1
Introduction

1.1 Key Concepts

Quality improvement (QI) frameworks, Define–Measure–Analyze–Improve–Control (DMAIC), Plan–Do–Check–Act (PDCA), variation, data visualization, statistical tools.

1.2 Quality Improvement in Healthcare

Quality improvement (QI) is an integral component of the healthcare delivery landscape, necessitated by cost escalation and the drive to achieve better individual and population health outcomes. Government and nongovernment organizations at all levels provide resources, strategies, and mandates to achieve global, national, and local health goals. The United States has adopted a national strategy for healthcare quality improvement with three aims: better care, healthy people/healthy communities, and affordable care (Agency for Healthcare Research and Quality 2017). The World Health Organization articulates quality dimensions of effectiveness, efficiency, accessibility, patient-centered, equity, and safety that are applicable to all countries for improving health systems (World Health Organization 2006).

Quality improvement can be defined as the use of a continuous and systematic approach to achieve measurable improvement in healthcare delivery and individual and population health outcomes. Adopting a culture of quality improvement in a healthcare organization can lead to increased efficiency and productivity, better patient and employee satisfaction, the ability to retain and attract high-performing employees, better clinical outcomes, and reduced errors, risks, and costs. Quality improvement should be practiced continuously at all levels and functions of

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an organization. Additional information on quality improvement can be found at the websites of the American Society for Quality and the Institute for Healthcare Improvement.

There are a number of related activities found in healthcare delivery (and beyond) that differ from quality improvement. Quality assurance is a periodic, systematic review of a process to identify and correct errors and ascertain whether standards are being met. Quality improvement and quality assurance both focus on existing systems and processes, with quality improvement programs being driven from within the organization and quality assurance being driven by external organizations (e.g. government and accrediting agencies). Research activity can be found in healthcare organizations, but the emphasis is on attaining knowledge that supports the development of new interventions, products, systems, and processes. Quality improvement, quality assurance, and research share many methodologies and tools; the statistical tools presented in this book focus on quality improvement applications, but can also be used in research and quality assurance.

1.3 Understanding Variability: The Key to QI

Quality improvement can be realized by measurable reductions in cost, errors, or risk, improved health indicators for individuals and populations, and increased patient satisfaction. Healthcare systems and processes are subject to variation due to factors such as the inherent differences in patients, operational practices and procedures, clinician skill and training, and facilities and equipment. Improvements can be made by reducing variation. For example, hospitalized patient satisfaction can be raised and food waste reduced when meals are delivered as scheduled. Achieving improvement requires identifying and understanding the many sources of variation that can affect process performance. For example, timely hospital patient discharge can be affected by variations in staffing levels, pharmacy fulfillment times, demand for beds, etc.

A key step in quality improvement is to create a map or diagram that shows the sequence of the main process steps. Figure 1.1 shows a high-level process map for the preoperative total joint replacement (TJR) process, which will be the subject

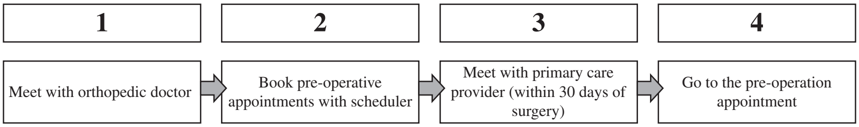

Figure 1.1 Process map for the preoperative total joint replacement.

of three chapters of this book that illustrate the lifecycle of a process improvement initiative.

Such process maps are useful for bounding the scope of the project. Process maps with more detail are good for identifying sources of variability and whether or not these sources of variation are controllable by the organization. Understanding which variability sources are controllable and which are not helps in defining potential improvement actions that an organization can undertake. For example, in Figure 1.1, process step 3 (when the patient meets with the primary care provider), is mostly outside of the control of the hospital, whereas process step 2 (book preoperative appointment) can be changed and is more likely to yield process improvements because patients' preoperative appointment scheduling takes place at the orthopedic clinic.

Sources of variation are also classified as common-cause or special-cause. Common cause variation is inherent in the process and reducing this type of variation, requires a change in the process itself. For example, the variation in the time between process steps 2 (preoperative appointment) and 3 (the preoperative clearance) is between two and four days for knee or hip replacements and seems to be reasonable variation for this part of the process. As such, this would be considered common cause variation. However, the variation in the time between the preoperative appointment and the preoperative clearance can be as high as 40 business days. This unusual variation is attributed to special cause, which arises from unusual circumstances. The variability for the Conformis-brand prosthetic knee replacement process is explained by additional preoperative steps, which not only require extra studies such an magnetic resonance imaging (MRI) but also the fabrication of a prosthetic by a vendor. If there is a problem with the prosthetic, the process takes longer than expected. This special circumstance leads to longer elapsed times than usual, and hence greater process variability that is outside the control of the clinic, adversely affecting the process performance. Identifying variation as either common-cause or special-cause can assist in developing and prioritizing potential improvement actions. In this casebook, we present tools for assessing variability both graphically and numerically. Data visualization and data slicing (or subgrouping) are powerful methods for identifying and quantifying process variation. Additional discussion on variability in the context of quality improvement can be found in Deming (1986) and Hoerl and Snee (2012).

1.4 Quality Improvement Frameworks

Establishing a quality culture requires an ongoing focus on quality throughout an organization, along with a framework and a set of tools for identifying, making, and maintaining improvements. These frameworks serve as a common approach within an organization, enabling project teams to undertake improvement initiatives in a systematic way using a well-defined series of steps. A key component of quality improvement is data collection and analysis to assess process performance. Thus, statistical tools play a key role. Nonstatistical tools, such as brainstorming and process mapping, also have an important role in quality improvement initiatives, particularly in the early stages. There are a number of different frameworks that can be adopted; we will provide a brief overview of two of the most commonly used frameworks.

1.4.1 Define–Measure–Analyze–Improve–Control (DMAIC)

The DMAIC framework is a systematic approach to quality improvement applied in Six Sigma programs. The American Society for Quality (ASQ 2019), defines Six Sigma as "a method that provides organizations tools to improve the capability of their business processes." The DMAIC cycle begins with the Define phase where a team is assembled to develop a project charter that describes the process to be improved and the objectives of the initiative. During this phase, requirements and improvement opportunities are elicited from stakeholders. A clear problem statement is a central part of the project charter. In the Measure phase, a process or value stream map is created to provide stakeholders with a common understanding of how the process operates and serves as the basis for generating improvement ideas. Process performance indicators are also identified, such as delay times and errors. In the Analyze step, the process and associated data are examined to discover potential sources of variation or error. During the Improve phase, process changes that will reduce or eliminate sources of error or variation are developed. Once process changes have demonstrated their effectiveness, they are implemented. Finally, the Control phase puts in place monitoring systems, such as control charts, to ensure that the quality improvements are maintained over time.

The TJR project, parts of which are described in Chapters 12–14, employed the DMAIC framework. Statistical tools including process capability analysis, hypothesis tests, box plots, and dot plots were used in each of the various steps of the process. Insights gained from these tools were critical for the identification of the root cause of the unnecessary process delays. Taken together, in the Improve stage, process root cause countermeasures were brainstormed, solutions designed and evaluated, and pilot testing took place to measure the effectiveness of the solution before its full implementation. In the Control stage, the process elapsed time was monitored in order to maintain the improvements.

1.4.2 Plan–Do–Check–Act (PDCA)

The PDCA framework, synonymous with the Plan–Do–Study–Act framework, is frequently applied to develop and test a quality improvement idea. In the Plan phase, a plan is developed to see if a process change idea will yield a desired improvement. This phase includes developing a problem statement and identifying data to collect to evaluate the change. During the Do phase, the change is implemented as specified in the plan, usually on a small scale. The Check phase evaluates the change using data collected in the Do phase. Finally, in the Act phase, a change that demonstrates significant improvement is deployed as appropriate throughout the organization. If the change does not produce the desired effects, it may be modified and retested or discarded.

As an example, nurses in a hospital wanted to reduce the severity of injuries associated with patient falls. They initiated a PDCA cycle to experiment with fall mats placed next to a patient's bed. They developed a plan to acquire and test the fall mats on a single unit. This change reduced the severity of injuries associated with falls and was adopted on a hospital-wide basis. PDCA initiatives are often conducted sequentially devising, testing, and deploying a series of process changes.

1.4.3 Choosing a Framework

Often, the DMAIC or the PDCA framework is seen as THE framework for quality improvement. While it is good for an organization to have a framework that they typically employ, there should also be a recognition of other frameworks and tools that should be used, depending on the problem to be addressed. The difficulty of process improvement efforts is not the lack of improvement or analysis approaches but matching the right approach to the problem under study. Figure 1.2 provides a matrix for consideration when deciding how to approach a particular type of problem. Typically, process improvement objectives fall into three main categories: (i) reduce process errors, (ii) reduce processing time or waiting times, and (iii) increase utilization of resources. Likewise, there can be three difficulty levels of problems: (i) too easy, problems with known root cause/solutions, (ii) just right, focused problems with nonobvious solutions, and (iii) too difficult, complex, and large problems with unknown root causes most likely coming from different sources. Projects that attempt to solve category three problems are typically known for trying to solve "world hunger." This type of project should be narrow-scoped before attempting any improvement effort. Nevertheless, the improvement methodology should match the problem difficulty level and improvement objective. For example, as shown in Figure 1.2, less difficult projects can be approached with Kaizen. Kaizen is a continuous improvement approach that utilizes short, intensive "events" where dedicated teams work to develop and implement incremental improvements. Lean is the term coined by MIT researchers to describe the way Toyota improved their processes by focusing on value-added activities to identify waste and thus streamline processes (Roos et al. 1991). Thereby, lean works well for projects with less complex problems

Type of project	Easy	Non-obvious solution	Systemic
Defect reduction/ Elimination	PDCA Kaizen	DMAIC/Six Sigma	Design for Six Sigma TRIZ-robustness
Cycle time reduction	Lean Kaizen	Lean Six Sigma/DMAIC	Lean product development
Resource consumption minimization	Lean for sustainability Kaizen	Six Sigma/DMAIC for sustainability	Lean Six Sigma for sustainability
	Project difficulty		

Figure 1.2 Framework-type of problem matrix.

and when the primary interest is in minimizing time and reducing wasteful activities. For nonobvious solution projects, more analysis is often required; in particular, Six Sigma/DMAIC is well suited for minimizing errors. Lean Six Sigma lies at the intersection of these two process improvement objectives, and for more complex problems, process methodologies that look into the redesign of products, processes, and sustainability of resources are better suited for systemic problems such as design for Six Sigma (DFSS).

There are other methodologies used when designing new products such as TRIZ, which is a Russian acronym from "Theory of Inventive Problem Solving," which is based on universal principles of creativity and invention for the design of innovative solutions to design problems (Altshuller 1999). Last, the concept of robustness is also used when solving complex design problems where the objective is to reduce variability in the performance of a product by making improvements in the product design. While these latter approaches originated in the manufacturing sector, these can also be applied to healthcare by focusing on the process or products used necessary for providing patient care. These quality improvement approaches, however, are beyond the scope of this casebook.

1.5 Statistical Tools for Quality Improvement

The use of data and measurement is key to the quality improvement philosophy. Therefore, data collection and analysis tools play an important role in improvement initiatives. The process of applying statistical tools to a quality improvement initiative begins with collecting data that will address the question posed. Generating pertinent and reliable data forms the basis for analysis that guides process changes. The application of formal methodologies in study, experiment, and survey design help assure that the data collected meets the needs of a quality initiative.

Once data has been acquired, a variety of data cleaning techniques, such as subsetting, recoding, or formatting may be needed prior to analysis. An important part of data preparation is making sure variable definitions are clearly understood. Data dictionaries accompany many databases and should be consulted for such definitions. Once the data is ready for analysis, the next step is to become familiar with the data through the use of descriptive statistics and visualizations. These initial data summaries are invaluable to help the analyst identify data anomalies, missing data patterns, outliers, time trends, and patterns of variation. They also assist the analyst in identifying additional statistical analyses that may prove useful in better understanding process performance. Figure 1.3 shows the data analysis process in relation to the DMAIC and PDCA frameworks.

In each of these analysis steps, there are a number of statistical and data management tools that can be applied. For example, hypothesis testing may be needed to ascertain if there are significant differences between average wait times of two different urgent care facilities within the same healthcare network. Data visualization is an integral part of the statistical analysis process. The statistical tools presented in this casebook are those most commonly applied in quality improvement. Additional detail on these tools and other statistical analysis techniques can be found in Babbie (2015), Hoerl and Snee (2012), Polit (2010), and Rosner (2015).

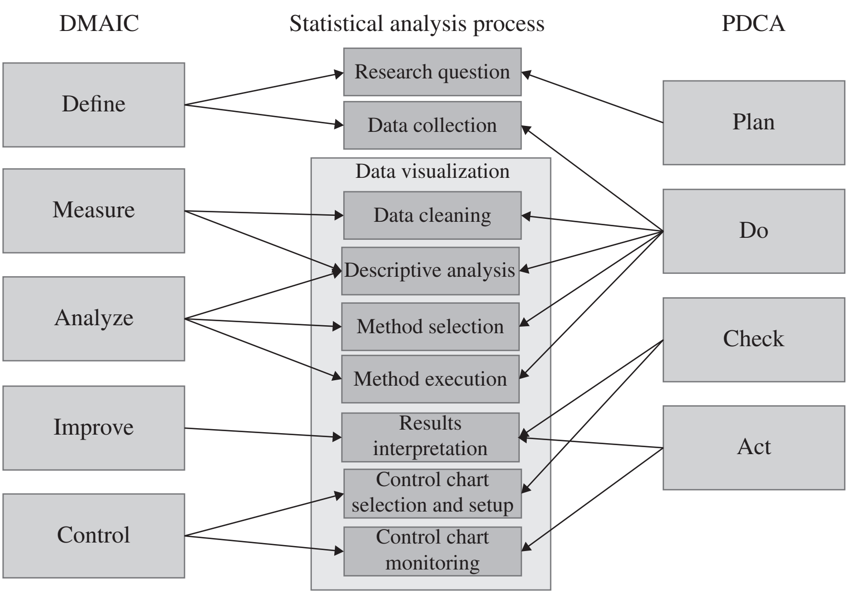

Figure 1.3 Statistical analysis process in QI framework.

1.5.1 Data Visualization

Data visualization plays an important role in quality improvement, as can be seen in Figure 1.3. Once data has been collected, visualizations are useful in the data cleaning process, for assessing variation, in understanding relationships between variables, and for monitoring key process indicators.

Univariate graphs such as histograms and box plots aid in identifying data anomalies, such as transcription errors or misspellings in character fields. These graphs also familiarize the analyst with the distribution of the observations. Outliers are easily seen in histograms and box plots. Outliers may be legitimate, but unusual values of a process or they may be errors that require either correction or removal from the data set. Careful study of outliers may lead to insights that benefit the quality initiative. A control chart, which will be described in more detail later, is another type of univariate graph used to monitor process performance over time.

Bivariate plots, such as scatterplots and run charts allow analysts to detect patterns of variation and time trends. They are also helpful to the analyst in choosing an appropriate form for a statistical model to quantify the relationship between two variables. Multivariate graphs such as bubble plots and scatterplot matrices are effective for displaying three or more variables. Maps are another valuable way to visualize geographic data. JMP®'s Graph Builder offers many options for creating multivariate graphs and implements the data visualization technique of "small multiples" (Tufte 2001). This method displays multiple variables using similar graphs with the same axis scales sequenced over one or two other variables. Small multiples allow the observer to focus on changes in the data rather than changes in the graphical elements.

Data visualizations are easily understood by participants in quality improvement projects and facilitate evaluation of process performance. They are also powerful tools for communicating with management, stakeholders, and the general public. There are a number of principles and best practices to create effective visualizations. The reader is referred to the works of Cleveland (1994), Tufte (2001), Few (2012), and Knaflic (2015) for more guidance on creating compelling data visualizations. The cases presented here illustrate how visualizations are applied in various phases of the DMAIC process and provide step-by-step instructions for how to create a variety of different types of graphs.

1.5.2 Subgrouping Data

Examining data in subgroups, also known as "slicing" the data, or stratification can help project teams discover opportunities for process change. For example, analyzing the time required for nurses to respond to a patient call by shift may identify needed changes to staffing levels to improve patient satisfaction. JMP provides many features that facilitate data slicing, such as the Data Filter, Graph Builder, and Tabulate. Data subgrouping was crucial in the preoperative TJR process improvement effort. Even though the main steps of the preoperative TJR process are the same regardless of the type of implant, the improvement team discovered that there were some extra steps for a particular kind of knee implant. This stratification led the team to analyze these processes separately. Indeed, this data slicing allowed the improvement team to run comparative studies that facilitated the identification of the root cause of the problem as discussed in Chapters 13 and 14.

1.5.3 Control Charts

In practice, process changes are most effective right after they are implemented when awareness is high, but over time, these changes may not be sustained. Control charts are a key tool for monitoring quality improvements to be sure that the desired effect is maintained over time. They track key process variables and alert the user when something has changed in the process performance.

An important feature of control charts is that they display the region corresponding to the expected variability (common cause variation) of a process indicator when it is operating normally (i.e. in control). Observations lying outside of this region alert the user that the process has changed and action should be taken to understand what has changed and deploy any needed corrective actions. There are different types of control charts that depend on the measurement level of the process variable. “Variables” charts are for those variables measured on a continuous scale. “Attribute” charts apply to count measurements, such as number of errors per insurance claim. Figure 1.4 shows some of the commonly applied attribute and variables charts.

Attributes are counts, classified as either defectives or defects. A defective is an item that does not meet the requirements, while defects are the number of nonconformances per item. For example, consider the process of hospital bills being audited periodically. If a bill contains an error, it would be considered defective, and the count of all defective bills during the audit period would be appropriately monitored by P- or NP-charts, depending on whether the number of bills audited in each period is variable or fixed, respectively. In contrast, if the auditors count the number of errors on each bill, then U- and C-charts are applicable, again depending on whether the number of bills audited in each period is variable or fixed, respectively.

A process variable that is continuous is typically monitored using two charts, one to track the process average and one to track the variation. The I–MR chart combination (in JMP referred to as IR) allows a process to be monitored when there

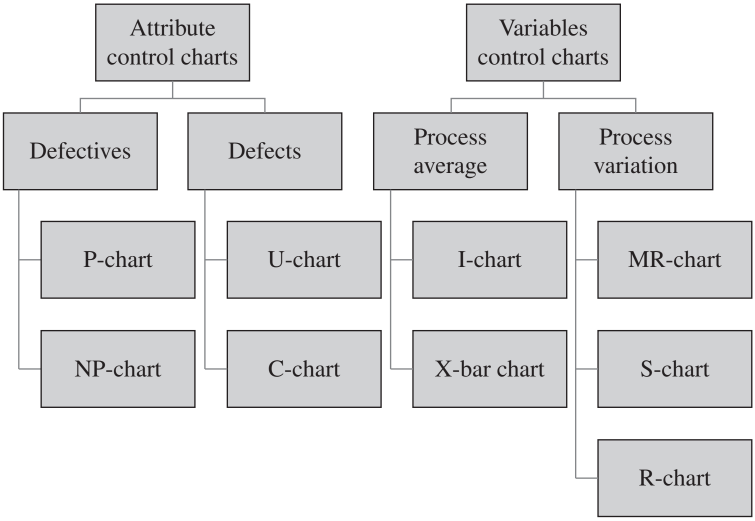

Figure 1.4 Types of control charts.

is only one observation per unit time. For example, an emergency department monitoring the number of hours they are not accepting incoming ambulances (ambulance diversion) would employ I- and MR-charts. X-bar and either an S- or R-chart are applicable when monitoring a process where there are multiple observations per time period, such as the waiting time until a patient completes the intake process in an emergency department. The case "Monitoring Ambulance Diversion Hours" explains the construction and use of I- and MR-control charts. Chapter 11 illustrates several types of control charts. Additional information on control charts can be found in Montgomery (2012).

1.5.4 The Importance of Assumptions

Many of the traditional statistical methods, such as hypothesis testing, have assumptions that must be satisfied for the conclusions to be valid. For example, the assumptions underlying the one sample *t*-test are that the data are continuous and follow a Normal distribution and were obtained as a simple random sample. Always check the assumptions underlying a statistical method to avoid drawing an erroneous conclusion. For example, constructing a Normal probability plot or performing a Shapiro–Wilks test verifies normality. The degree to which each method is robust to deviations from the assumptions varies. When assumptions are violated, there are often other methods that can be applied. In the case where the normality assumption does not hold in a one sample *t*-test, the Wilcoxon signed rank test is an alternative. Additional information on dealing with violations of assumptions can be found in Rosner (2015).

1.6 Using this Casebook

This casebook focuses on the use of statistical tools as implemented in JMP for healthcare quality improvement. The cases take a holistic approach to data analysis beginning with background and a specification of the task to be undertaken. The available data is presented and the processing needed to prepare the data for analysis is illustrated. Every analysis begins with descriptive analysis and may be followed by the application of statistical methods, the results of which are interpreted in the case context. Insight and implications from the analysis are then discussed and next actions are suggested. Each case concludes with a table that summarizes the key concepts of statistical analysis, data management, JMP features, and quality tools illustrated. This table is followed by exercises and discussion questions that may be used to master and extend the material presented in the case.

Figure 1.5 shows the correspondence between the case structure and the DMAIC and PDCA frameworks. The key concepts are presented at the beginning of each case and associated with the relevant DMAIC and PDCA steps.

The 13 cases presented in this book cover the most commonly applied statistical tools in quality improvement and show the step-by-step instructions to execute the methods in JMP. The three cases on TJR comprise a complete quality improvement project. Pairs of cases related to a single topic or data set show the application of a sequence of methods, as in the diabetes patient hospitalization

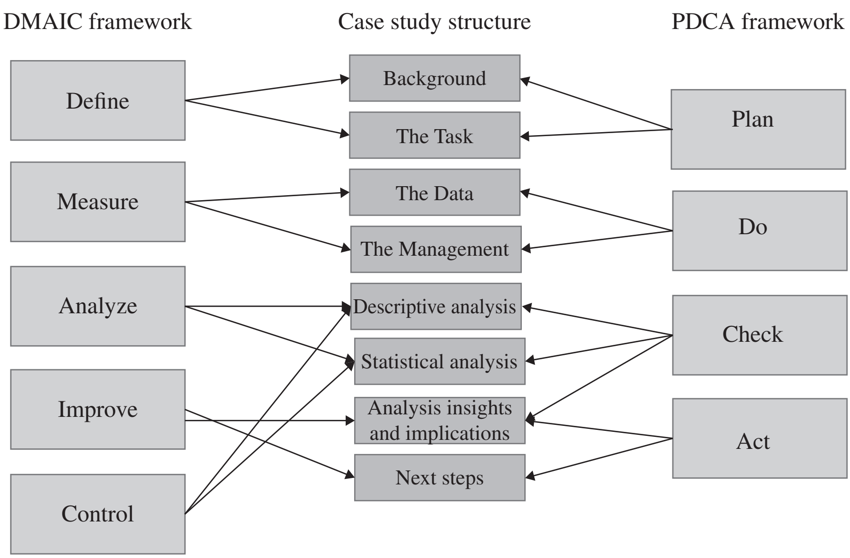

Figure 1.5 Case structure and DMAIC and PDCA frameworks.

data where the first case shows the creation of data visualizations and the second case integrates the data and visualizations in a dashboard (Chapters 3 and 4).

1.7 Summary

Table 1.1 summarizes the statistical tools covered in each of the cases.

Table 1.1 Summary of statistical tools.

Chapter	Title	Statistical tools
2	Improving Patient Satisfaction	Data visualization Descriptive statistics
3	Length of Stay and Readmission for Hospitalized Diabetes Patients	Data visualization Descriptive statistics
4	Identify and Communicate Opportunities for Reducing Hospital Length of Stay Using JMP Dashboards	Data visualization Dashboards
5	Variability in the Cost of Hip Replacement	Data visualization Descriptive statistics Outlier analysis
6	Benchmarking the Cost of Hip Replacement	Descriptive statistics Data visualization Hypothesis test of mean Confidence interval for mean
7	Nursing Survey	Data visualization Descriptive statistics Hypothesis test of proportion Hypothesis test for difference between two proportions Confidence interval for proportion
8	Determining the Sample Size for a Nursing Research Study	Hypothesis testing Sample size determination Power analysis
9	Mapping California Ambulance Diversion	Descriptive statistics Data visualization Geographic mapping

(Continued)

Table 1.1 (Continued)

Chapter	Title	Statistical tools
10	Monitoring Ambulance Diversion Hours	Descriptive statistics Data visualization IR Control charts
11	Ambulatory Surgery Start TImes	IR Control charts X-bar R charts P charts
12	Pre-Op TJR Process Improvement – Part 1	Data visualization Descriptive statistics Time series
13	Pre-Op TJR Process Improvement – Part 2	Data visualization Descriptive statistics Process capability
14	Pre-Op TJR Process Improvement – Part 3	Data visualization Descriptive statistics Hypothesis test on mean difference Confidence interval on mean difference

1.7.1 Exercises

1. Choose a process that occurs daily in your personal or professional life.
   (a) Draw a process map that shows the steps.
   (b) Identify those steps that have controllable or uncontrollable variation.
   (c) For those steps that are within your control, develop actions that could be taken to improve the process.
2. Consider your travel to work or school. Briefly describe your mode of transportation, route, and duration of the trip. Identify the causes of variability in the time to complete your trip and classify them as either common- or special-cause variation. What actions could you take to reduce your travel time variability?
3. Each US state's health department issues a weekly report during influenza season. Choose a state and select one of the weekly reports during the height of flu season. Evaluate the data visualizations presented in the report. Write a paragraph critiquing the visualizations, commenting on those graphs that were effective and those that were not.
4. Draw a high-level process map for the steps involved in having a routine blood draw done as part of an annual physical exam. Identify the steps that add value

from the patient's perspective and the steps that do not, and the steps that are necessary from the clinical point of view. Identify where in the process interruptions or delays are encountered. Are the causes of delays obvious? Are the bottlenecks that prevent the tasks from flowing continuously easy to identify and eliminate? Use Figure 1.2 to identify the process improvement framework that would be appropriate for this case. Justify your answer and identify what kind of data would also be appropriate to collect to narrow scope the project.

1.7.2 Discussion Questions

1. Search the Internet and find a report or journal article that describes a healthcare quality improvement project. Prepare a brief summary of the project and include the following:
   (a) Describe the process to be improved and the associated problem(s).
   (b) What quality improvement framework was used?
   (c) What variables were used to measure the key aspects of the process?
   (d) What changes were made to the process and who developed these changes?
   (e) Specifically, how much improvement was realized (e.g. cost savings, amount of risk reduction) and what monitoring was done to assure that the improvement was sustained?
2. Research nonstatistical tools that are commonly applied in quality improvement initiatives. Give a brief description of each of these tools and identify the steps in the DMAIC and PDCA frameworks in which they are most applicable.
3. Research and share principles of effective data visualization. Identify visualization techniques that should be avoided.
4. Explore the literature to find other quality improvement frameworks. Discuss how they compare to DMAIC and PDCA.

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