness/orderliness at home and work leads to much more productive settings and more pride in what we do. Some people feel that far too much time is spent talking about uncleanliness and
disorder; however, it has been shown to be one of the more important factors contributing to why things do not always work the way they are supposed to. When things are not organized and clean, the likelihood of something going wrong increases exponentially.

The Japanese created a process referred to as the 5S method, which work groups use to ensure a clean, organized, and safe work environment (see Table 1). Many work teams spend a specific amount of time each day to ensure that their work areas are cleaned. This has the added benefit of allowing the staff who use the work area to take a close look at their environment for signs of future trouble.

The classic 5S includes sort, set in order, shine, standardize, and sustain. For 7S, we are adding safety, oversight.

<table>
<thead>
<tr>
<th>Japanese (S)</th>
<th>Translation</th>
<th>English (S)</th>
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<tbody>
<tr>
<td>Seiri</td>
<td>Cleaning up</td>
<td>Sort</td>
</tr>
<tr>
<td>Seiton</td>
<td>Organizing</td>
<td>Set</td>
</tr>
<tr>
<td>Seiso</td>
<td>Cleaning</td>
<td>Shine</td>
</tr>
<tr>
<td>Seiketsu</td>
<td>Standardizing</td>
<td>Standardize</td>
</tr>
<tr>
<td>Shitsuke</td>
<td>Training &amp; discipline</td>
<td>Sustain</td>
</tr>
</tbody>
</table>
The 5S method was created for a manufacturing setting. In a medical Practice, we must also be on high alert to ensure the safety of staff and patients as well as the oversight of our processes. Thus, we now have what can be called the 7S for the healthcare Practice. These sets include:

- **Sort.** Review and sort work tools and materials to ensure that all unnecessary items are removed and to ensure workplace organization. Look for unnoticed dangers: unprotected moving objects (such as file drawers), exposed or damaged electrical wires, and other issues that might get in the way of doing the work safely.

- **Set in order.** Have a place for everything and keep everything in its place when not in use. People need to know where things are supposed to be. Also, apply ergonomics to help prevent movement injuries.

- **Shine.** Clean everything in the work area inside and out regularly, inspecting each item for signs of defects or wear or other signs of future trouble.

- **Standardize.** Using the first three S’s, establish a pattern of how things are to be done. This is not meant to reduce creativity, but to help ensure that things
are done in a way that helps to reduce variation in the process. Continually maintain what has been accomplished and ensure that standards are lived up to.

- **Safety.** The process of avoiding injuries to patients from the care that is intended to help them.

- **Oversight.** Medical oversight is the process of reviewing care that is provided to patients, to ensure their safety.

- **Sustain.** Reinforce all of the above to ensure that this process becomes a part of your daily work.

The task for you and your fellow staff is to clean your work areas, address any unsafe issues that currently exist, and prevent those that may occur in the future. Put a red tag or other identification on anything that should be addressed. If there is a safety officer in your organization, ask him or her to periodically check your work space to help ensure a safe and clean working environment.
Have you ever heard the old saying “a stitch in time saves nine” or “an ounce of prevention is worth a pound of cure”? How about “measure twice, cut once”? What do these sayings mean? Most people will answer by saying that if you plan ahead of time, you can save time, money, resources, and sometimes frustration. In my own experience I have sometimes started a project only to have the parameters change later and have to redo work that was already done. The idea that we can plan, as best as possible, ahead of time to help prevent surprises and save valuable resources works in our jobs as well as in our homes. Anything that is to be done can be thought out first, or written plans can be completed to lay out a blueprint of what we are going to do.
This concept is referred to as *advanced practice quality planning*, or healthcare APQP.

APQP is a process whereby we first look at the parameters of what we are going to do. Do we have the right amount of resources or material available? Do we have the right people to do the job or provide the service? Do we have the right tools or training to do the job well? Do we know the correct way of using everything we have to provide a safe environment for ourselves, our patients, and other customers? All these questions, and many more, should be answered before we start work! One of several tools you can use to ensure that you have thought of all the elements (causes) that will give you the desired output or effect is the cause-and-effect diagram (see page 79). You can also think of APQP as the first step of the PDSA cycle, where you are going to *plan* before you *do* something.

In planning to meet future medical requirements, such as those espoused by the Committee on Quality of Health Care in America in *Crossing the Quality Chasm* (2001), we must ensure that the six aims for improvement are addressed:

- **Safe.** Avoiding injuries to patients from the care that is intended to help them.

- **Effective.** Providing services based on scientific knowledge to all who could benefit, and refraining from providing
services to those not likely to benefit (avoiding underuse and overuse, respectively).

- **Patient-centered.** Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.

- **Timely.** Reducing waits and sometimes harmful delays for both those who receive and those who give care.

- **Efficient.** Avoiding waste, including waste of equipment, suppliers, ideas, and energy.

- **Equitable.** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

Your organization may very well use some of the traditional quality tools (check sheets, run charts, Pareto diagrams, and so on) to ensure that the elements of APQP are being done in your organization prior to starting a new project or job. Tools such as check sheets can take on many forms and can be designed using the cause-and-effect diagram as a guide to help ensure completeness. You can and should use the various tools reviewed in this guidebook to help
ensure that the work you are going to do is of the best quality and reduces the greatest amount of time and wasted effort possible. The typical APQP model shown in Figure 11 incorporates a lot of the tools and strategies found in this book. Your role in this process is to ensure that the work you will be doing is the best given the tools and resources provided by management.

![Figure 11](The APQP model.)
Most people have heard of certified public accountants, or CPAs. A CPA maintains and checks financial records to ensure accuracy of the numbers. We need to work with our management in checking the working processes in our organizations to ensure that the processes are doing what they are designed to do.

This checking process is sometimes called quality auditing, and it is commonly done in organizations that are ISO 9001 registered or have applied for a quality award (Baldrige or state-level awards). Many customers require their suppliers to check their products and services before they are delivered. This is one reason your organization may have personnel designated to review items in the Practice for accuracy. This is com-
monly called *inspection*. Quality auditing is similar to inspection in that we are looking at how the *process* is doing instead of looking at specific parts or services that have been provided. Some organizations (as medical device manufacturers and pharmaceutical companies) use supplier quality engineers to visit their suppliers and/or perform incoming inspection to check products as parts are received from their suppliers.

The first thing you need to know if asked to audit something is “What is the standard that I will be auditing against?” If you are going to conduct a process audit in another department, you must ensure that there are standard operating procedures (SOPs) or some other form of process sheets that are used to ensure that things are being done in a standardized manner. If you were to conduct a safety audit, then having the written safety rules would be important. As you are starting to see, there are a number of things that can be audited. Some others are cleanliness, quality of product, quality of service, knowledge of the system, and emergency procedures. If your Practice is ISO 9000 or ISO 14000 registered, you already know a number of things that can be audited. If you have not seen either of these standards, you may wish to ask your supervisors about getting a copy.

As organizations move to become registered to national or international standards such as
ISO 9001 or ISO 14001, they will train some of their internal people to conduct quality system audits. This is to ensure that the system that the management has established is in fact working the way it was intended to. As an employee in a Practice you would be trained in auditing techniques and assigned to auditing teams that will periodically check the processes of other activities within your organization. This process of quality auditing is very different from what the Internal Revenue Service (IRS) does when they call taxpayers in for a financial review. When you are asked to be part of an audit team, you need to be aware of some basic guidelines:

- Be pleasant to the person being audited. You are not a cop looking to catch him or her doing something wrong.

- Be factual in what you observe. Hiding things does not help the company improve, and being too critical may harm personal objectivity.

- Be thorough in looking at the process as it relates to the standard. If you miss something, customer satisfaction may suffer or, worse yet, someone might get hurt.

- Ask questions for clarity. You want to be as positive as possible given the situation.
• Record your observations for the record and the next person who will audit the area.

• Follow what the internal lead auditor directs you to do.

Being an internal auditor for your organization can be both challenging and informative. We usually get a better view of what our company is doing if we have a chance to look at its activities. For some of us, it breaks up our everyday routine and gives us a chance to see how others might be doing things and to benchmark (see the next section) that against what we do.

Sampling is a methodology that reviews/inspects a small segment of some larger process/population to make a judgment/inference about the entire process. This idea works in part based on the central limit theorem, which basically states that over time, things tend to follow patterns. An example of this would be to simply flip a coin. Your basic assumption is that a coin is fair and that for any group (say 10 to 50) of flips that you should get roughly 50 percent heads and 50 percent tails. This is not always true, so we could do samples of flipping a coin to verify how “fair” the coin really is.

A sampling plan is a structured, planned sequence of samples that are to be taken on a given activity or process to verify the state of goodness of the process.
Benchmarking is the process of looking at a system and applying some or all of its concepts to another system. Granite Rock, a Malcolm Baldrige National Quality Award–winning company located in California, has used benchmarking in a dramatic way. Its processes had been the same as those of nearly any gravel yard in the United States. Any time a customer wanted some road materials it sent a truck and driver to the yard. The driver then placed the order at the front office and waited for a Granite Rock employee to get a front-end loader, go into the yard to obtain the material, and fill the truck with the appropriate amount. Then Granite Rock decided to capitalize on the technology of the ATM, the automated banking machine that
allows a customer to walk up and, by inputting some basic data, handle any number of banking transactions. The new process that Granite Rock developed allows the truck driver to pull into an area with overhead filling stations (instead of going to an office first) and punch in their customer codes and the materials desired. The material is automatically loaded into the truck. This new process cuts wait time to minutes instead of hours and allows customers to get materials 24 hours a day, seven days a week, year-round.

Some managers think benchmarking is only about taking trips to competing organizations and trying to copy something they do that is felt to be better than what is currently being done in their own organizations. During the late 1970s and early 1980s many managers went to Japan to learn what was being done there and to see why Japanese quality was so much better than that in the United States. Most of those trips resulted in disappointment as you can’t always see a physical difference in activities. Sometimes it is the small, subtle things that Practice staff have learned over time and shared with fellow workers that make the big difference.

Here are the basic process steps of benchmarking:

1. Flowchart the current process.

2. Identify the areas to be improved.
3. Brainstorm ideas (blue sky—this term is discussed under “Brainstorming”).

4. Investigate how others (internal and external) do similar processes.

5. Develop plans for application of ideas.

6. Pilot test ideas.

7. Initiate the new process.

8. Evaluate the new process.

Before starting a benchmarking project, you are advised to make sure you know exactly how your current process works. That may sound funny, but it has been shown that when people attempt to flowchart a process (see “Flowchart” section), there is often a lot of disagreement about the exact steps and/or the order of those steps. Thus, any time there is more than one person who performs a task in or around your Practice, the process should be flowcharted.

Once everyone agrees on how a process operates, you can start looking at the process for bottlenecks or other things that may not work or flow as well as you might wish. This could be anything about the current process from wanting to reduce the amount of variation in one part of the process to changing certain things about it that may help employees’ ergonomics. In looking at the process, it sometimes helps to get as creative
as you can and ask, “What if?” This is the “blue sky” part of benchmarking. What might this process look like in an ideal world? If money and technology were no object, how might it work? If we had the technology, what could happen?

Now it is time to do some research about how others, internal or external to your organization, may do similar things. By becoming internal auditors (discussed in “Auditing”), we sometimes get to see how others do similar things in our own organizations. Also, as in the case of Granite Rock (see “Auditing”), sometimes going outside the industry helps give you ideas about a different way of doing things. Say you need to move something from one place to another; maybe looking at mail service or delivery organizations would help.

Once you have seen other ways of doing things, it is time to figure out how you can do things differently in your own operation. Establish a plan for the changes, and acquire the needed resources from management. The plan should list the materials needed, when and where new activities will be initiated, any training that may be needed and when it will take place, and other details that allow for the changeover to the new idea. Then prepare and run a pilot test to ensure that the plan will work. Generally it is unwise to just jump right in with the new idea without testing it first. Even the best-laid plans may have
unforeseen bugs that can cause problems, so run a small test first.

As you move forward into the new operation, you should monitor it carefully to ensure that it lives up to your hopes for the new process. Sometimes changeovers will be conducted in stages instead of all at once. Either way, watch and evaluate the process to ensure that you are still meeting the customer’s wants and needs—and doing it faster, better, and/or cheaper than before.

A point to remember: Walt Disney was well known for showing any carnival company exactly how Disneyland was set up and operated. One day, after being criticized for this, Walt said, “I hope they copy me. That way as I create new things, they will always be playing catch-up, while I have the newest and greatest.” Benchmarking is not just about copying something; it is about looking at our processes for ways of doing things better overall. The challenge is to distance yourself from the way that it has always been done to see if other methods or technologies now exist that might help you in your work areas.


**BRAINSTORMING**

*Brainstorming* is the process whereby an individual, group, or team develops as many ideas about a topic as possible using various creativity techniques or methods. Two basic phases make up brainstorming: the creative phase, which is used to generate a large number of ideas, and the evaluation phase, where the ideas generated are evaluated for usefulness or practicality. Note that the team should take a break time between the two phases, as different parts of the brain are used in each phase. At a minimum, a 10-minute stretch break should be taken instead of going directly into the evaluation mode after being creative.

It is very important that during the creative phase no criticism or other distractions are allowed. Team members should keep their minds
open to all possibilities, no matter how wild the idea. One method here is to call for “blue sky”—that is, if anything were possible, what might it be? During this phase of brainstorming, the goal is to generate as many ideas as possible. If ideas are being put on a flip chart with a large group, you should have two or more recorders available to capture all the ideas as they develop. Otherwise you can have each person say what he or she is thinking and have him or her or another group member record the idea on a sticky note and put it on the wall. Facilitation can be used during the creative phase, but freewheeling also works well. Here are some basic guidelines for the creative phase of brainstorming:

- No criticism, compliments, or questions allowed
- Wild ideas are welcome
- Don’t wait
- Quantity is important (versus quality, at this stage)
- Hitchhike—build on previous ideas
- Think beyond the current way of doing things
- Think how things might be done 30 years from now
During the evaluation phase it is best to have a facilitator work with the group to look over the ideas in a sequence. There are many ways to go about evaluating the ideas you have generated. One good starting point is to organize the list of ideas into like groups or categories to help in the evaluation process. The caution here is not to get overly critical, as there may be something in one of those “crazy” ideas that might actually work for the given situation. This is often true because of new technology or different ways of doing things that are not common in your organization.

The brainstorming process can be fun and hard work at the same time. The main purpose is to “think outside the box” to get a new perspective on doing your own job. If you are unsure what “outside the box” means, try this exercise: In Figure 12, try connecting all the dots by drawing four consecutive straight lines without

![Nine dot exercise](image)

**Figure 12** Nine dot exercise.
lifting the pencil (or pen) off of the paper. One possible answer appears on page 216.

The brainstorming technique can be very helpful in looking at a process from all angles. It is also helpful if the group working on the project is cross-functional to the Practice, that is, comprising people who work in different parts of the healthcare community. And, optimally, people from various areas and levels of responsibility should be included in the brainstorming group. But during this exercise there should be no rank or level of employee recognized. Everyone has an equal right to say what he or she thinks, from the floor sweeper to the president. However, a few comments to watch out for are listed here as idea stoppers—they are warning signals that the brainstorming process may not be working as well as it could. If any of these idea stoppers come up during the meeting, stop and address them right away so the group or session can move forward in a positive manner:
Idea Stoppers

Don’t be ridiculous.  We’ve never done it before.
Let’s shelve it for right now.  I have something better.
It won’t work here.  It’s too risky.
Our business is different.  Let’s be sensible.
Let’s think about it some more.  We’ll never get it approved.
We did all right without it.  They won’t like it.
It’s too radical a change.  It’s good, but . . .
Management won’t like it.  Let’s check on it later.
Where did you dig up that idea?  Too much work.
It’s not practical.  Let’s get back to reality.
It’s too expensive.  That’s been tried before.
You can’t be serious.  That’s not my job.
You can’t do that.  You do not know how we do things around here.
The technology will not allow that.  That’s too high-tech for us.
Where did you get . . .  It will never work.
BUSINESS OPERATING SYSTEM (BOS) FOR HEALTHCARE ORGANIZATIONS

BOS (AIAG 2007) is a process that aims to aid in the development or improvement of a fundamental management system for healthcare organizations that provides for continual improvement, emphasizing error or adverse-event prevention and the reduction of variation and organizational waste.

The BOS process focuses on the objectives of:

- Providing process improvements to increase the value added to the organization, customers, and stakeholders
- Improving delivered healthcare quality and safety to complement existing accreditation, or to aid in
achieving accreditation, certifications, or registrations

• Improving the image of the organization, increasing customer confidence, and having a tool to reward results

• Developing/incorporating a process that is actionable

• Minimizing burden on healthcare organizations

• Aligning with the Malcom Baldrige National Quality Award Program’s Healthcare Criteria for Performance Excellence to help the organization prepare for state, national, or international award programs.

The Healthcare Criteria are built on the following set of interrelated core values and concepts:

• Visionary leadership

• Patient-focused excellence

• Organizational and personal learning

• Valuing staff and partners

• Agility

• Focus on the future

• Managing for innovation
• Management by fact
• Social responsibility and community health
• Focus on results and creating value
• Systems perspective
Originally developed in the 1940s by Kaoru Ishikawa in Japan, the *cause-and-effect diagram* is a graphical analysis tool that allows the user to display the factors involved in a given situation. “Cause-and-effect diagrams are drawn to clearly illustrate the various causes \((x)\) affecting product quality by sorting out and relating the causes. Therefore, a good cause-and-effect diagram is one that fits the purpose, and there is no one definite form” (Ishikawa 1976). The causes can be any item or occurrence that is related to the effect \((Y)\) being studied. Thus, the effect is a function of the causes: \(Y = f(x)\). This tool is sometimes called an Ishikawa diagram (for its originator) or a fishbone diagram, or even a feather
Figure 13  A basic cause-and-effect diagram.

diagram, given the shape of the graphic (see Figure 13).

Reminder: Ask the five W’s and H: what, why, when, where, who, and how.

When creating this diagram, it is best to try to keep an open mind and to work as a team to view and discuss what the system or process is doing. You want to capture everything you can about the process, looking for all the actual activities in the process, not just what you think is happening. Besides using the five W’s and H in creating the cause-and-effect diagram, some people use brainstorming, but many people start by reviewing some of the eight M’s:

- Man (people—Practice staff)
- Machine (equipment)
• Methods (operating procedures)
• Materials
• Measurement
• Mother Nature (environment)
• Management (person[s] who runs or directs the Practice)
• Money

This tool is relatively simple to use, yet it is very powerful. Once completed, it graphically portrays the factors of the process to management and other teams. Imagine you want to have donuts at your next team meeting. What are some of the factors that would be involved? You first need to decide where the donuts will come from, what type you want, who will make or buy them, and other issues. A simple cause-and-effect diagram for this appears in Figure 14.

As the team works on the process, more detail can be added to the diagram. Let’s say that in our donut example the team wants to look at the measurement stem of the diagram to see how the amount of cream in the donut could vary. Some factors you might add are consistency of the cream, types of cream used, size of insertion equipment, cooking temperature effect on cream, and so on (see Figure 15). This allows the team to get as detailed as needed to ensure
Figure 14  Cause-and-effect diagram for donuts.

Figure 15  Cause-and-effect stem: measurement breakdown.
that it understands the process and can show the causes and effects of the given situation. Once completed, the cause-and-effect diagram can be shown to other groups (for example, accountants, maintenance, administrators, other Practice staff, management, customers, suppliers) as a visual aid or training aid so that everyone involved in the activity understands what the process is doing.
A check sheet (sometimes called a checklist) is any set of words, tally lists, or graphics designed to assist us in conducting a planned review or observation of our process or system. An aircraft pilot, before taking off or landing a plane, is required to use a check sheet to ensure proper operation of the airplane (see Figure 16). For us in the healthcare Practice, check sheets can either be a list of things to do or a data collection method that allows us to tally the issues/items being monitored on a list or on a pictorial image.

As can be seen in Figures 17 and 18, these check sheets are designed to collect data for analytical purposes from our work areas. Practice staff need to have simple tools that allow for quick and easy collection of data. During the
Preflight Inspection: Cessna 152

1) CABIN
   1. Control Wheel Lock—Remove
   2. Ignition Switch—OFF
   3. Master Switch—ON
   4. Fuel Quantity Indicators—CHECK QUANTITY
   5. Fuel Shutoff Valve—ON

2) EMPENNAGE
   1. Rudder Gust Lock—REMOVE
   2. Tail Tie-Down—DISCONNECT
   3. Control Surfaces—CHECK freedom of movement and security

3) RIGHT WING Trailing Edge
   1. Aileron—CHECK freedom of movement and security

4) RIGHT WING
   1. Wing Tie-Down—DISCONNECT
   2. Main Wheel Tire—CHECK for proper inflation
   3. Before first flight of the day and after each refueling, use sampler cup and drain small quantity of fuel from fuel tank sump quick-drain valve to check for water, sediment, and proper fuel grade.
   4. Fuel Quantity—CHECK VISUALLY for desired level
   5. Fuel Filler Cup—SECURE

5) NOSE
   1. Engine Oil Level—CHECK, do not operate with less than four quarts. Fill to six quarts for extended flight.

*Figure 16*  Cessna 152 checklist.
Game day: 6/1/09  
Opponent: Falcons  
Final score: 4 to 2 W

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**Totals** | 11     | 5    | 3   | 4   | 2   | 1    | 3   | 16  |       |

**Figure 17**  Traditional check sheet.
collection of data on a check sheet, it is common to see developing patterns or trends that may affect the outcome of a process. This is especially true in healthcare settings where we do not see repetitive activities on a daily basis. You want to make this data collection as easy as possible; otherwise the information you obtain may not be as reliable as you need or the time it takes you to collect the data may be prohibitive. Here are the basic steps in making a check sheet:

1. Identify and agree on the causes or conditions that are to be collected.
2. Decide who will collect the data, over what time period or periods, and how the data will be collected.

3. Create a check sheet that will work in the area where it is to be used.

4. Collect the data as designed to ensure consistency and accuracy of the information.

Check sheets can be the basis for other analytical tools and are often incorporated into attribute process behavior charts (discussed under “Process Behavior Charts”). It is sometimes surprising how just creating and using a check sheet can help you focus on continual improvement and how changes may occur just because of the use of the check sheet. As you strive to improve your organization using the tools of Lean Six Sigma, check sheets become a powerful tool.
Continual improvement (CI) is the process of keeping an open mind and looking for ways to make the things that you do better, do them less expensively, or do them faster. As the Industrial Revolution progressed into the early 1900s, Frederick Taylor developed a method of work specialization that many organizations still use today. It was during this time that workers first stopped checking their own work, and specialized inspectors were employed in inspection teams. This process developed for several decades, and professional organizations were born that focused on doing inspection better.

During the late 1920s Walter Shewhart developed the first control chart, and statistical process control (SPC) was born (some now call this
process behavior charting). Many organizations continued to rely on inspectors, but the use of charting, which could bring the staff back into the process of looking at the quality of their work, became a requirement in the United States during World War II. It was in 1951 that Armand Feigenbaum first published his book *Total Quality Control*, and the TQM (total quality management) age commenced.

During the 1960s and 1970s the use of quality circles and employee involvement became the next evolutionary phase in continual improvement. This was followed by a major resurgence of SPC during the 1980s. During the 1990s the International Organization for Standardization’s quality management system (QMS) ISO 9000, and the Malcolm Baldrige National Quality Award were the major advances in continual improvement. With the turn of the century, Six Sigma started receiving a lot of attention.

Other terms used of late include value analysis/value engineering, lean manufacturing/lean office, kaizen, poka-yoke, and others. Lean Six Sigma is the latest wave in the ongoing continual improvement movement and is bringing together many fields of study and putting them in the hands of the people doing the work.

Some people refer to these various methods as continuous improvement because they feel
we should always make breakthrough strides in everything we do. Unfortunately, nature and human beings do not work that way. Even in evolution, things have to step back or level off every now and then. As we learn new things, sometimes humans have to relearn old knowledge. Thus Dr. Deming changed the term *continuous* to *continual*.

Concurrent with this change, Dr. Deming also developed a system he called *profound knowledge*. This concept involves the following: appreciation for a system, knowledge about variation, theory of knowledge, and psychology. By using each of these aspects of profound knowledge, continual improvement can and will become a reality in our organizations. Our goal is always to maintain and improve the quality of the products or services we provide to customers, both internal and external.

One common way of implementing continual improvement is to use the PDSA cycle (see) and SDCA cycle (see “Standardization”) together (see Figure 19): the Practice staffer will see a complete process for identifying processes, improving those processes, and applying lessons learned. The two cycles working together with the other tools in this book will help the Practice worker to continually improve the work that is done with an eye to satisfying the customer.
Kaizen is a Japanese term that literally means continuous improvement.

A kaizen event is a preplanned activity or sequence of actions to be taken over a short period of time to make/allow for a desired outcome to occur. An example of a kaizen event could be the planned rearrangement of the Practice furniture based on studies conducted to improve the workflow to better satisfy patients or the workflow of the Practice. Another example might be a special one- or two-day effort to load patient chart data into a registry to allow for better utilization of information and for preplanning of patient visits.

Figure 19 PDSA and SDCA working together.
Cost–Benefit Analysis

(COST OF QUALITY, QUALITY COST, COST OF POOR QUALITY, RETURN ON INVESTMENT)

Cost–benefit analysis is a financial tool that reports how quality levels are being sustained in the Practice and its patient base. Many costs in the Practice can be classified into one of four categories: prevention costs, appraisal costs, internal failure costs, or external failure costs. However, not all expenses of the company are used for the cost–benefit analysis, only those that relate in some way to products or services that we deliver to our customers (see Table 2). The real power of this tool is not so much in our using the exact or “right” measures for each expense, but in looking at trends over time to see how the organization
<table>
<thead>
<tr>
<th>Prevention costs</th>
<th>Appraisal costs</th>
<th>Internal failure costs</th>
<th>External failure costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing/customer/ user</td>
<td>Purchasing appraisal costs</td>
<td>Product/service design failure costs (internal)</td>
<td>Complaint investigations/ customer or user service</td>
</tr>
<tr>
<td>Product/service/ design development</td>
<td>Operations (manufacturing or service) appraisal costs</td>
<td>Purchasing failure costs</td>
<td>Returned goods</td>
</tr>
<tr>
<td>Purchasing prevention costs</td>
<td>External appraisal costs</td>
<td>Operations (product or service) failure costs</td>
<td>Retrofit costs</td>
</tr>
<tr>
<td>Operations (manufacturing or service) prevention costs</td>
<td>Review of test and inspection data</td>
<td>Other internal failure costs</td>
<td>Warranty claims</td>
</tr>
<tr>
<td>Quality administration</td>
<td>Miscellaneous quality evaluations</td>
<td></td>
<td>Liability costs</td>
</tr>
<tr>
<td>Other prevention costs</td>
<td></td>
<td></td>
<td>Penalties Customer/user goodwill Lost sales Other external failure costs</td>
</tr>
</tbody>
</table>
is doing. We want to look at what the total cost is to provide our customers with products and services.

Traditionally, when cost of quality is first calculated for an organization, a picture such as that in Figure 20 will emerge. This is partly because many accountants and managers have not been taught about this tool in their formal education, nor does any government or professional organization require the reporting of financial data in this format.

Organizations that have learned to use the cost–benefit analysis of quality costs typically are very surprised at the amount of waste that they’re producing. By focusing on prevention and

![Figure 20](image-url)  
**Figure 20** Traditional quality costs.
appraisal activities, the failure costs will slowly start to come down. This will not happen overnight, and it may take years in some stubborn cases to show improvement as the old procedures work their way out of your organization’s system.

No one should be blamed for the poor results of the first measurement. It is important to look at those numbers as a benchmark against which to measure improvement. The results of the first measurement should be made available to everyone in the Practice so that people can start to generate ideas about what can be done and how to go about doing it. There’s an old adage: “What gets measured, gets done!” Thus, if everyone knows that management is watching the numbers of the cost–benefit analysis, things should start to improve.

The ultimate goal is to change the overall picture to look like the one in Figure 21. As an organization continually improves its operations, it will see an overall reduction in the total cost to provide its products and services.
Figure 21  Quality costs—moving to continual improvement.
Once you identify the boundaries of your process (see “SIPOC Diagram” and “Process Identification”), you can now set a starting benchmark for what is being done. Knowing what is happening currently will give you a base from which to evaluate the effect of future improvements. It is surprising to note that many healthcare organizations do not know what their cycle times are nor what the yield of the process is. Yield can be defined as the total number of units handled correctly (with no rework or rechecking) through the process step(s).

In using the cycle time or yield tool, one common approach is to look at the value added for each step in the process. Do items, people, or information sit around in holding patterns
waiting for something to be done? Are multiple reviews or signatures required where no value is added (does the item really need the VP’s signature, which in reality is only a rubber stamp)? How long is it currently taking to accomplish all the process steps versus how long it should take the information or item to go through the system? A common suggestion is to imagine yourself as the object or item going through your system and see what is really going on. From this perspective, you can then look for possible areas of improvement.

The four basic principles of cycle time reduction are: eliminate, combine, simplify, and change. Can certain steps be eliminated? These could be sorting, storage, or movement of the item or information. Can some of the steps be combined? This could be having the same person do multiple activities at the same time or having the customer speak to only one person instead of several. Can the steps or information be simplified in some way? Is a complicated form really necessary or is it just the way things are done? Finally, should things or the process be changed? The “current state,” “could be,” and “should be” flowchart maps are useful at this point to look at ways to make changes (see “Flowchart”).

Your manager or supervisor may have you collect information about the cycle times in
your process to calculate something call *rolled throughput yield*. This is a measure used to track the overall process as to the quality output of your system. It is a good metric to use to evaluate your success in how the process is being improved.

A cycle time analysis was conducted at a Practice where a quality improvement coach (QIC) noted that a lot of billing errors were being returned from the payer. In following the trail back through the various personnel in the Practice, the root cause was discovered to be the poor handwriting of the doctor and the first person to have to input the information into the computer system for billing purposes. Since it was so hard to track down the doctor each time the person had a question (which was happening many time each day), the person had to guess at what they thought the doctor intended. The data clerk was able to guess correctly only some of the time. Thus the Practice was forced to hire two people (one data entry clerk and one person to chase down the errors for correcting billing issues) to handle the workload. Finding a better way for the doctor to communicate his/her intent to the computer system would allow for one full-time person to be better utilized to add value to the Practice instead of chasing down errors.
The failure mode and effects analysis (FMEA) was first extensively used in the aerospace industry in the 1960s to look at all the possible effects of failure of a given piece of equipment. (The concept of FMEA was first developed in 1949.) These documents typically have been created by engineers or the quality officer and often do not get down to the shop floor or to the work areas where they are needed. Sometimes three versions of the FMEA are created during the design, development, and implementation of a new service. The system FMEA looks at the concept of creating a new service, what the effects on the service might be, and what Practice staff may need to go through to be able to provide the service. Design engineers use the design FMEA to determine
how the service should be offered. The process FMEA (the one staff should have available to them) looks at how the service actually is provided and the various effects that can arise.

The process FMEA is useful because it analyzes the operation to determine what could go wrong if things are not controlled, maintained, and set up properly, and what to do about each issue. If done well, the FMEA should predict what could happen if something goes wrong in the process and assign a priority number for each issue raised. One of the more famous FMEAs was done on O-rings used in the space shuttle program. Engineers predicted that if a certain series of environmental circumstances occurred, the shuttle would blow up on takeoff. Sadly, we all know what eventually happened.

If you have never seen an FMEA for your operation (see Figure 22), you should ask your supervisor or local expert if one exists. Otherwise, you might ask whether someone could work with you to create a process FMEA for your work area. The process of developing this document will assist you in a number of ways: it will help ensure that the processes in your work area are running as smoothly as they can given the current environment, and it will help you look for initial areas of improvement in your Practice.

The FMEA is a matrix of process issues that could happen in the system. A numerical scale
### System FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The problem</td>
<td>The ramifications of the problem</td>
<td>The cause(s) of the problem</td>
</tr>
</tbody>
</table>

### Design FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The causes of the problem from the system FMEA</td>
<td>The effect from the system FMEA with perhaps a better definition</td>
<td>New root causes for the design failure modes</td>
</tr>
</tbody>
</table>

### Process FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The causes of the problem from the design FMEA</td>
<td>The same effect as the design FMEA</td>
<td>Specific root causes for the process failure modes</td>
</tr>
</tbody>
</table>

**Note:** It is not unusual to have an iteration of the causes in a process FMEA. The flow of the iteration is demonstrated. The iteration stops when the RPN is sufficiently low—less than 50 in a 1 to 10 guideline scale.

**Figure 22** Relationships of a process FMEA in an iteration mode of failure identification.

has been developed to look at the severity of an issue, the likelihood of occurrence, and the possibility of detecting an issue during the current operation before it gets downstream. One typical set of scores is shown in Figures 23 through 25. (Granted that these are manufacturing examples; adaptation will have to be made to your Practice setting.)

The three scores in the tables are then multiplied across the matrix to get a single number called the risk priority number (RPN), which is used by management to decide what issues, if any, need to be addressed further. This document should give the Practice worker a clear picture of the operation and how the service should be provided.
<table>
<thead>
<tr>
<th>Rank</th>
<th>Resolution</th>
<th>Resolution</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor: Unreasonable to expect that the minor nature of this failure would cause any real effect on the product and/or service. Customer will probably not even notice the failure.</td>
<td>Unreasonable to expect that the minor nature of the failure would cause any noticeable effect on the product and/or the service. Customer most likely will not be able to detect the failure.</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number. If the team has a disagreement in the ranking value, the following may help:</td>
</tr>
<tr>
<td>2–3</td>
<td>Low: Low severity ranking due to nature of failure causing only a slight customer annoyance. Customer probably will notice a slight deterioration of the product and/or service, a slight inconvenience in the next process, or minor rework action.</td>
<td>Low severity ranking due to slight annoyance of the failure. Customer probably will notice a very minor deterioration of the product and/or service.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8, \frac{8}{2} = 4$).</td>
</tr>
</tbody>
</table>

Figure 23  Severity process and/or service guideline.*

*All of the above guidelines and rankings may be changed to reflect specific situations.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Failure Mode and Effects Analysis (FMEA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4–6</td>
<td>Moderate: Moderate ranking because failure causes some dissatisfaction. Customer is made uncomfortable or is annoyed by the failure. May cause the use of unscheduled repairs and/or damage to equipment.</td>
</tr>
</tbody>
</table>

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in the team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.

Figure 23  Continued.
<table>
<thead>
<tr>
<th>Rank</th>
<th>Resolution</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–8</td>
<td>High: High degree of customer dissatisfaction due to the nature of the failure, such as an inoperable product or inoperative convenience. Does not involve safety issues or government regulations. May cause disruptions to subsequent processes and/or services.</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number. If the team has a disagreement in the ranking value, the following may help: 1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8$, $8/2 = 4$).</td>
</tr>
</tbody>
</table>

*Figure 23  Continued.*
<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>9–10</td>
<td>Very high: Very high severity is when the failure affects safety or involves noncompliance with government regulations. In this scale 9–10 is reserved only for safety and government compliance requirements. All other rankings may be used as they seem applicable.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in the team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
</tbody>
</table>
### Resolution

If the numerical value falls between two numbers, always select the higher number.

If the team has a disagreement in the ranking value, the following may help:

1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8$, $8/2 = 4$).

### Failure Mode and Effect Analysis (FMEA)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Failure is unlikely. $C_{pk}$ greater than or equal to 1.67 ($&lt;1 \times 10^6 \text{ or } \approx \pm 5\sigma$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Very low: Process in statistical control. Isolated failures exist. $C_{pk}$ is greater than or equal to 1.33 ($1 \text{ in } 20,000 \text{ or } \approx \pm 4\sigma$)</td>
</tr>
<tr>
<td>2</td>
<td>Low: Process in statistical control. Isolated failures occur sometimes. $C_{pk}$ is greater than or equal to 1.00 ($1 \text{ in } 4000 \text{ or } \approx \pm 3.5\sigma$)</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Process in statistical control with occasional failures but not in major proportions. $C_{pk}$ is less than or equal to 1.00 ($1 \text{ in } 1000 \text{ or } 1 \text{ in } 80 \approx \pm 3\sigma$)</td>
</tr>
</tbody>
</table>

### Figure 24  Occurrence process and/or service guideline.*

*All of the above guidelines and rankings may be changed to reflect specific situations.

### Failure Mode and Effects Analysis (FMEA)

#### Resolution

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in the team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.

#### Table

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>8–9</td>
<td>High probability of occurrence. Process in statistical control with failures often occurring. Capability shows $X$-bar $\pm 1.5\sigma (1/100–1/20)$</td>
<td>7–8</td>
<td>High: Process not in statistical control. Have failures often (1/40–1/20).</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Very high probability of occurrence. Failure is almost certain. (1/10+)</td>
<td>9–10</td>
<td>Very high: Failures are inevitable.</td>
<td></td>
</tr>
</tbody>
</table>

*Note:* To use a criteria scale such as this, one must have a substantial amount of data to support statistical control and $C_{pk}$ values. This is a very powerful scale if one has the data; if not, do not try to generate the data to support the scale. Use a theoretical scale that is more qualitative but through the synergy of the team becomes just as powerful.

---

**Figure 24  Continued.**
<table>
<thead>
<tr>
<th>Resolution</th>
<th>Remote likelihood that the product or service will be delivered (1/10,000). The defect is functionally obvious and readily detected. Detection reliability at least 99.99 percent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution</td>
<td>Low likelihood that the product would be delivered with the defect. The defect is obvious (1/5000–1/500). Detection reliability at least 99.80 percent.</td>
</tr>
<tr>
<td>Resolution</td>
<td>Moderate likelihood that the product will be delivered with the defect. The defect is easily identified (1/200–1/50). Detection reliability at least 98.00 percent.</td>
</tr>
<tr>
<td>Resolution</td>
<td>If the numerical value falls between two numbers, always select the higher number. If the team has a disagreement in the ranking value, the following may help: 1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 + 6 = 8, 8/2 = 4).</td>
</tr>
</tbody>
</table>

Figure 25 Detection process and/or service guideline.*

*All of the above guidelines and rankings may be changed to reflect specific situations.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Rank</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Low: Controls more than likely will not detect the existence of a defect.</td>
<td>High likelihood that the product would be delivered with the defect. The defect is subtle (1/20). Detection reliability greater than 90 percent.</td>
</tr>
<tr>
<td>10</td>
<td>Very low: Controls very likely will not detect the existence of a defect.</td>
<td>Very high likelihood that the product and/or service will be delivered with the defect. Item is usually not checked or not checkable. Quite often the defect is latent and would not appear during the process or service (1/10+). Detection reliability 90 percent or less.</td>
</tr>
</tbody>
</table>

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in the team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.

Figure 25  Continued.
FLOWCHART (FLOW MAP, PROCESS MAP, CURRENT STATE/COULD BE/SHOULD BE MAP)

When you create a flowchart, you are creating a picture of the steps in a process or system as it actually operates or is supposed to operate. Given the old adage that a picture is worth a thousand words, this tool allows you to communicate, using standard symbols (see Figure 26), how your process works (see Figure 27). The flowchart is very useful when looking at a process that you want to improve (note that it is included in the control plan—if done in your Practice). By actually creating three flowcharts—1) what you think it is (before you check reality), 2) what it actually is, and 3) what you would like it to be (see Figure 28)—you can analyze what changes
need to be made and study whether the changes are doable given your training and resources.

Each organization should decide for itself what symbols to use, as there are many versions available today. After you decide what symbols to use, you can follow some basic steps to create the flowchart:
1. Create the boundaries of the process that you intend to flowchart. This might involve identifying the inputs and outputs of the process or identifying who the suppliers and customers are for the process.

2. Determine the various steps in the process. Do not worry about sequence here, but do collect all the steps. The foundation material from a failure mode and effects analysis (FMEA) or control plan can be used if available to help start this process. If a group is brainstorming ideas,
you could list each idea on a flip chart or a wall using sticky notes.

3. Build the sequence of the process, putting everything into the appropriate order.

4. Draw the flowchart using the symbols appropriate for your organization.

5. Verify that the flowchart is complete and appropriate for the given operation. This can be very important if more than one group is working on similar processes. Overlaps or deletions may otherwise occur between processes.

Flowcharts are a good analytical tool for monitoring a process over time and also in conducting training for new Practice staff or supervisors. By referencing the flowcharts on a regular basis, you can use them as visual standards to help ensure that things are still running as they are supposed to. Note that if a change is made to the process, it is important to update the flowchart to reflect the change. Regular audits may be done in your area for any number of issues (safety, quality, environmental, and so on), so having the flowcharts readily available helps everyone involved.

Tip: Some organizations like to start with the “what you think it is” flowchart to get a sense of what is happening in the Practice. Other groups
like to start with “what you would like it to be” so that they can set the vision for the future. The challenge for many organizations is to finalize the “what it actually is” flowchart, as there are often many viewpoints within the Practice as to how and why things work the way they do.
HISTOGRAM

A histogram is a frequency distribution that graphically displays the measurements taken from a process and shows how those data are distributed and centered over a measurement scale (usually horizontally—see Figure 29). Histograms give us a picture of what a process is producing over a specified period of time and how much variation exists. This picture can then be compared with our expectations of the process, or older histograms, to see if it is operating within specifications and to the desired plan for that particular process. Sometimes you will see a normal bell-shaped curve included with the histogram to show the theoretical placement of the numbers as compared with the actual measurements taken from the process (see Figure 30).
Figure 29  Basic histogram.

Figure 30  Histogram with bell-shaped curve.
A histogram is usually quick and easy to construct and is typically one of the first tools you will use in looking at the output of a process. It can be created by hand or with the aid of a computer. Given that some test equipment can now be tied directly to computers, a wealth of information becomes available very quickly using the histogram as the base. Using the histogram, calculations can be made on the process’s mean (average), median (middle number), and standard deviation (measure of how the numbers are distributed in the data, sometimes compared with the normal curve expectations).

If the Practice staffer needs to make a histogram by hand, here are the basic steps:

- Set up a check sheet to collect the data—this could be the histogram graph itself.
- Collect the measurements as they occur and record them on the check sheet.
- Order the data on the histogram graph, if not already done through the check sheet.
- Post the histogram where others can see the process.
- Interpret the data.
Since the histogram is made up of individual numbers, it is possible to show the specification limits for the parts on the histogram. This is done to look for shifts in the process or the overall capability of the process.
KANBAN (WAIT TIME, PATIENT PULL-THROUGH)

A system is best controlled when material, people, and information flow into and out of the process in a smooth and rational manner (without periods of waiting). If process inputs (patients, staff members, supplies, and so on) arrive before they are needed, unnecessary confusion, inventory, wasted time, and costs generally occur. If process outputs are not synchronized with downstream processes, delays, disappointed customers/patients, and associated costs may occur.

A properly administered kanban system will improve system control by assuring timely movement of products, people, and information. This method is used in a process to signal an upstream supplier (internal or external) that more material or product is needed downstream. Originally, it
was just a manual card system, but has evolved into more sophisticated signaling methods for some organizations (by use of patient charts, colored lighting systems, and so on). It is referred to as a pull system because it serves to pull material or product from a supplier rather than relying on a scheduling system to push the material or product forward at predetermined intervals. It is said that the kanban method was inspired by Toyota’s Taiichi Ohno visiting a United States supermarket.

In the past, many Practices were designed with large patient waiting rooms and areas where needed supplies were stored. If you see the patient waiting area filled with people on a daily basis (versus once in a while), then this is an indication of a systemic problem. The physical layout of the office area may need to be discussed in the Lean Six Sigma team meeting to brainstorm possible rearrangements to the way we approach the scheduling of patients and how we move patients and staff around the office, to allow doctors and other staff to better utilize everyone’s time. Asking anyone (patients, doctors, staff members, and so on) to wait is a form of waste and needs to be minimized.
LESSONS LEARNED

We have all learned to do things through our experiences, the people we have met, and the articles or books we have read. We now apply this learning to the work that we do every day. Some things are repetitive, while others take thought to accomplish. Either way, there is a standard process that we use to accomplish our work. If we were to take a vacation day or be out sick, could the work be done reasonably well without us?

We are not talking about replacing ourselves here; however, there should be a way for someone else to be able to figure out how to do our work if we are not there. Some companies rely on standard operating procedures (SOPs) to tell new or replacement staff what to do. But those rarely tell the whole truth about a job. Lessons learned is a system that allows for the collection, storage,
retrieval, and distribution of knowledge—the important learnings—to other people to use when needed. This could be used for many purposes: to do someone’s job in his or her absence, to conduct internal benchmarks, or to look for better ways of doing another job in the organization.

Learning just to gather knowledge is part of what a learning organization is all about. In lessons learned, companies formally establish a system for collecting important learnings about particular customers, activities, or processes for use at a later time. The author’s dentist, after each checkup, records what he has talked about with the patient on cards that stay with the patient’s dental records. This allows him to review what has been or is happening in the patient’s life prior to the next dental visit. This process could be captured for use by any service organization. A process should exist for collecting and using these “Aha!” insights, for example, the Ritz Carlton is well known for greeting returning guests with personalized service learned from prior visits. “What are we going to do differently in this Practice regarding this process, and for our customers, based on what we have learned?” Thus, we learn to not repeat our past mistakes.

In the ideal setting, the culmination of lessons learned should lead your Practice to becoming the best healthcare organization that it can be.
In the study of economics, one finds the theories of *bubble up* (worker taking the lead to do things) and *trickle down* (management taking the lead to do things). In either case, as we have seen in the Practice, we need to have management’s buy-in and support to ensure that things last over time. Management involvement, then, is the way that supervisors and managers support employees through time and resource allowances to not only do the job well, but to study how to do an even better job for the customer. Merely asking staff to work harder or work better will not be enough over time to make a real difference for the customer.

To demonstrate management involvement, managers and leaders need to operate with integrity and be guided by moral principle. To be
involved, they must be courageous, be willing to ask the tough questions (even if they do not like the answers), be willing to defend the decisions of teams and employees who work for them, and be willing to instruct upper managers to do what is right. Employees must know that the environment is safe, that the system is being well taken care of, and the business is being managed fairly. Also, the managers and leaders must be willing to uphold processes and principles that say, in effect, that this organization will be successful and people will be proud to work here.

Dr. J. M. Juran (1989) points out in his *Juran on Leadership for Quality* that managers should:

- Establish quality goals
- Provide resources
- Review progress
- Give recognition
- Revise the reward system
- Serve on project teams
- Face up to employee apprehensions

This is an area where you will “know it when you see it.” If supervisors continually try to push staff to only work harder to make their numbers, then you know that quality and customer concerns are minimal. On the other hand, if supervisors care
that the services and products that are presented to customers are the best they can be, and they show concern for satisfying or delighting the customer, then managers are showing commitment to quality and how work is being done.

For Lean Six Sigma to work well in your organization, management must be committed during all phases of the process to ensure that adequate time and resources are allocated to achieve continual improvement. Practice staff will notice that managers are not cutting corners to save costs, that safety remains a prime concern, and that they, the Practice staff, are being treated fairly. Also, Practice staff will see workload distribution and expectations being managed in an equitable fashion and that employment agreements are managed equitably.

Peter Senge’s comment on the subject is worth repeating here: “Top management buy-in is a poor substitute for genuine commitment and learning capabilities at all levels in an organization. In fact, if management authority is used unwisely, it can make such commitment and capability less likely to develop” (Senge 1990).
In healthcare environments, we do not often think about analyzing the equipment or processes we use to study or verify work that has been done according to a standard or specification. Whenever we measure anything with a gage or a scale, we typically assume that it will give us a true reading or measurement. Have you ever put an envelope on a postage scale and then put the same envelope back on again to see if you get the same postage reading? Usually you will, but more often than you might think, you can actually get a different reading. This is especially true if you are just between two different rate codes. Or have you stepped on a bathroom scale only to try it again a little later to see if you get the same reading? Depending on the
scale (some newer electronic scales have blockers in them to prevent variation) you may very well see different readings. What is happening?

Any form of measurement has variation in it. Even if a gage or scale is being used, results can be different. If you have multiple people reviewing data entry information, the odds are that incorrect information will get through! That is why many accounting processes have so many rework and rechecking loops in them. Why does this happen? It is a well proven fact that inspection is only about 80 percent effective. Also, even if you have a standard to work to (say, a written procedure that is to be followed for some outcome), there is always a chance for something to not be evaluated the same way by different people. Ask almost any police officer who has had to take eyewitness testimony of a traffic accident from a number of people. The officer will probably tell you that there were as many versions of the story as people interviewed!

Each of us relies on measurement processes (visual inspection, verification loops, actual testing equipment, and so on) to measure our processes and the outcomes of our work. The question measurement systems analysis (MSA) addresses is “How effective are those measurement processes?” It is surprising how quickly a measurement process can get out of calibration or otherwise give poor readings. Even after
installing the measurement system properly and using it the way that it was designed, things can still go wrong with how the measurement process performs. Sometimes we will see two identical processes that will give different outcomes for the same thing being studied. In other cases, two or more Practice staff will use the same or similar processes but get different results.

Measurement systems analysis is a method of checking how well people are using a measurement process and judging whether the measurement system is effective and efficient, in order to provide your customers with the services they want. The process of testing is sometimes called gage repeatability and reproducibility (GR&R), and through the use of software we can look at the gage’s accuracy, repeatability, reproducibility, and stability. If the MSA shows problems, then you must take action to ensure that the service you provide will meet customer requirements.

One common MSA method involves a group of people (two or more) using the same or similar measurement processes and testing a blind set of numbered samples (around 10 or so). The test items (reports, financial information, timed events, and so on) are given to the people randomly with only the tester knowing which item is which. Each person tests each item a total of three times in a random order so that the person
will not know what outcome the item may have had on a prior test. After all items have been measured the appropriate number of times, the data can be put into any of a number of computer software programs for analysis.

Other methods of MSA are used for processes that can only be checked once for each item. The main point here is that checking processes can vary, and our methods of verifying or validating what is done must be understood so that decisions can be made on the overall effectiveness of how things are being evaluated. With this information, we can start studying the variation of the processes with confidence that we know the variation of the measurement system.
Mistake-proofing (also called error-proofing or poka-yoke) is the process of either ensuring that there is only one way (or limited ways) to do any given task in a process or ensuring that any mistake is very obvious as soon as it happens. Such efforts help reduce variation in the process and help prevent nonconformity issues from arising in the process downstream or when a customer uses the product or service. Have you ever noticed that when you try to plug an electrical appliance into an electrical outlet, the plug can go in only one way (this is true for either two- or three-pronged plugs)? This is an example of mistake-proofing that allows the electronics industry to ensure proper usage of appliances in the office or home.
Jobs in your organization can be looked at in the same way. Is it possible for a process to be completed in more than one way? Can the process be done in a different order than what the process design states (or worse yet, does each person develop their own method for doing the work)? If any of these issues or any number of others exist, you should help ensure that things are done more consistently to help reduce variation in the process. Note: We are not talking about reducing or stopping independent thought or creativity here! Some things can be done differently with little to no impact on the outcome of the process. What we want to look at is how to give customers more consistency in what they see.

You may need to get quality assurance or management involved with some changes to your processes; however, some changes you can do with the help of your natural work groups. If there is a series of similar processes that comes through your area, look over the paperwork that accompanies these processes. Is everything arranged logically for your work space? Is the paperwork aligned to show similar steps in the same order or sequence? Do some reports sit in in-boxes for long periods of time with no value added? If you could change anything about your work area, what would it be? Tell your supervisor or team your ideas.
The originator of this method was a Japanese engineer named Shigeo Shingo, and there is now a yearly prize (Shingo Prize) in the United States to promote the use of mistake-proofing and other world-class operational excellence strategies.
Dr. J. M. Juran applied the concept of the Pareto principle (based on the work of a 19th-century economist and priest named Vilfredo Pareto) to industry during the 1950s. Basically, the Pareto principle, or 80/20 rule, states that 80 percent of effect(s) are the result of 20 percent of causes. The result of this work is a graphical tool—called a Pareto chart—that shows frequency of occurrences (or ranks the effects of problems). See Figure 31.

The Pareto chart organizes data to show which items or issues have the greatest frequency in the process, system, or service. The chart stratifies the data to show the ranking of the groups, starting with the largest and working across to the smallest group (see Figure 32.
for a pictorial version of the Pareto chart). The idea is that by organizing the data in this format, we can develop a plan to work on problems that will give us the biggest return on our process improvement efforts.

A Pareto chart is easy to develop by hand; however, there are computer software programs that can do this as well. Here are the basic steps:

- Collect the data—the Practice staffer can again start with the check sheet to collect information.
Pareto Chart

- Organize and group the data from highest frequency to lowest frequency.
- Draw the Pareto chart.
- Analyze the data.
- Work on the issues.

Once the Pareto chart has been created, the Practice staffer and team can start developing plans and actions (use a problem-solving method) for improving the process, starting with the most frequently occurring issue or problem. As that problem is improved (you may not be able to totally eliminate the problem, but you still
try), the team can go to the next most frequently occurring problem and work on that, and so on.

When creating multiple Pareto charts over time for the same process, it is helpful to maintain the same scale (see Figures 33 and 34). If a computer is used, the Practice staffer may have to manually set the scale. This will allow for easier comparisons to demonstrate continual improvement.

![Before Improvement Pareto Chart](image)

**Figure 33** “Before” Pareto chart.
Figure 34  "After" Pareto chart.
PDSA Cycle (Plan–Do–Study–Act)

PDSA is a strategy intended to be a guiding light for the way we work and do our jobs. Building on the work of Walter Shewhart in the 1930s, Dr. W. Edwards Deming changed the PDCA improvement model (plan–do–check–act) to PDSA (plan–do–study–act). The latter model is the foundation for various methods such as advanced quality planning, problem solving, Lean Six Sigma, and process improvement (see Figure 35).

The PDSA cycle is used as a road map to work through a process to identify possible aspects that can be improved. First, a plan is established regarding what is to be worked on. In the do phase, we do the work of the process. Then we can study the process and outputs of the process to identify possible improvements. Finally,
we take some *actions* on what we have seen and observed. This cycle should be repeated until the process is as good as it can be given the current process parameters and materials. The challenge is that as new methods, materials, and technology become available, we keep open minds to allow for changing the way we do our work.

Another view of the PDSA cycle is represented by the data–knowledge–action cycle (see Figure 35).
This may allow the Practice staffer or manager to understand PDSA by starting with the basic building blocks of the process. You need to have knowledge about the process, have data from the process, and be willing and able to take action to make necessary changes. Without all three components, nothing will change. Just as a three-legged stool will give solid support, once all three parts are present, you can work with the process to understand what it is doing. Then you can work to improve it.

A fascinating point that the author has noted while observing people such as Deming, Juran, and Feigenbaum is that each of them applied the

![Continuous improvement model](image-url)

**Figure 36** Continuous improvement model.

PDSA technique to his own life and work. Each of them continually challenged their beliefs and training to look for new and better ways of doing any work or assignment. The point is to continually improve everything that we do, both on the job and in our life.
Building a practice strategy involves a lot of project planning to ensure that the desired goals and outcomes of the Practice will be achieved. The old adage that “failing to plan is planning to fail” applies to medical Practices as much as anywhere else. If we give little to no forethought to how we run our Practice to deliver quality and safe healthcare for our patients, then the outcomes can not be predicted. In the books *Curing Health Care* (Berwick, Godfrey, and Roessner 1990) and *Crossing the Quality Chasm* (Committee on Quality Healthcare in America 2001), a bleak picture is presented on how well, or poorly, we in the United States as a society design and deliver our healthcare to patients. The challenge here is for Six Sigma team members to utilize
the tools outlined in this pocket guide to set a strategic plan in place to help ensure that your Practice is delivering the very best quality and safest healthcare available to your patients.

Project planning is the disciplined monitoring of how and when a practice strategy will be accomplished. If you want to go on a long trip, do you just jump in the car and go? Some people do because they like the spontaneity of adventure. Most of us, however, would rather plan the trip, some in more detail than others. We do so to know what needs to be taken, how long we will be gone, and any number of other details. Those of you with young children know that this is very important.

Too often, Practice staff use the tools and processes listed in this book as independent events to satisfy some issue of the moment. Using project planning, you should look at the entire system and strive for synergy as you use communication and the tools and processes to contribute to continual improvement. Project planning becomes the tracking system to ensure that all the elements, tools, processes, communications, and so forth, are brought together as a whole system for doing the work that you do in your Practice.

Effective project planning requires skills in the following areas (Kerzner 1995):

- Information processing
• Communication
• Resource negotiations
• Securing commitments
• Incremental and modular planning
• Assuring measurable milestones
• Facilitating top management involvement

At times Practice staff may become part of project plans that are developed in your Practice or aligned healthcare units. Working with such plans should help ensure the successful demonstration of continual improvement and the satisfaction of customer’s wants and needs.
Some of the more successful attempts to solve problems have been accomplished through the use of a model or strategy that outlines the steps that should be followed in investigating and containing issues, and fixing the problems so that they will not return. Unfortunately, many of us have seen situations in which a problem has been fixed, only for the same issue to crop up again in a week, month, or year. The question is “How do we permanently solve problems?”

One common approach to problem solving is called the *eight discipline* (8D) approach (Stamatis 1996). The steps commonly followed in this process are:

1. *Use a team approach.* Organize a small group of people (note that we did not say
that you have a team at this point—this is just a starting group) with knowledge of the process/product, authority to make changes in the Practice, and skill in the technical disciplines required to solve the problem and implement corrective actions. The group must have a designated Champion.

2. *Describe the problem.* Specify the internal/external customer problem by identifying the quantifiable terms—the who, what, when, where, why, how, and how many (five W’s and two H’s) for the problem. Use SIPOC, brainstorming, flowcharts, and any other methods that the group feels is appropriate.

3. *Start and check interim (containment) actions.* Define and implement containment actions to isolate the effect or issue from the problem “right now.” Verify the effectiveness of this containment action to ensure that the internal or external customer does not see further problems.

4. *Define and check root causes.* Identify all potential causes of the problem (a cause-and-effect chart is useful here). Isolate and verify the root causes by
testing each potential cause (sampling is used here) against the problem description and test data (individual test or a DOE if needed). Identify alternative corrective actions to eliminate root causes, using a process behavior chart to ensure that the process remains stable.

5. **Check corrective action.** Through a sampling plan, quantitatively confirm that the selected corrective actions will resolve the problem for the customer and will not cause undesirable issues (FMEA and control plans).

6. **Start permanent corrective action.** Once a corrective action is verified to be working, update all procedures and processes to incorporate the new process. This should include training where appropriate.

7. **Stop future problems.** Modify the management systems, operating systems, preventive maintenance, processes, and procedures and documentation to prevent recurrence of this and all similar problems. Note: If similar processes are found in the Practice, look closely at them also to ensure that they do not develop the same issue.
8. *Congratulate your team.* Improvements happen only because many people work together. Everyone deserves credit.

Your external customers may have a prescribed problem-solving methodology other than 8D that they want your organization to use. Other methods that can be used in problem solving are the PDSA cycle and, although not recommended, the scientific method that you probably learned in high school.
The foundation for process behavior charts was laid by Walter Shewhart (called the father of modern-day quality control) in the late 1920s. The charts were originally called control charts as they were thought to help control the process. Today, more than 30 different charts can be used; however, we typically use only six or seven on a regular basis; Practice staff will find the IMR, $p$, and $u$ the most useful. These charts follow the premise of creating a picture of the process variation while the work is being done (see “Run Chart”). This allows the Practice staffer to ensure that the process is stable and continuing to operate within the process boundaries (not necessarily specification limits) that have been established for that process. If something does
start to deteriorate or change in the process, the process behavior chart will give the Practice staffer an early warning that something needs to be adjusted or changed to bring the process back into control. Note: the healthcare worker should remember that in pursuing continual improvement, you want the process to change for the better; thus, instead of a stable process you should see the variation on the process behavior chart follow the standard out-of-control rules (found in many texts)!

This book will not go into the details of creating and maintaining process behavior charts as you can find many references on the subject (see “control charts” in most texts). We will discuss in general the basic charts and some of the ways to use them. Table 3 lists these basic charts.

The “Data type” column in Table 3 indicates two different types of data. Variable data are information in number format that comes from scales (for example, length measures, weighing devices, temperature controls, distance measures, or time measures). Attribute data are information on the goodness of something (for example, pass/fail criteria, acceptance standards, accuracy of procedure, or accuracy of counts).

Variable data are usually considered more valuable in understanding process behavior than attribute data as more information is available and trends and patterns are more easily and
Table 3  Process behavior chart types.

<table>
<thead>
<tr>
<th>Chart name</th>
<th>Data type</th>
<th>Measure*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$X$-bar and $R$</td>
<td>Variable</td>
<td>Averages of variable data</td>
<td>Subtract the smallest sample value from the largest to identify the range</td>
</tr>
<tr>
<td>$X$-bar and $s$</td>
<td>Variable</td>
<td>Averages of variable data</td>
<td>Use a computer to identify the standard deviation</td>
</tr>
<tr>
<td>Individual moving range (IMR)</td>
<td>Variable</td>
<td>Individual variable data</td>
<td>Used when averages are not available</td>
</tr>
<tr>
<td>$p$</td>
<td>Attribute</td>
<td>Fraction of nonconforming units</td>
<td>Percentage of all units checked</td>
</tr>
<tr>
<td>$np$</td>
<td>Attribute</td>
<td>Number of total nonconforming units</td>
<td>Number of units found to have issues</td>
</tr>
<tr>
<td>$c$</td>
<td>Attribute</td>
<td>Number of nonconforming</td>
<td>Number of issues found</td>
</tr>
<tr>
<td>$u$</td>
<td>Attribute</td>
<td>Number of nonconforming per unit</td>
<td>Average number of issues found per the number of units checked</td>
</tr>
</tbody>
</table>

* Some references refer to nonconforming as “defect” or “defective.” Your industry may have a product liability issue with the terms “defect” or “defective,” so “nonconforming” is used in this text.
more quickly seen in the variables. The home gas usage run chart (see Figure 37) is an example of plotting using variable data.

In either type of process behavior chart (variable or attribute), the healthcare worker or supervisor needs to ensure that the measurements from the process are recorded, calculated, and plotted appropriately. In variable data charts the healthcare worker should ensure that the process average is calculated and then refer to an appropriate table to calculate the upper (UCL) or lower (LCL) control limits (see Figure 38), which can be found in most SPC books (Stamatis 1997).

Figure 37  Home gas usage.
When working with attribute charts, calculating the control limits with a handheld calculator can be relatively simple. See Figures 39 and 40 for the steps to follow on the calculator for the $p$ and $u$ charts (most commonly used in the Practice setting) without having to learn the technical formulas found in many reference books.

The most important thing about process behavior charts is that you actually use them to understand what your process is doing. Just making the charts and posting them on the wall is often sarcastically called statistical process display (SPD) and does little to help the healthcare worker monitor or improve the process. Learning to use and read the charts can go a long way toward helping your Practice maintain and/or improve the quality of services that you provide. The term “being in statistical control” refers to the plot points on the chart following a random pattern between the upper and lower control limits.

**Figure 38** Calculating process average, UCL, and LCL for variable data.

First add up all the $x$'s and divide by the total number; this equals $\bar{x}$. Record this number. The UCL and LCL can be calculated using a standardized table that can be found in many control chart references or in SPC software.
First add up all the $p$’s and divide by the total number; this equals $\bar{p}$. Record this number.

On your calculator, follow these steps:

1. 1 minus $\bar{p}$.
2. Times $\bar{p}$.
3. Divide by the total number of $p$’s.
4. $\sqrt{\text{}}$
5. Times 3 equals some value; record this value.
6. Add the value to $\bar{p}$ for UCL.
7. Subtract the value from $\bar{p}$ for LCL.

**Figure 39** $p$ chart control limit calculations.

First add up all the $u$’s and divide by the total number; this equals $\bar{u}$.

On your calculator, follow these steps:

1. Enter $\bar{u}$ into the display.
2. Divide by the total number of $u$’s.
3. $\sqrt{\text{}}$
4. Times 3 equals some value; record this value.
5. Add the value to $\bar{u}$ for UCL.
6. Subtract the value from $\bar{u}$ for LCL.

**Figure 40** $u$ chart control limit calculations.
PROCESS IDENTIFICATION

Anything we do can be defined in terms of a process or system. Many of the tools discussed in this book can be used to help identify causes and effects, frequency and distribution of measures, most frequently occurring data, process flow as it is occurring, and other aspects of the process. If you plan to study a process, it is very important that you first identify the boundaries that you will work within. Many books talk about the basic “input, process, output” model for process identification (shown earlier in Figure 2, page 6). Today, some people use the SIPOC model (see Figure 3, page 8)—supplier, input, process, output, customer—which gives defined boundaries to the old model.

In any sporting event, besides knowing the rules of the game, you must know the boundaries
of the game field. This does not prevent us from thinking outside the box (boundaries), but it does give us guidelines for what we are dealing with as we go about our daily tasks and endeavors. Taking the time to actually list or draw components of the process will help us find issues more quickly than might otherwise be possible.

One common method of identifying the process is called the *storyboard* method. This tool is similar to flowcharting but involves drawing pictures of the various tasks instead of just using words. This technique is used by movie producers to sequence scenes of a film prior to shooting to ensure that everyone on the set (actors, sound technicians, cinematographer, support personnel, and so on) knows what is supposed to happen ahead of time. The same scenario can be used in the Practice to lay out a pictorial sequence of the process as it should happen. This technique can be especially useful if you have customers from different cultures visiting your Practice who may not speak your language as their native tongue.
Process improvement is the method of making a system work better to satisfy customer wants and needs. It is vital if continual improvement is to become a reality. In process improvement you should look at reducing overall variability, not just the variation. Variability is made up of three components: instability, variation, and off-target conditions.

In dealing with variability, most practitioners traditionally have addressed only the variation question. Variation is important, and we use the tools listed in this book to help reduce it as much as possible. But the other two components are also important. Without knowledge of these two—instability and off-target conditions—
we could miss some very important factors and even cause major problems in the Practice.

*Instability* is the lack of a stable operating process; common cause and special cause variation are unchecked and not responded to. Without a stable process, capability values are not worth calculating and customers can, and do, see any number of issues come and go without rhyme or reason. The best method for monitoring a process is to use process behavior charts, but far too often the charts either are not kept up-to-date or are not used at all. Practice staff play a big role in monitoring the processes to ensure that the jobs they perform are stable and in control.

Whether a process is *off target* is often determined by the managers who design the operation or services. The Practice staffer can only monitor whether the process is centered within the specifications and/or control limits. Even though today we talk about the Taguchi loss function and how processes should be centered with regard to what the customer wants and needs, many jobs we work in today were designed years ago when managers put the target wherever it made the most economic sense for the company at that time, instead of for the customer. In other cases, we have done something the same way for so long that it is now assumed that there is a rule
or even a governmental law that it must be done that way. So the Practice staffer should monitor the process and be ready to give up-to-date information to managers when processes are to be redesigned, so that the new thinking becomes a reality in your Practice.
A run chart is a graph that shows measurements from an operation or process in relationship to time. Virtually no calculations are required for this chart, and it is very useful in monitoring process variation for patterns, trends, and shifts. The run chart, sometimes called a trend chart or line graph, is the basis for a number of the process behavior charts and can be used almost anywhere (try tracking the utility usage of your home, and then look for ways to cut energy usage to save cost—see Figure 41).

The run chart is created by setting up a timeline and a measurement scale. Then, as measurements are taken from the process during production runs, the data can be plotted on the grid to form a graph of the process. The healthcare worker can then monitor the process as it is
running to see the process variation and determine whether the process is changing with sudden shifts (spikes) or moving up or down over time (trends). The home gas usage run chart was made with actual numbers for a northern state. Notice the general trend of summer versus winter usage. The winter of 1998 used less energy than either the winters of 1999 or 2000 because an elderly father came to live in the home during the last two years. You can also see a spike in February 2000, which was caused by an estimated bill being generated instead of an actual gas reading taken during January. During the summer months, the furnace is not used very
much, but the gas dryer is being used more and more to handle additional laundry needs.

Other uses of the run chart show the healthcare worker if there are cycles (as in the gas usage example above) or how events around the work area may be affecting the operation or process. Sometimes we work with an operation for so long that we don’t notice little things happening around us that may have an impact on how the process works. By monitoring a run chart, we can get a picture of what is going on in the system.
SCATTER DIAGRAM

The scatter diagram is a graphic display used to identify a relationship or association between two variables, cause and effect, and so on. To create the diagram, you plot the intersection of the two data points, maintaining one variable on the x-axis and the other variable on the y-axis. Once all of the data is on the graph, the observer can eyeball a line of best fit (which can also be calculated on a computer for accuracy). The plot pattern (line of best fit) identifies whether there is a positive, negative, or no correlation in the data. There is also the possibility for a nonlinear relationship between the variables (see Figure 42).

One caution in the use of this tool is to ensure that the two variables being compared actually are related to each other. By accident, you
No correlation:

![Scatter plot](image)

Strong negative correlation:

![Scatter plot](image)

**Figure 42** Scatter diagrams.
Strong positive correlation:

Quadratic relationship:

Figure 42  Continued.
could show that there is a relationship between two variables when there may be a third factor in play. An example of this would be to say that drowning is caused by increased ice cream sales. On the graph, it might be noted that as drownings go up, so do ice cream sales. However, as everyone could guess, both of these events occur more frequently during summer months versus winter. So drowning and ice cream sales are actually factors of warmer weather, versus having a causal relationship to each other.
The SIPOC (supplier–input–process–output–customer) diagram can be a flowchart, quasi–value stream map, turtle diagram, and so on, that shows the variables involved in a given process (see Figure 43). Traditionally, we would have mapped the IPO (inputs, process, outputs) of a process, which could be the entire Practice or one aspect of the Practice. Today, we typically include the items, people/patients, or processes that are needed at the beginning of the process flow and then list the items, people, or processes that are a result of what is being done/studied in the core event. One of the primary uses of the SIPOC diagram is to ensure that everyone in the system has a clear, visual reference for what is to be done in the process (a road map of how things are supposed to work).
### SIPOC Diagram

<table>
<thead>
<tr>
<th>Suppliers</th>
<th>Inputs</th>
<th>Process</th>
<th>Outputs</th>
<th>Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providers of the required inputs/resources to ensure that the process executes as planned.</td>
<td>Resources required by the process to obtain the intended output.</td>
<td>Top-level description of activity.</td>
<td>Deliverables from the process. Note: deliverables can be hardware, software, systems, services, data, information, and so on.</td>
<td>Any organization that receives an output or deliverable from the process. Note: can also capture systems/databases that receive outputs, information, data, and so on.</td>
</tr>
</tbody>
</table>

![SIPOC Diagram](image)
This is a method of aligning everyone to a common goal (what is to be accomplished).

To develop a SIPOC diagram, start by defining the process and its boundaries. Next, identify the outputs of the process, including data, services, products, information, records, and so on. For each identified output, identify all of the associated inputs. Then move on to the internal and external customers—those that receive the identified outputs. Finally, move back to the supplier column to identify the internal and external suppliers for each identified input. Although it may seem odd to bounce back and forth from side to side on the chart, this is done to help stimulate thinking. For example, new outputs are often identified when discussing inputs or customers.

External suppliers to a process are those outside the enterprise that provide process inputs, including materials, purchased parts, contracted services, electrical power, and so on. Internal suppliers to a process are departments or processes inside the enterprise that provide process inputs. Similarly, a process’s external customers are those outside the enterprise who receive process outputs while internal customers are those inside the enterprise who receive process outputs. Suppliers of either type are responsible for meeting the requirements of their customers. Customers of either type are responsible for communicating their requirements to their suppliers.
Standard operating procedures (SOPs) are known by many names: work instructions, level three ISO 9001 documentation, operating guides, job aids, standard job procedures, and more. Your Practice may already have a policy and procedures manual (sometimes called a quality manual) that can include at least some of the SOPs for your Practice. In your Practice, what do you call the step-by-step description of how to carry out a task? These descriptions should give the details of how you do your various jobs. They should address such things as: What is the job? Where does the SOP apply? When does the SOP apply? Who is responsible? And so on.

Practice staff are responsible for following SOPs as written. If any deviations are made,
the healthcare worker needs to document what was done and why (either in the patient charts or other designated area for such information). This will be a big help if at a later date a problem arises and an investigation is done in the healthcare worker’s area. Documented evidence will go a long way toward preventing finger-pointing or faultfinding and the healthcare worker being blamed for something out of his or her control.

The SOP should be a living document, changing as Practice staff change the work that they do. If something changes in the system, the healthcare worker should ensure that the SOP is updated. Once something changes in the process, and a new, desirable level is achieved, the healthcare worker should help update all documents relating to that process appropriately and destroy the old documents.
STANDARDIZATION (SDCA—STANDARDIZE–DO–CHECK–ADJUST)

*Standardization* is the process of locking in the gains that you have made during the improvement process. It is commonly referred to as the SDCA cycle (standardize–do–check–adjust). This tool is generally used once a process has been improved, to update the control plans, FMEA, process sheets, and other process documentation to lock in the improvements and standardize the changes throughout the organization (see Figure 44). Thus, everyone who is involved with the process in question will provide the service in the same basic way.

The SDCA cycle involves updating (standardizing) any documentation related to the process that has been improved, then doing the work
to ensure that it runs smoothly. The process is then checked or inspected to ensure accuracy and, finally, adjusted to ensure that the process output satisfies the customer’s wants and needs. This cycle should be used any time that improvements have been achieved and the Practice wants to ensure that the lessons learned will become part of everyday work.
Define

Control

Measure

Improve

Analyze

SYSTEMS THINKING

Systems thinking is recognition/identification and consideration of all the various individual elements that interrelate with a common purpose toward the whole function of a unit (Rice 1997). Many of us are so busy doing our daily jobs that we have little time to think about what we are actually doing. In systems thinking, you use all the tools and methods around you to look at what is being done in a given operation. You must examine the operation as it is for aspects of the process, equipment, methods, procedures, environment, or other factors, that could be changed to give faster, better, and cheaper service to customers (internal and external). Often, however, we notice that someone (maybe even yourself) has made a change in one part of an operation only to cause new problems somewhere else.
Using systems thinking, you can understand the process and know that if one factor is changed or influenced in some particular way, then something different might happen downstream in the process. For example, if a computer glitch occurs in one Practice, will that prevent other tasks in other healthcare units from being completed? If one healthcare worker changes something in the way data is collected, but does not let others know, what might happen to the integrity of the information downstream? If programming is changed on a database with little or no updated training provided, how long will it take to get accurate and reliable information? All of this is part of systems thinking.

You should constantly be looking at the variability in the system for opportunities for continual improvement. As the author has noted in other sections of this guide, variability is made up of three factors: instability, variation, and off-target conditions. Instability of a process says that you can not be sure what it will do at any given time. Process behavior charts are useful tools to graphically show how the process is operating and whether the process is in a state of statistical control. However, instability goes beyond just statistical control. A process can become unstable for any number of reasons. Some of these include lack of poor housekeeping disciplines, poor materials from suppliers, vague
or unknown customer requirements, inadequate procedure definition, or equipment shortages. Learning about your process and how it fits into the overall activities in your Practice is the foundation of systems thinking.

Variation is discussed in the “What Is Variation” section of this book, so let’s look at off-target conditions. Given today’s views on quality processes, process designers should always set target values of characteristic measurements. With tools such as quality function deployment (not discussed in this book), specialists should be able to center the target values according to what the customer wants and needs. But this has not always been the case.

A service call recently experienced by the author may be a good example of a lack of systems thinking. In making an appointment, I was told to expect a wait of a couple of hours. I arrived at the organization a little early with a book to read. A person took the order and sent the information to the back for the service to be performed. After three hours of not hearing anything (the first person had noted that I was waiting on the premises), I went to check on how things were going. I was told that things were not right and that I must have done something, but that the service should be completed shortly. After another hour, I again went to check on the service to find that things had been completed, but I had not been
called yet. It seems that there was some need to transfer paperwork between a number of people before I could be called. A couple of days later, a quality representative called me to see how I liked the service. After recounting the above story, the rep repeatedly apologized and said that she would look into what might have caused the long delay, which should not have occurred. It turned out that part of the delay was due to someone taking a lunch break and my paperwork being buried on their desk. After they returned from lunch, the person started from the top of the pile and they worked their way down to my file at the bottom.
Useful and productive team meetings are structured events with a purpose. Just meeting for the sake of meeting wastes time and energy that could be used more productively in other areas. Many of us do not think much about meetings since we attend so many of them that it seems almost second nature. We rarely ask if the meeting is necessary and a valuable use of the attendees’ time. Any time two or more people come together to conduct business, we should remember that time, energy, and resources are being spent. For an in-depth study of the topic, see How to Make Meetings Work by Michael Doyle and David Straus (1976).

The first question should always be, “Why are we having this meeting?” There are actually many good reasons to hold meetings, and there
are different meeting types. Five of the most basic are problem solving, information sharing (both gathering and/or giving), planning and coordination, decision making, and reaction or feedback. Any meeting can be a combination of these types. Each type of meeting may require different roles, more or fewer people, and a variety of meeting methods. It is important to be clear about the type of meeting you want and to plan accordingly. Be sure everyone who will be attending knows the type of meeting it will be and why it’s being held so that they can arrive with a common set of expectations.

You should always set an agenda because:

• It is an essential step in determining whether a meeting is needed and, if it is, to building a successful one

• It helps define what needs to be accomplished (outcomes)

• It spells out how the outcomes can be accomplished (process)

• An agenda establishes a time frame

• It helps identify who needs to be present

Here are some rules to ensure that you have a good meeting:

1. Treat others as equals, not as inferiors.
2. Be sincere, not manipulative and sneaky.

3. Genuinely care about others; don’t be indifferent.

4. Keep an open mind rather than being certain and dogmatic.

5. Be descriptive and specific, not evaluative and vague.

6. Concentrate on solving problems, not blaming others.

7. Assume that others have good intentions rather than assuming that they are devious.

8. Explain the what and the why; don’t assume that your intentions or purpose are automatically understood.

9. Listen for the other person’s point of view; we don’t always share the same reality.

10. Encourage everyone to give their input; don’t dominate.

11. Accept and appreciate the differences in others; don’t let stereotypes run your life.

12. Watch and respond to the way people interact at every meeting; how people work together affects the outcome and the meeting’s effectiveness.
Here are the typical roles of meeting participants:

- Leader
- Facilitator
- Timekeeper
- Recorder
- Team member
- Historian—lessons learned

Planned and handled properly, meetings do not have to be a waste of time and energy. Ensuring that there is a good reason to hold the meeting and establishing a good agenda are the best ways to use everyone’s time well.
TEAMS (EMPLOYEE INVOLVEMENT, IMPROVEMENT, SELF-DIRECTED)

Employee Involvement Teams

Some companies call their employees their most valuable assets. When this is true, managers spend time and resources to coach and train the employees to be better at whatever they do. This is especially true when it comes to allowing employees to become more involved with the work that is done in healthcare. Employee involvement is about encouraging and allowing all employees to do better work by using their minds as well as their hands to do the job. This notion is feared by many managers who were trained in classical management theory—they may think they will lose control over the work environment. By using
the whole person instead of having the employee check his or her brain at the door when they enter work, managers actually can have more productive processes and better activities. Going from “do what I say” to “what will it take to satisfy our customers?” will go a long way toward developing an environment where continual improvement is a way of life.

Thus, a basic definition of employee involvement is the process of including employees at a variety of levels and across functional areas for the purpose of having meaningful input/involvement in the business (Rice 1998). This is different from prior business models (for example, Theory X, Taylorism) where managers sat in their offices and dictated their wisdom to employees and directed them to “just go do it” or “do it exactly as I told you.” Empowerment is about personal responsibility and having personal and organizational goals aligned.

Evidence that employee involvement is alive in your Practice includes but is not limited to the following: no surprise decisions are made, as input is sought from many people; instead of managers ordering employees what to do, an atmosphere of cooperation is evident in the Practice; if something does go wrong, groups of people work on fixing the issue versus the manager or supervisor assigning blame; employees are not afraid to approach managers or even the
owner of the organization. Every Practice needs to define employee involvement given its culture, its organizational goals, and its customer base. Just as real teams take a long time to become efficient operating units, so too it takes time to build employee involvement into the culture of the Practice. But the personal and productivity rewards for doing so can be outstanding.

**Improvement Teams**

An improvement team consists of a group of appropriate individuals who have been chosen to work on a specific process to find ways of improving the operation (cost, cycle time, quality of product or service). These teams are meant to be active for a certain time frame, working on specific processes, and then report to management their findings and recommendations.

This is the team that works to make the big changes (what Juran calls managerial breakthroughs) in processes for continual improvements. These changes usually will be on the order of a factor of 10 or more change in the process as measured in process capability or in customer delight (versus satisfaction). It is important for members of this team to keep an open mind and think out of the box, and not be afraid to call in experts as needed to make the big improvements. Use of the “could be” process map is
useful here to help with brainstorming ideas of what is possible.

The improvement team’s members usually will be highly trained in the use of the tools and methodologies surveyed in this book (as well as in other techniques) and probably will be some of the teachers of these tools to other Practice personnel. Practice staff and improvement team members do not need to be certified to be able to use these tools, and because of their working every day with the process, they can sometimes solve problems better than those who are certified. When more expertise is needed, some of the highest mastery certifications that exist for using these tools are the Lean Six Sigma Master Black Belt and the ASQ Certified Six Sigma Black Belt.

**Self-Directed Teams**

A self-directed team is a group of people who have been authorized by management to work on a process or to improve a process using all the resources available to them and to manage their own time and energy, as a self-operating unit, for the good of the organization. Self-directed teams tend to share leadership equally among the group members; thus, rather than one person being the leader, they are all responsible for the output of the team.
These teams tend to be more important in a company that has evolved into a lean manufacturing or lean Practice organization. Whereas the old system of mass review does not require people to be prepared to change anything quickly, in a lean organization changeover of production must be quick and often, and sometimes occurs many times each shift. Mass customization has become a new buzzword for manufacturing, given customer demand for large quantities of service transactions made to individual customers’ requirements.

In lean Practice organizations, natural work cells or groups are usually formed around a certain service area. These groups are ideal candidates to become self-directed teams as they work closely together and can work as a single unit to satisfy customers instead of as individual staff. The team then is able to provide its own reward and recognition to each of its members. The team members have shared goals and take responsibility for communication with the rest of the organization.

Team Basics

Remember the famous quote, “There is no ‘I’ in ‘team’”? The essence of this idea is to imply that a team is a collective effort of individuals. To harness the best of each individual, the
team members need to understand each other’s strengths, roles, responsibilities, and the scope of the task. There are a number of books that go into detail about how to form a team, organize meetings, manage projects, and accomplish the desired goals. In the context of Six Sigma, we will cover areas important to a Green Belt. Protocols such as setting the team agenda, recording the minutes of the meeting (with proposed actions), sticking to the set meeting time, and enforcing meeting attendance need to be followed for an effective team meeting. An initial meeting to kick off the team with introductions and high-level discussion on the goals, objectives, milestones, and so on, will provide an opportunity for the team to get to know each other and understand the expectations. A team agenda can be flexible but you need to have one.

Some teams have their team goals, objectives, and scope/boundaries visibly displayed at every meeting to keep the members on track. Management presence during kickoff and at regular intervals during the project helps enforce the importance of the team objective.

Team Formation

A team usually comprises five to nine members (seven is considered an ideal size) with complementary skills to achieve the goals and objectives
of the team. Team composition should be driven by the size and scope of the project; it is possible to have a team of one or two for a smaller project and a large team with sub-teams for a big project. The team includes subject matter experts and stakeholders. Subject matter experts sometimes remain outside the team as resources or extended team members. Stakeholders are always part of the team. The team will not be able to implement their ideas and solutions without having stakeholders represented on the team. Teams smaller than five reduce the opportunity for interaction problems and are easier to manage, whereas teams greater than nine produce a lot of interaction that can be counterproductive to a team’s progress. Teams with greater diversity tend to produce better interaction between team members. Some teams also bring in individuals who are neither subject matter experts nor stakeholders but are outsiders to the team. The outsider helps the team ask questions that might never be explored by the team members closer to the process. This needs to be moderated as the outsider might ask too many questions and frustrate the core members. Typically, Six Sigma teams are cross-functional so as to address the issues from every angle.
A value analysis is a review of a process to identify what parts or steps of a process actually add value for interested parties that need access to that portion of the healthcare system. The issue here is that our current tasks and assignments take a certain amount of time. What if we could eliminate some of the steps that are deemed unnecessary so that more time could be spent doing the things that really mean something to the patients, clients, stakeholders, and so on, of the Practice? One of many possible ideas here would be to eliminate the need to constantly go to a fax machine (which could be at the other end of a long hallway) to receive information that could just as easily be sent directly to the computer that the person is working on.
To do a value analysis, it helps to imagine yourself as the thing going through a process (such as information, blood test results, or some other patient evaluation). What happens from the very first thought of getting the process accomplished? If a doctor orders a blood work request, what are the steps that are actually needed to allow the doctor to discuss the results with the patient?

To start this analysis, create a list of all of the actions/steps that need to be accomplished and the amount of time each takes from the viewpoint of the thing going through the process (for example, blood test—doctor’s request, script, patient goes to have blood drawn, waiting time, actual blood draw event, samples labeled properly, travel to laboratory, tests conducted, results recorded, records sent to doctor, wait for next patient visit, doctor remembers to discuss results with patient, any follow-up actions needed).

Once the process has been mapped and times recorded, review each entry to see which ones meet all three criteria below to say that the step actually adds some value:

- Does a customer (patient, stakeholder, other important person) recognize the step as being important?

- Does the step add value to the thing going through the process? (For example, signatures do not add value.)
• Was the step done right the first time?

Only when an item meets all three criteria (you can say yes to each) is that step considered a value-add to the process. All of the other items are non-value-added steps and need to be considered for elimination or at least diminished impact as they relate to the process.

Please note that we are “leaning” the process with the value analysis instead of trying to make the Practice staff work harder or longer hours to complete the tasks as we have them currently established. There are many process steps in every Practice, which have developed for any number of reasons, that do not add value to the process. Eliminating as many of the non-value-added steps as possible will free up a lot of time of the Practice staff and allow them to do the most important work. It has been estimated that many offices can eliminate 50 percent to 80 percent of their current time requirements in doing nearly any task by conducting a value analysis. This is typically one of the first places (low-hanging fruit) for the Six Sigma team to look when analyzing a Practice for possible improvement efforts.
A value stream is the series of activities that an organization performs, such as scheduling, organizing, ordering, counseling, record keeping, and accounting, to provide the healthcare services. A value stream often starts with a first contact with a patient or supplier’s supplier and ends with the payment for services or customer’s customer (as the SIPOC diagram will show). Wastes are both explicit and hidden along this value stream.

The three main components of a value stream are:

1. Flow of information/materials, from receipt of supplier material to delivery of finished goods and services to customers. Examples:
• Scheduling patients for office visits and then ensuring that they are checked in when they arrive

• Raw material/supplies shipped weekly from a supplier to the organization by truck

• Movement of material from raw material storage to areas where it is needed in the Practice

• Shipping of finished goods to an overseas customer via customs

2. The transformation of raw materials/information into completed services, or inputs into outputs. Examples:

• Getting the patient routed around the Practice to ensure that a full evaluation is completed

• Sending patients to a specialist if needed for further testing/consultations

3. The flow of information required to support the flow of information/material and transformation of goods and services. Examples:

• Patient charts updated properly and stored in an appropriate location (not being left on desks)
• Billing done appropriately and all payments timely received

This concept is visually illustrated via a lean tool called the *value stream map*. This map uses simple graphics and icons to illustrate the movement of material, information, inventory, work-in-progress, operators, and so on. Value stream mapping is a very powerful tool. The analysis subsequent to value stream mapping, called *value stream analysis*, can help uncover hidden wastes within the organization. An organization that effectively uses lean thinking and applies lean tools to reduce waste throughout the value stream and offer value to their customers is a *lean enterprise* organization.

Figure 45 shows a quasi value stream map (VSM) without the time allocations inserted in each box. The time is an important factor in completing a full VSM, and each process, once flow-charted, needs to be studied to understand the actual time averages and variation found at each step in the process. This will allow you to understand the bottlenecks better and to see the process as a whole functioning system.
Figure 45  Total quality assurance management value stream map.
Variation is a fact of life. If the measurement instrument (gage) or process that you are using does not show that the process is varying, then it is not sensitive enough and needs to be replaced. If you get one complaint about something, you can be assured that there are probably 10 more complaints that your system did not pick up. The author is aware of one organization who thinks that it provides pretty good service to customers. But one long-time customer (nearly 20 years) has recently become very upset about the overall service being received, and on one particular order was triple-charged for a wrong product sent that took an excessive amount of time to arrive. It wasn’t until the author made a call to the president of the organization that the vice president of customer service got involved in trying to
straighten things out. The organization still does not have a good method to accurately collect customer concerns, and the customer in question is still very unhappy.

Since all processes vary, the question becomes how to improve the process by reducing the amount of variation that is currently present (see Figure 46). This book lists various tools and methods to help identify variation. In variation reduction, you use those same tools to identify and monitor your progress toward improving what you do. Does the run chart show a reduction in variation? What can be seen in the cause-and-effect diagram, the histogram, the Pareto chart, or other tools? These and many other questions should be answered to understand the process as well as possible.

Just buying a new electronic instrument may actually cause more variation in the system due to

![Figure 46 Variation reduction curves.](image-url)
measurement error (see “Measurement Systems Analysis”). Throwing money at the system (say, a gift certificate for a future purchase) rarely helps improve the process. Studies will need to be done to understand all aspects of the process variation (for example, equipment, Practice supplies, people, communications, or paperwork), and you’ll need to work to reduce the causes in the system. The key is to identify and provide what the customer wants and needs from your process to the best of your abilities, given any limitations of the process.
When you drive a motor vehicle, what visual controls help you get to where you are going? This could be a great thought starter in asking Practice staff what would help them accomplish their tasks better. In an automobile, we have various monitoring devices inside the vehicle. Then there are numerous street signs, traffic lights, construction barriers or other warning devices, law enforcement personnel, and signals (hopefully) from other drivers on their intentions. In our Practice, we can include any number of techniques (some very simple) and ways to help our fellow staff to know what is coming through the Practice or what is going to happen next.

Remember the old adage “a picture is worth 1000 words?” The author has a copy of one of the first Toyota manuals used in the United States
for what is called the Toyota Production System. It contains mostly pictures! Why might this be? If you were to go to Japan, or any other country where you could not speak the language, how would you communicate with others? Now think about your patients. Do they speak the medical language that you do? The odds are, they do not, and some of our patients may even feel threatened by all of the medical terminology that they hear in the Practice even though it is in English.

Many of our Practices already have models and pictures in the examination rooms to help clinicians explain to patients how the body works. Can this be expanded? Using computers any number of things can be done to show how the body is or should be functioning. There are even high-end holographic devices today that can show the actual organs of the body in real time. How about simpler techniques—pictures or models that a patient can touch and feel to get the information to them as needed?

The challenge then is to set up a system that allows anyone to quickly see where information, people, supplies/materials, and so on, belong and where they are going next. Use pictures, directional indicators (how do you feel when you walk into a new hospital for the first time), and any other indicators to assist everyone in knowing how things work or how to get from point A to point B.
Customer feedback is a method or process of finding out what the customer actually thinks of your products or services. It is said that for every customer who actively complains to you, there are at least 10 others who for one reason or another will speak badly to others of your products and services. Finding out what the customer thinks, wants, and needs is a time-consuming effort, and many customers are getting tired of filling out surveys. Sometimes when customers (internal or external) do tell us something, we can not do anything about it, we do not want to hear what they are saying, or they expect something other than what we offer.

There traditionally have been many techniques for talking with customers, and with the
advent of e-mail and the Internet, even more exist today. The problem with many surveys is that we really do not know what proportion of our customers or which of our customers actually bothered to send them back. Also, paper surveys tend to have a very low return rate overall; thus, they really do not give us a very good picture. The point is that we must keep trying to talk with customers as often as possible to ensure that we know what their wants and needs are.

The most effective method still seems to be actually getting out into the world with your customers to experience what they experience and to interact with them as they use your products and services. Have you ever thought about what you do? What is it like for the next person in the organization to use your work? For Practice staff, finding this out should be a lot easier than it is for shop floor personnel, as staff can simply communicate with the next person in the healthcare chain. Practice staff might want to talk with that person directly, observe how he or she uses the information supplied to him or her, and study the data that are collected in the process to look for better ways to do work to make things easier for the internal customer.

A good starting point for collecting customer feedback is to set up a display for all employees and visitors to see. On that display, have samples of the ultimate products/services that are
produced in your Practice. It has often been noted that employees work all day yet do not know how their work is used. Once the display is up, employees can point out their work to others and take pride in what they do. Some of this information may not relate to the services provided by your Practice, so it should be passed along to an immediate customer who buys the services. Doing this well will allow your Practice to provide additional services to your immediate customers that they did not ask or pay for, giving you an advantage over your competition.
If you attended grade school in the United States, somewhere in the early grades you probably had a teacher play the telephone game with the class. The telephone game involves the teacher putting the class in a semicircle and whispering a short phrase to the first student. Then each student in turn whispers what they heard (or think that they heard) into the ear of the next student in line. By the time the last student received the message and repeated what they heard, it usually sounded nothing like what the teacher started with. Note: the author has done the same with degreed engineers and they still can not keep the phrase consistent.

So, given this scenario, think about your own work area. Are things being done the same way
as they were a year ago, two, five, or even 10? Small things are changing all of the time. Unless some form of standard (visual, written, and so on) is employed, the odds are that things will change over time. The purpose of the walkthrough is to identify these areas of change or to highlight areas or things that should be or could be changed to improve the operation of the Practice.

Avedis Donabedian (2003) defined quality assurance as “all actions taken to establish, protect, promote, and improve the quality of health care.” With this in mind, walk around your Practice and start asking the question, “What if?” We are often limited by our perceptions of money, time, physical surroundings, and so on. What if we could change something? How would that impact the staff’s ability to provide a better experience for the patient?

One primary challenge with this technique is to be able to view your work area with an open mind and stay out of the mind-set that we do things this way because of some preconceived notion that it must be that way. Continually ask yourself, “If we could do this better for the customer (internal or external), how might the customer appreciate the better service?” If a doctor could open any patient folder in the Practice and find everything in the same order, with summary run charts at the front giving an overview
of the patient’s health, how might that affect the doctor’s work and the patient’s experience?

During the walkaround of the Practice, one thing to keep in mind is elimination of what the Japanese call *muda*, or waste.

**Eight Categories of Muda**

1. Overproduction above demand
2. Waiting for processing, use, work
3. Material and/or information movement
4. Overprocessing
5. Excess inventory
6. Unnecessary motion
7. Inaccurate work (defectives)
8. Underutilized people

**Causes of Waiting Waste**

- Unbalanced workload
- Waiting for information
- Queuing delays
- Late deliveries
- Upstream quality problems
• Unleveled scheduling

Causes of Processing Waste

• SOP changes without communication
• Just-in-case logic
• True customer requirements undefined
• Overprocessing to accommodate downtime
• Lack of communication
• Redundant approvals
• Extra copies/excessive information
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