



CHAPTER TWELVE

QUALITY CONTROL

Quality in Health Care

Quality in general terms means meeting and exceeding customer expectations. In health care, the definition of customer and the criteria for quality are complicated matters in comparison to the meaning of those terms in industry. Obviously, it is patients who receive health care services. However, what they receive is often not understood by them, when diagnosis and therapy are purchased on their behalf by providers. Hence, quality in health care is evaluated from differing perspectives of recipients and third-party payers.

Most clinicians accept the Institute of Medicine (1990) definition: “Quality is the extent to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” In accordance with this definition, health care organizations have developed many valid technical measures to evaluate diagnostic and therapeutic clinical processes. A different set of measures are based on health care outcomes that become available or are obtained at the same time or after health services were rendered. If the outcomes can be related to a process or series of processes known to improve outcomes, they also are considered to be valid measures of quality. However, an outcome measure that is related to patients’ or clinicians’ experience, particularly their feelings about processes (collected using satisfaction

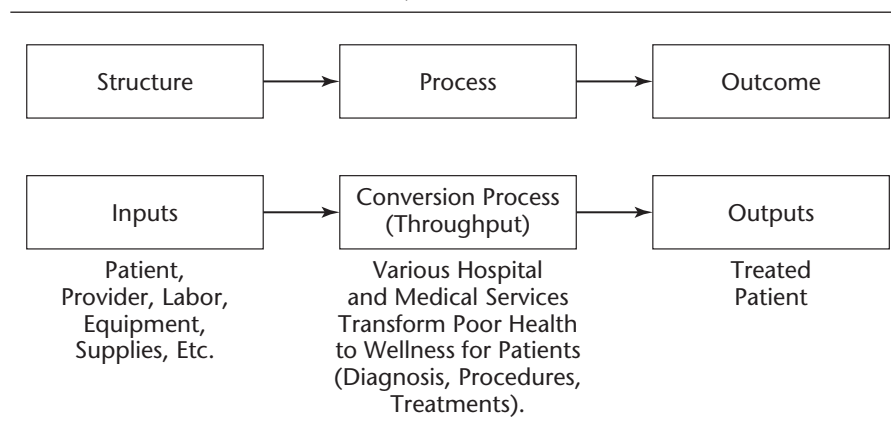
surveys), is defined as a subjective perception about the quality of care (Chassin, 1998).

Figure 12.1 illustrates Donebedian's structure-process-outcome conceptualization extended to health services. The input-throughput-output sequence facilitates conceptualizing measurements that can be taken at various stages of providing health care services production. Applying Donebedian's concepts, inputs are part of structure, comprising patients' request for services from providers who have facilities, staff, equipment and materials to serve them. At the next stage, the conversion process (for example, from ill health to good health) encompasses diagnostic and therapeutic procedures. At the third stage, outputs, patients exit the system, at which point we assess their conditions as either treated successfully, treated with morbidity, or mortality. Patient satisfaction surveys with follow-up give health care managers feedback on how a patient assessed the treatment process, the overall experience, and the final outcome.

A health care system that has less than acceptable patient satisfaction reports, repeated morbidity, and unacceptable mortality must examine its conversion process. That is, the health care managers must investigate what mistakes and errors were committed systematically to produce the undesirable outcomes.

Another way to look at the maintenance of quality is how mistakes are to be avoided—design mistake proof processes across the whole spectrum of care, to reduce undesired outcomes. Variance in diagnostic and therapeutic interventions and the associated errors hamper the delivery of safe, effective patient care and add to poor outcomes. To minimize the variation and the errors—sometimes euphemistically called “quality gaps”—and work toward completely eliminating

FIGURE 12.1. QUALITY MEASUREMENT.



them are major goals for health care systems. Chassin (1998) classifies the underlying causes of “quality gaps” into three categories: 1) overutilization; 2) underutilization; and 3) misutilization.

1) Overutilization—when the potential benefit of a therapy is less than its risk, overuse of health services affects the quality of care. Pressures for overuse of services may come from either providers or patients. Pressures from the provider side are: physician ownership in facilities or equipment and consequent self-referrals, the zeal and enthusiasm of a physician to perform a procedure, specialists performing procedures because they are expected to by their referring primary care colleagues, and providers’ fear of malpractice suits. Pressures from the patient side are cultural factors: expectations for physicians to perform and the desire to have the latest, most publicized and/or technologically advanced treatment.

2) A patient’s lack of insurance or insurance that has high copayments and deductibles can cause underutilization of necessary health care. A lack of standardization for various procedures, due to their complexity and also the overwhelming amount of information on therapies, creates selection bias in physicians’ choices of treatment.

3) Avoidable complications, negligent care, mistakes, and mishaps create misutilization of services. Health care providers who generate such conditions harm the quality of patient care and produce poor outcomes; they also waste the organization’s resources and increase lengths of stay (Chassin, 1998).

It is not uncommon to learn from the media about mistakes that occur in health care facilities: patients undergoing second surgeries because something was left in their bodies during the previous one; chemotherapy overdoses; the wrong organs being removed; organ transplants done with mismatched blood or tissue donors. What shows up in the media are the high profile cases, yet mistakes occur continuously in health care organizations, and, especially in medications, with the wrong medications given to patients or medications given before checking allergies or interactions. Some of those errors occur because appropriate existing technologies are not in place, for example, in a hospital pharmacy, use of drug interaction software; bar coding technology to match unit dose medications to patients; proper measurements of weight, height, age and other conditions of a patient to avoid mistakenly calculated doses. Of course, despite the presence of sophisticated systems, everyone must still be on guard against human error or negligence causing such mishaps as delivering medication to a patient without scanning, mislabeling blood tubes, ignoring the alarm sound from an IV dropper, or not checking a patient’s oxygen supply.

Health care providers do have an arsenal of methods to deal effectively with the problems affecting quality of care. They include the programs called quality control (QC), total quality management (TQM), continuous quality improvement

(CQI), reengineering, and Six Sigma. All of these programs include data gathering, analysis and statistical monitoring to identify the problem and its cause. Nevertheless, the crux of the solution to quality problems lies in changing human behavior; changing minds to perform care in new ways. That is a colossal task in health care, especially as it involves clinicians. The hopeful aspect is that when evidence is provided, clinicians are more willing to adopt and follow changes. Thus health care managers and leaders should provide such evidence.

Quality Experts

The ideas behind the methodological programs listed above emanated from various experts who have contributed to and shaped contemporary methods for improving quality. W. Edwards Deming is known for his list of fourteen items to achieve quality in organizations. The main message of the list is that poor quality occurs as a result of the system and so should be corrected by the management. Deming also stressed that variation in output should be reduced by identifying particular causes that differ from random variation. Later in this chapter we will examine statistical methods for identifying such causes in output variation. Joseph M. Juran's thought was geared towards what the customer wanted and he asserted that 80 percent of quality gaps can be corrected by management through quality planning, control, and improvement. Philip B. Crosby introduced the concept of zero defects and stressed prevention. He pointed out that the cost of achieving higher quality also reduces costs, hence the quality is free (Stevenson, 2002; pp. 402–406).

Quality Certifications and Awards

Like many other organizations, health care facilities seek certifications and hope to win prestigious quality awards so that they can gain a larger share of the market and confidence of—in their case, their patients—and also of other customers. Such awards are given annually to raise awareness of the desirability of quality and to recognize those institutions that successfully pursue good quality management in their operations. The Baldrige Award is given annually, up to two awards, for large service organizations as well as for large manufacturers and small businesses in the United States. The Deming Prize is given by Japan for organizations' successful efforts to demonstrate quality.

Apart from awards, organizations can seek quality certification through the International Organization for Standardization (ISO). The ISO is an amalgamation of national standardization institutes from 91 countries. The American National Standards Institute (ANSI) is the U.S.-based participant in ISO. ISO 9000 are a set of international standards on quality management and quality assurance;

it takes one to one-and-a-half years to go through the process of documentation and on-site assessment to obtain such certification (Stevenson, 2002; pp. 407–410).

Organizations can earn awards or achieve certifications and accreditations by international organizations or by their own trade organizations; for instance, hospitals are evaluated periodically by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). For the medical group practices, the Medical Group Management Association (MGMA) is the principal voice. “MGMA’s 19,000 members manage and lead 11,500 organizations in which approximately 237,000 physicians practice. MGMA leads the profession and assists members through information, education, networking and advocacy” (Medical Group Management Association, 2004). Quality is always a major concern in those advocacy and accreditation bodies.

To comply with known standards or to establish new benchmarks, health care providers can implement well known quality methods to improve or overhaul their clinical care and management processes. As noted such methods include QC, TQM and CQI as well as the more contemporary Six Sigma programs. We will discuss the nature of those programs and examine the tools used to implement them in health care organizations.

Total Quality Management (TQM) and Continuous Quality Improvement (CQI)

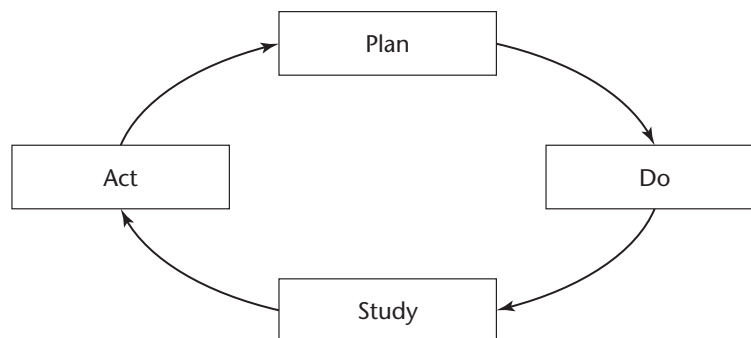
TQM combines certain concepts introduced by the quality experts mentioned above, to create a systematic approach for achieving better outcomes of care and also more patient satisfaction through an organization’s continual efforts. Many successful applications of TQM in health care have been conducted as the projects of various provider institutions. Often the projects sought to improve the “conversion process” through care pathways and disease management, identification of the causes and prevention of medical errors, risk management in nursing units or in ambulatory health care, and so on.

As a systematic approach, TQM requires the dedication and combined effort of every person in the health care organization. The success of a TQM program depends upon how well the following steps are taken: 1) measuring patient wants as well as needs from the providers, through surveys and focus groups; 2) designing a process for health care service process that will meet and even exceed patient expectations; 3) designing process for health care services that is fail proof (“pókayoke”) or fail-safe—that is, systems are designed so that they can work only one way, the safe way (the medication system), so human error is eliminated; 4) monitoring the results and using that information to improve the system; and 5) benchmarking the system by comparisons to peer providers (Stevenson, 2002; pp. 470–472).

TQM is achieved through a team approach that creates synergies among clinicians, administrators and all the support staff involved in health care delivery. TQM projects have often failed for a variety of reasons: lack of motivation, communication, dedication, plan, and/or leadership; or hodgepodge implementation of the project. To implement successful TQM projects, health care managers see to it that standardized problem-solving techniques are adopted across the organization and for all processes. A framework for problem solving and improvement activities is identified by the Deming wheel/Shewhart cycle which contains these activities: Plan-Do-Study-Act (PDSA).

Figure 12.2 displays the PDSA cycle, in which each step can be broken down to more detailed steps. In general, the planning activity would comprise recognition and definition of the problem in a current process by health care management, followed by forming teams that include clinical and administrative personnel to document and detail the problem. The team would develop performance measures to evaluate the problem, and identify goals (benchmark), collect data and analyze. In the “Do” cycle, the possible causes of the problem are identified and the solution to fix the problem is implemented. Then, in the “Study” cycle, the solution is monitored, evaluated, and compared against available benchmarks to ensure that performance is acceptable. If implementation has proved successful, the health care manager’s action, in the “Act” cycle, includes standardization of the procedures, making them formal through training and communication across the organization. Otherwise, to further improve the process, revision of the plans and a repeat of the process are required. Even when targets have been achieved, the health care quality team can continue the process to set a new benchmark; that is known as continuous quality improvement (CQI). Some health care managers, though, may choose to stop the process at this point and pursue other methods (Stevenson, 2002; pp. 475–477).

FIGURE 12.2. THE DEMING WHEEL/SHEWHART CYCLE.



Continuous quality improvement (CQI) of various clinical and administrative processes is a systematic approach that also involves documentation, measurement, and analysis. The objective for CQI is to increase patients' and clinicians' satisfaction, while achieving higher quality, reducing waste and cost, and increasing productivity. The CQI is a detailed version of a PDSA cycle that comprises: 1) selecting a process that needs an improvement; 2) studying and documenting the current process; 3) seeking ways to improve it; 4) designing an improved process; 5) implementing the new process, 6) monitoring and evaluation; 7) documenting the process if it worked successfully and publicizing it through the health care organization; or 8) if it did not achieve its goals, restarting from step 1.

Six Sigma

Six Sigma is one of the latest quality improvement concepts to have emerged during the 1990s. Its name comes from the measure of variation from the normal distribution (six standard deviations). General Electric and Motorola are major companies that have successfully adopted a Six Sigma quality strategy and been examples for other organizations that followed. Adopting a Six Sigma strategy as a quality goal sets tolerance levels for errors (defectives) to levels that occur only 3.4 times per million observations. The defect rates in health care can be defined in such distinct areas as public health, inpatient care, ambulatory care, and so on. For example, infant mortality rates can be considered as defects per million population. Similarly, rate of deaths caused by anesthesia during surgery or of injuries to patients due to negligence are measures of defects for inpatient facilities (Chassin, 1998). According to Chassin (1998), health care organizations have reduced the deaths caused by anesthesia from twenty-five to fifty per million cases to five per million cases since the 1980s through improved monitoring techniques, adaptation of practice guidelines, and other systematic approaches to reduce errors. Hence, this is one area that comes very close to Six Sigma standards (Chassin, 1998). That example portrays the essence of the Six Sigma method: the defects are measured in terms of deviation from the norm, and strategies are adopted to eliminate them through a process and get as close to zero defects as possible.

Adopting Six Sigma strategies in service systems, especially in health care, has lagged by about a dozen years. According to various sources, about one percent of health care providers in the United States have deployed Six Sigma methods. It is expected that the adoption rate will increase (Redinius, 2004).

Deployment of Six Sigma to improve the quality of health care and delivery performance can be considered in the following areas: clinical excellence, service delivery, service costs, and customer satisfaction. The deployment can use either of these methodological sequences: DMAIC—define, measure, analyze, improve, and control; or DMADV—define, measure, analyze, design, and verify. DMAIC is

generally used to improve existing systems that have fallen below Six Sigma levels, DMADV is used to design and develop new processes or products at Six Sigma levels (Stahl, Schultz, and Pexton, 2003).

The essence of Six Sigma methodologies is both improvement of the knowledge and capability of employees, and also behavior changes through training. Thus, Six Sigma employs a classification system that identifies education and training for employees, project managers and executives. Emulating karate honors, certification is granted at Green Belt (GB), Black Belt (BB) and Master Black Belts (MBB) levels. Green Belts are the employees who have taken the training courses on implementing the projects. Black Belts are the project leaders, whose training may be more intensive; they may complete several projects a year depending upon their size and scope. Master Black Belts are generally assigned to an area that needs improvement (for example, human resources), to ensure that objectives are set, targets are identified, plans are made, and resources are secured to implement the projects in their assigned area. MBBs may oversee many Six Sigma projects at a time, working with various BBs.

Six Sigma projects require BBs and MBBs to have expertise in basic statistical tools such as Pareto Diagrams, descriptive and higher level statistics including regression, and statistical modeling techniques as well as control processes. In addition to statistical concepts, they are expected to understand project management, finance, leadership, measurement through sociometric (survey) analysis, reliability and validity.

Examples of successful Six Sigma deployments in health care include reduction of emergency room diversions, fewer errors in operating rooms' cart materials, reduced bloodstream infections in an ICU, and improved radiology turnaround time (Stahl, Schultz, and Pexton, 2003). As health care organizations increase scrutiny in monitoring clinical outcomes, health care managers must develop and adopt fail proof systems to achieve the desired quality levels (Morrisey, 2004).

In order to define, measure, analyze, and monitor systems in health delivery, managers need various quality deployment tools. These tools are useful whether the program used is quality management through TQM or DMAIC, or quality improvement through CQI or DMADV.

Quality Measurement and Control Techniques

Process Variability

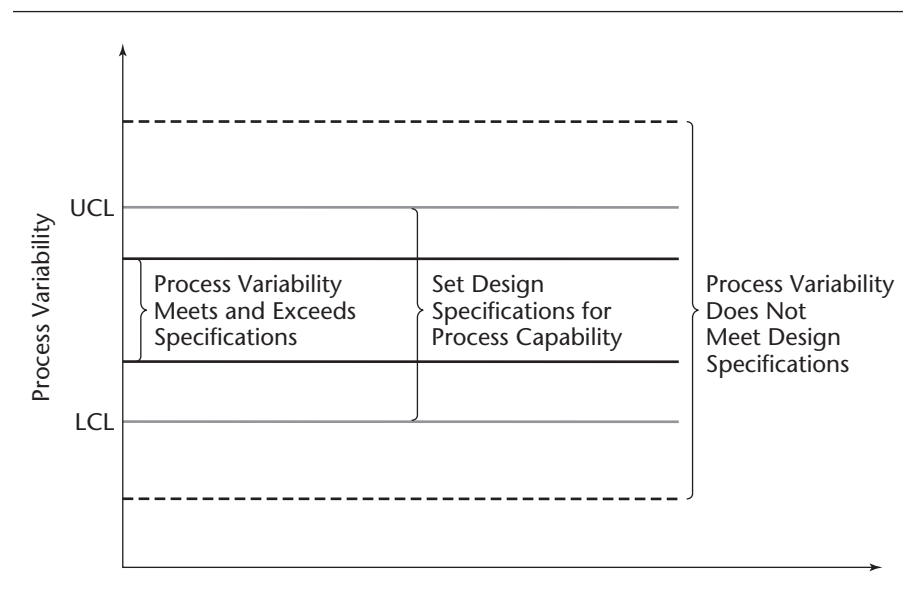
In the delivery of health care, there are many occasions when an error can happen in the tasks performed by physicians, nurses, or allied health professionals such as radiation or physical therapists. Often the same task may not even be performed

the same way for all patients, though minor alterations within defined limits can be acceptable. When, however, provider performance falls beyond acceptable limits, the errors that occur require investigation and correction. In order to detect noteworthy variations in process, or tendencies that may cause unacceptable levels of errors, health care managers must monitor the processes for quality, using various charts. The intent of the monitoring is to distinguish between random and nonrandom variation. The common variations in process variability that are caused by natural incidences are in general not repetitive, but various minor factors due to chance and are called **random variation**. If the cause of variation is systematic, not natural, and the source of the variation is identifiable, the process variation is called **nonrandom variation**. In health care, nonrandom variation may occur by not following procedures, using defective materials, fatigue, carelessness, or not having appropriate training or orientation to the work situation, among many reasons.

Process variation is the range of natural variability in a process for which health care managers use control charts to monitor the measurements. If the natural variability or the presence of random variation exceeds tolerances set by control charts, then the process is not meeting the design specifications.

Figure 12.3 shows a chart with design specifications to achieve a certain level of quality as determined by the lower confidence level (LCL) and the upper confidence

FIGURE 12.3. PROCESS CAPABILITY.



level (UCL). (We will show later how the LCL and UCL can be determined.) From this chart, three possible outcomes can be seen to occur. First, the actual outcomes can be so good that process variability would be contained in a narrower band than the design specifications. That may be due to an excellent quality program, or on the other hand, to design specification being too lax. In the second scenario outcomes could occur within LCL and UCL so that the expected quality would be achieved. However, in the third scenario, outcomes could occur beyond the design specifications, not meeting the expected quality outcomes. Then, health care managers should focus on the causes that create such variation by conducting investigations. Such outcomes are generally not random but systematic, and the sources in systematic factors must be found and corrected. In such situations, the health care manager usually must consider redesigning the system that causes such nonrandom outcomes. For example, high turnover and improperly trained new staff could be one of the sources for the process variation in nursing care units. Therefore, the health care manager may have to redesign and enforce the in-service training as well as having to attack problems causing high staff turnovers.

Monitoring Variation through Control Charts

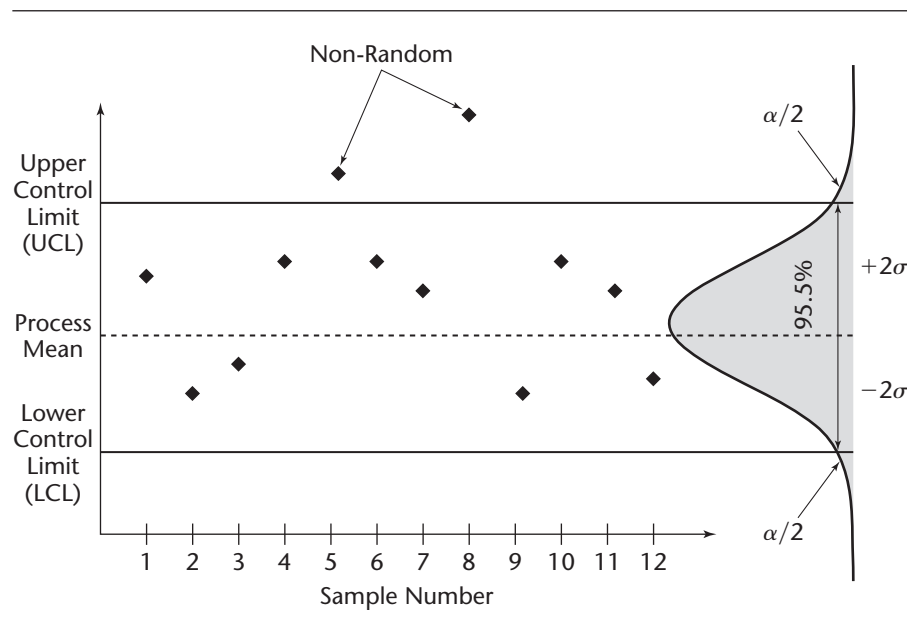
A control chart is a tool to display in graphic form the control limits on process outcomes. In the hospitals, the outcomes can be staff response to patient requests, accuracy of medications, infections, accuracy of laboratory tests, and expedience of admissions and discharge processes, to name just some among the many that can be monitored with control charts. The health care manager has to use the appropriate type of control chart for the process being monitored, and that depends on how the process is measured. For example, how many times a staff member did not respond within the appropriate time to a patient request is a counting process, and the variables used to measure this outcome are attributes. Thus a **c-chart** for attributes is the appropriate control chart for such count-type measurements. Similarly, if the process is measured by the percentage of the responses received by patients that were inappropriate, or the percentage of design specifications that were not met (for example, percentage of discharges that are not processed within two hours of discharge orders), then the appropriate attribute-based control chart is a **p-chart**. The other two commonly used charts are **mean and range charts**, which monitor process mean and range. Note that mean and range charts must be used together to monitor process variation.

Although the construction of control charts depends on the measurement variable (monitoring attribute versus process mean/range), all control charts have common characteristics. Each chart has a process mean and lower and upper control limits that are calculated according to the type of measurement variable. The

control limits theoretically separate random variation from nonrandom variation. Samples taken from the process in a time order are shown in Figure 12.4, where the variation within ± 2 sigma level—95.5 percent probability—can be described as random variation.

However, we must approach this determination with caution. If all points appear within the LCL-UCL, we are sure about this with only 95.5 percent confidence; that means there is a 4.5 percent chance that we may be erroneously concluding the process is random, when it is not. This is called **Type II error**. Similarly, consider the two points (samples 5 and 8) beyond the UCL in the graph, where we conclude the variation is nonrandom. Again, we are able say this with only 95.5 percent confidence, and 4.5 percent of the time we may commit the error of concluding nonrandomness when randomness is present; that is called **Type I error**, or α risk. Since Type I error can occur above or below the confidence levels, the risk is divided evenly for each part, $\alpha/2$. One can reduce Type I error by using wider limits such as ± 3 sigma. However, then detection of nonrandom variations would become more difficult, leading to greater Type II error of concluding that nonrandom variations are random. In practice, ± 2 sigma level is usually used to determine LCL and UCL for control charts.

FIGURE 12.4. CONTROL LIMITS, RANDOM AND NONRANDOM SAMPLE OBSERVATIONS.



Control Charts for Attributes

When process characteristics can be counted, attribute-based control charts are the appropriate way to display the monitoring process. However, counting can be conceptualized in different ways. If the number of occurrences per unit of measure can be counted, or there can be a count of the number of bad occurrences but not of nonoccurrences, then a *c*-chart is the appropriate tool to display monitoring. Counting also can occur for a process with only two outcomes, good or bad (defective); in such cases, *p*-chart is the appropriate control chart. The *p*-chart arises from binomial distribution where only two outcomes are possible.

***c*-Chart.** Certain processes require counting bad occurrences as quality defects. For example, the number of wrong medications delivered in one thousand patient days, or the number of infections occurring during a month are such occurrences. Remember that counting occurs over a sample or over time, and that occurrences can be counted per unit of measure. The theoretical conceptualization of this process is described by Poisson distribution, with a mean of c and standard deviation of \sqrt{c} . When there are enough samples in the quality control process, by invoking central limit theorem we can use normal approximation to Poisson and define the control limits of the *c*-chart as follows:

$$UCL = c + z\sqrt{c} \quad [12.1]$$

$$LCL = c - z\sqrt{c} \quad [12.2]$$

where c represents the population mean for the number of defects over a unit (or time period). In the absence of population parameters, estimates of the sample mean and standard deviation can be used by replacing c with \bar{c} , and confidence limits can be established as:

$$UCL = \bar{c} + z\sqrt{\bar{c}} \quad [12.3]$$

$$LCL = \bar{c} - z\sqrt{\bar{c}} \quad [12.4]$$

If LCL values are negative, for practical reasons they should be set to zero.

EXAMPLE 12.1

The number of infections from the Intensive Care Unit (ICU) at the ABC Medical Center over a period of twenty-four months is obtained. These numbers are the counts of stool assay positive for toxin, segregated by month. The patient population and other external factors such as change in provider have been stable.

Months	Infections in ICU	
	Year 1	Year 2
January	3	4
February	4	3
March	3	6
April	4	3
May	3	4
June	4	3
July	5	5
August	3	6
September	4	3
October	3	3
November	7	6
December	4	3
Total	47	49

The nurse manager who serves on the quality team wants to discover whether the infections are in control within 95.5 percent confidence limits.

Solution: If we consider each month as a sample of bad quality outcomes, for twenty-four samples we have a total of ninety-six quality defects (infections), and the average would be:

$$\bar{c} = 96/24 = 4.0.$$

Since the z -value for 95.5 percent confidence level is equal to 2, using formulas [12.3] and [12.4] we obtain

$$UCL = \bar{c} + z\sqrt{\bar{c}} = 4 + 2\sqrt{4} = 4 + 2 * 2 = 8.$$

$$LCL = \bar{c} - z\sqrt{\bar{c}} = 4 - 2\sqrt{4} = 4 - 2 * 2 = 0.$$

The corresponding control chart for ICU at ABC Medical Center is shown in Figure 12.5. ■

p-Chart. The proportion of defects in a process can be monitored using a p-chart that has binomial distribution as its theoretical base. The center of the p-chart represents the average for defects and LCL and UCL are calculated as:

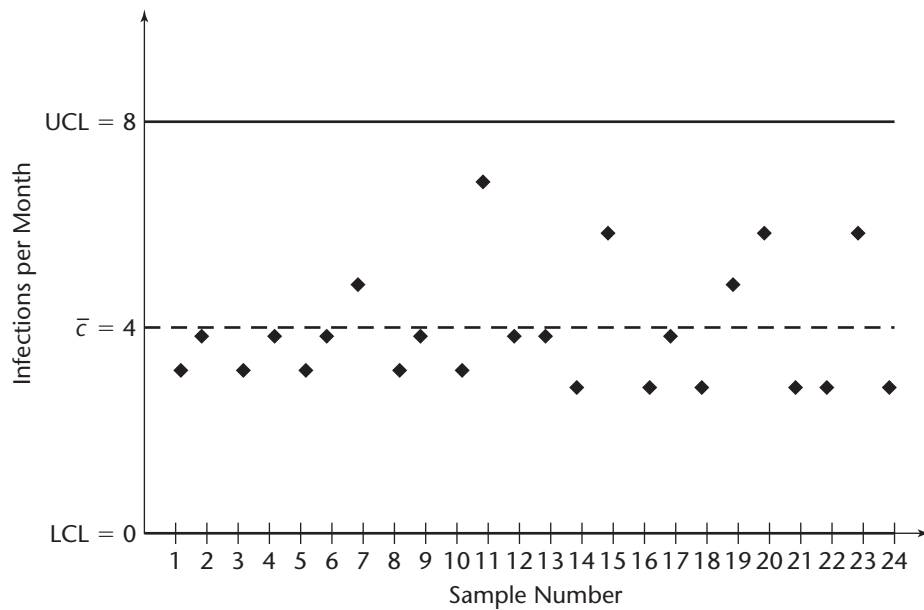
$$UCL = \bar{p} + z\sigma_p \quad [12.5]$$

$$LCL = \bar{p} - z\sigma_p \quad [12.6]$$

where

$$\sigma_p = \sqrt{\frac{\bar{p}(1 - \bar{p})}{n}}.$$

FIGURE 12.5. ABC MEDICAL CENTER INFECTION CONTROL MONITORING.



If the average proportion of defects is not known, then the sample average for the proportion of defects (\bar{p}) can be used and the above formulas can be rewritten for sample proportions as:

$$UCL = \bar{p} + z \sqrt{\frac{\bar{p}(1 - \bar{p})}{n}} \quad [12.7]$$

$$LCL = \bar{p} - z \sqrt{\frac{\bar{p}(1 - \bar{p})}{n}}. \quad [12.8]$$

Here also, the negative LCL values for practical reasons should be set to zero.

EXAMPLE 12.2

The indicator Family Satisfaction, which is part of the National Hospice and Palliative Care Organization's survey, reflects the percentage of respondents who would not recommend the hospice services to others. The following data are from Holistic Care Corporation's completed surveys from two hundred families each month during a year, showing the number of respondents each month who expressed dissatisfaction with the organization's services.

Months	Dissatisfied Patient Families	Percent Dissatisfied
January	12	0.060
February	14	0.070
March	16	0.080
April	14	0.070
May	25	0.125
June	14	0.070
July	15	0.075
August	16	0.080
September	14	0.070
October	14	0.070
November	24	0.120
December	14	0.070
Total	192	0.080

The manager in charge of quality wishes to construct a control chart for this data within 95.5 percent confidence intervals.

Solution: First, we need to estimate the proportion mean,

$$\bar{p} = \frac{\text{Total number of quality infractions}}{\text{Total number of observed}} = \frac{192}{12(200)} = \frac{192}{2400} = .08$$

Since the z value for the 95.5 percent confidence level is equal to 2.0, using formulas [12.7] and [12.8], we obtain:

$$\text{UCL} = .08 + 2 \sqrt{\frac{.08(1 - .08)}{200}} = 0.118.$$

$$\text{LCL} = .08 - 2 \sqrt{\frac{.08(1 - .08)}{200}} = 0.042.$$

The corresponding control chart for the Holistic Care Corporation data is shown in Figure 12.6.

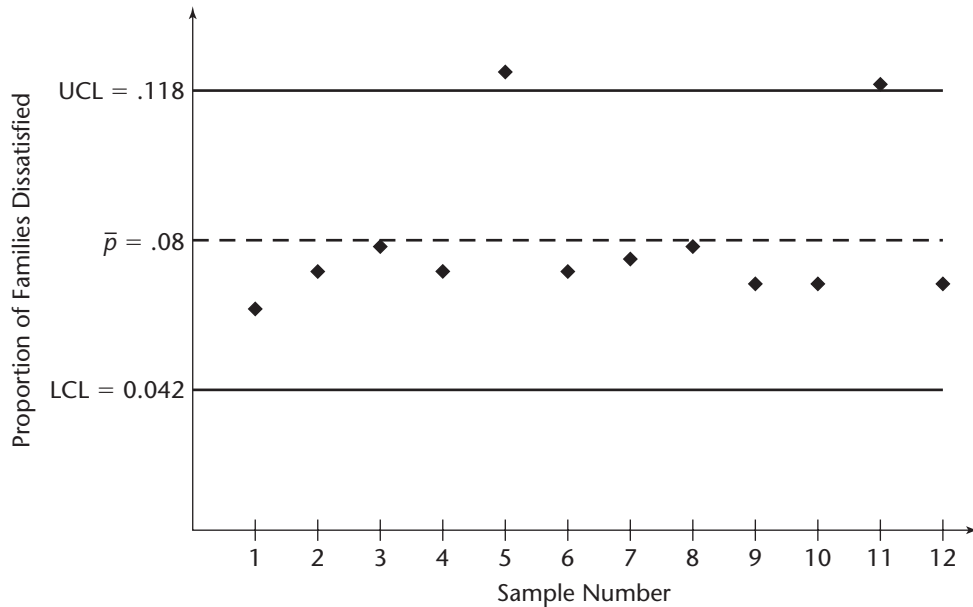
As can be observed from the chart, the percentages of families dissatisfied with the care in samples #5 and #11 are over the control limit. ■

Control Charts for Variables

Mean and range charts are for variables measured continuously, such as “time” it takes to admit or discharge a patient. Mean charts monitor a central tendency or process average, and range charts monitor the dispersion of a process. These two charts are used together to determine whether a process is in control.

Figure 12.7 displays two situations where neither chart alone can detect anomalies in the process quality. The upper chart in the figure shows that the process

FIGURE 12.6. HOLISTIC CARE CORPORATION’S QUALITY MONITORING.



mean is stable, but that dispersion (variability) in the process is increasing. In this situation the mean chart would not detect the shift in process variability, but the range chart would, as the range indicator increases steadily. The lower chart shows a process with stable range; however, the process mean increases. In this situation, the range chart would not detect the increasing trend in the process average; however, the mean chart would.

Mean Charts. Depending upon the available information, a mean chart can be constructed using either standard deviation or range information.

Standard Deviation Approach. In general the population standard is unknown, and so the average of sample means $\bar{\bar{x}}$ and the standard deviation of sample distribution $\sigma_{\bar{x}}$ are used to construct the confidence limits as:

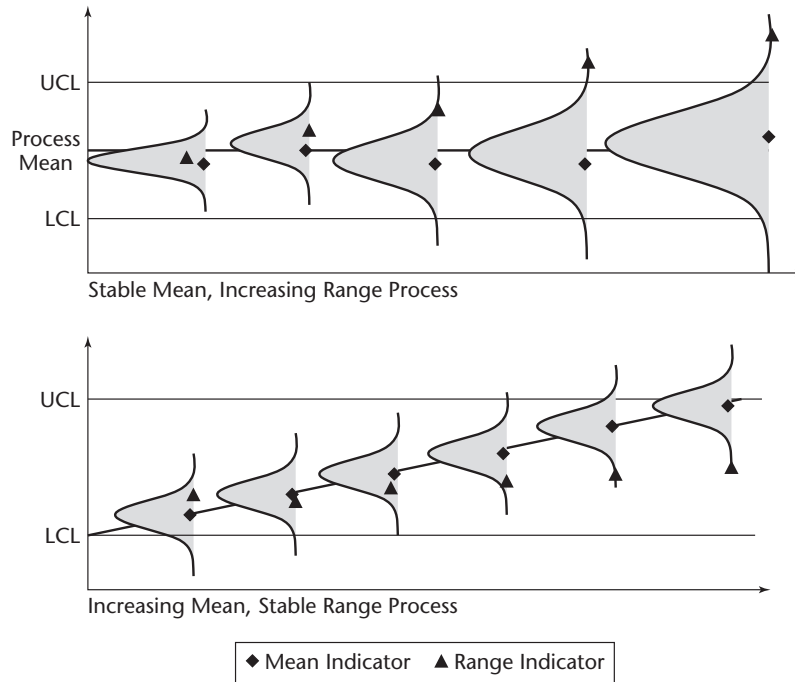
$$UCL = \bar{\bar{x}} + z\sigma_{\bar{x}} \tag{12.9}$$

$$LCL = \bar{\bar{x}} - z\sigma_{\bar{x}} \tag{12.10}$$

where

$$\sigma_{\bar{x}} = \frac{s}{\sqrt{n}}$$

FIGURE 12.7. USE OF MEAN AND RANGE CHARTS.



EXAMPLE 12.3

With a time-motion study, the IV start-up process has been examined in a medical center nursing unit for five weekdays to determine whether in the future, additional training of nurses is required. Each day nine new patients' IV start-ups were observed and the measurements recorded in minutes, as shown below. Construct 99.7 percent ($z = 3$) confidence limits for IV start-up times.

Observation	Day 1	Day 2	Day 3	Day 4	Day 5
1	5.1	4.9	5.5	6.1	6.0
2	5.4	5.7	5.6	5.8	5.2
3	5.5	6.3	5.3	5.9	6.3
4	5.8	7.5	4.9	6.0	5.0
5	5.6	5.8	5.2	6.2	5.5
6	5.8	5.9	5.4	5.7	5.1
7	5.3	5.5	6.4	4.8	5.9
8	4.9	5.8	7.5	6.3	5.3
9	6.2	5.5	5.8	5.9	4.8

Solution: Observation means, \bar{x} , for each day (sample) are calculated and shown in the last rows of the following table.

Sample	Day 1	Day 2	Day 3	Day 4	Day 5
\bar{x}	5.51	5.88	5.73	5.86	5.46
s	0.6				

The sample standard deviation (s), for the nine observations over five days is calculated to be 0.6 as shown above. The grand mean, $\bar{\bar{x}}$, calculated over five days of observations

$$\bar{\bar{x}} = (5.51 + 5.88 + 5.73 + 5.86 + 5.46) \div 5 = 5.69.$$

Using formulas [12.9] and [12.10], $UCL = \bar{\bar{x}} + z\sigma_{\bar{x}}$, $LCL = \bar{\bar{x}} - z\sigma_{\bar{x}}$ with $z = 3$, $n = 9$ observations per sample (day), and $s = 0.6$, we obtain:

$$UCL = 5.69 + 3(0.6/\sqrt{9}) = 5.69 + 3(0.2) = 6.29.$$

$$LCL = 5.69 - 3(0.6/\sqrt{9}) = 5.69 - 3(0.2) = 5.09.$$

Note that on the following days the specific observations are beyond the control limits.

Day 1: observation 8.

Day 2: observation 1.

Day 3: observations 4 and 8.

Day 4: observations 7 and 8.

Day 5: observations 3 and 8.

Managers responsible for quality would investigate the variations to determine whether they are caused by one or more individuals who need additional in-service training. ■

Range Approach. Another way to construct a mean chart is to use the average of sample distribution ranges, \bar{R} . This approach requires a factor to calculate the dispersion of the control limits.

$$UCL = \bar{\bar{x}} + A_2\bar{R} \quad [12.11]$$

$$LCL = \bar{\bar{x}} - A_2\bar{R} \quad [12.12]$$

Where A_2 is a factor from Table 12.1.

TABLE 12.1. FACTORS FOR DETERMINING CONTROL LIMITS FOR MEAN AND RANGE CHARTS (FOR THREE-SIGMA OR 99.7 PERCENT CONFIDENCE LEVEL).

Sample Size n	Factor for Mean Chart, A_2	Factors for Range Chart	
		LCL, D_3	UCL, D_4
5	0.58	0	2.11
6	0.48	0	2.00
7	0.42	0.08	1.92
8	0.37	0.14	1.86
9	0.34	0.18	1.82
10	0.31	0.22	1.78
11	0.29	0.26	1.74
12	0.27	0.28	1.72
13	0.25	0.31	1.69
14	0.24	0.33	1.67
15	0.22	0.35	1.65
16	0.21	0.36	1.64
17	0.20	0.38	1.62
18	0.19	0.39	1.61
19	0.19	0.40	1.60
20	0.18	0.41	1.59

Source: Adopted from R. S. Russell & B. W. Taylor, *Operations Management*, 2nd ed. (Upper Saddle River, NJ: Prentice-Hall), 1995.

EXAMPLE 12.4

During five weekdays, each day the number of minutes spent for each of ten patient registration operations were observed in a time study as follows:

Observation	Day 1	Day 2	Day 3	Day 4	Day 5
1	10.2	10.3	8.9	9.5	10.5
2	9.7	10.9	10.5	9.7	10.2
3	10.3	11.1	8.9	10.5	10.3
4	8.9	8.9	10.5	9.8	10.9
5	10.5	10.5	9.8	8.9	11.1
6	9.8	9.7	10.2	10.5	9.8
7	10.0	8.9	8.9	10.4	9.5
8	11.3	10.5	10.5	8.9	9.7
9	10.7	9.8	9.7	10.5	10.5
10	9.8	11.3	10.5	9.8	8.8

Solution: The overall mean for each sample and range is required to apply the formulas [12.11] and [12.12], using the range approach. Here each day is considered as a sample. The range is calculated by taking the difference between

the maximum and minimum of each sample (day). The mean for each day also is calculated and shown as follows:

Sample	Day 1	Day 2	Day 3	Day 4	Day 5
Maximum	11.3	11.3	10.5	10.5	11.1
Minimum	8.9	8.9	8.9	8.9	8.8
Range	2.4	2.4	1.6	1.6	2.3
\bar{x}	10.12	10.19	9.84	9.85	10.13

Before the step of using the formulas, calculation of the averages of sample means, \bar{x} , and ranges, \bar{R} , is required.

$$\bar{x} = (10.12 + 10.19 + 9.84 + 9.85 + 10.13) \div 5 = 10.03$$

$$\bar{R} = (2.4 + 2.4 + 1.6 + 1.6 + 2.3) \div 5 = 2.06.$$

Finally, using the formulas [12.11] and [12.12], we get

$$\text{UCL} = \bar{x} + A_2\bar{R} = 10.03 + 0.31(2.06) = 10.67$$

$$\text{LCL} = \bar{x} - A_2\bar{R} = 10.03 - 0.31(2.06) = 9.39$$

where A_2 is a factor selected as $n = 10$ from Table 12.1.

There are observations, in Day 1 and Day 2, and Day 5 with values above the mean chart in this example. ■

Range Charts. Process dispersion is best monitored by range charts. The control limits for range charts are constructed using factors. To calculate LCL, factor score D_3 is obtained from a factor chart based on the number of observations in the sample distributions. Similarly, to calculate UCL, factor score D_4 is required. Control limits for range charts using these factor scores are then constructed as follows:

$$\text{UCL} = D_4\bar{R} \quad [12.13]$$

$$\text{LCL} = D_3\bar{R}. \quad [12.14]$$

EXAMPLE 12.5

Use the information provided in example 12.4 to construct a range chart.

Solution: For $n = 10$, D_3 and D_4 from Table 12.1 are 0.22 and 1.78, respectively. Using formulas [12.13] and [12.14], we obtain:

$$\text{UCL} = D_4\bar{R} = 1.78(2.06) = 3.67$$

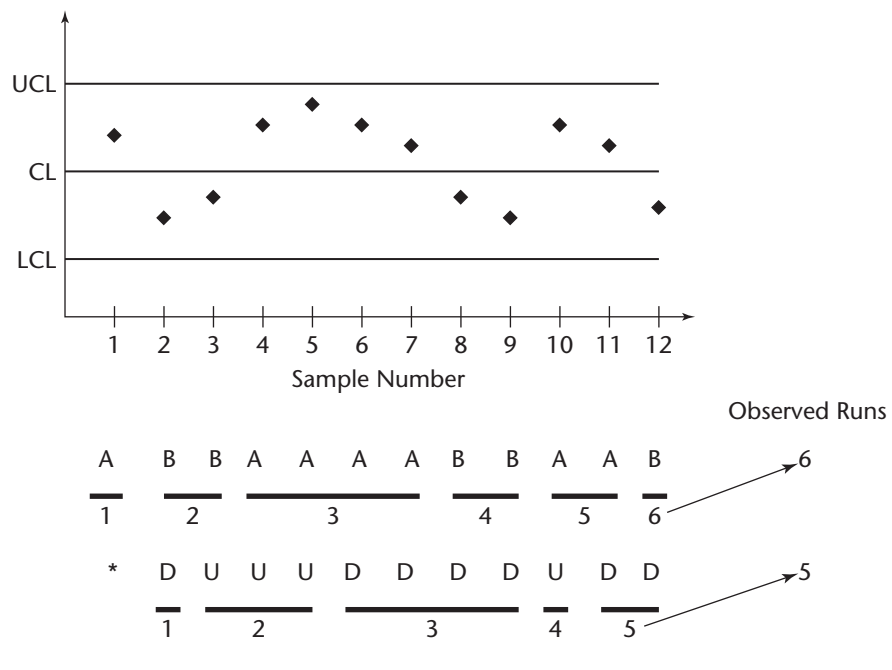
$$\text{LCL} = D_3\bar{R} = 0.22(2.06) = 0.45. \quad \blacksquare$$

Investigation of Control Chart Patterns

It is necessary to evaluate control chart patterns for anomalies, even though the observations stay within the confines of control limits. Although quality managers expect the sample variations to occur around the average line, sometimes consistent patterns can occur within control limits that are due to nonrandom causes and may require investigation. Such behavior can be characterized as consistent observations above or below the average (or center line); persistent zigzagging above and below the center line may signal disturbances in the system. Furthermore, high magnitude jumps from LCL to UCL or even beyond those limits may suggest nonrandomness and invokes investigation.

Run-Based Pattern Tests. A pattern in a control chart described by a sequence of observations that have similar characteristics is called a “run.” A simple classification of sample observations with respect to the center line that identify consecutive patterns is called an Above/Below run, or A/B run. For example, twelve observations shown in Figure 12.8 are classified as being above or below (A/B) the center line (CL). If their classification is consecutive, it constitutes a run. In this

FIGURE 12.8. IDENTIFICATION OF RUNS.



example, an above (A) observation is followed by two consecutive below (B) observations, which are followed by four consecutive above observations, and so on. Whenever there is a switch in a classified observation, a new run starts. Hence there are six such A/B runs in this chart.

Up (U) and down (D) runs is another way to classify and observe patterns. To classify sample observations as U or D, the first observation is used as a reference point, shown with “*” in Figure 12.8. Starting with the second observation one can classify each observation with respect to its predecessor. Here the second observation as compared to the first observation has a lower value, so its position is classified as down (D). The third observation as compared to the second observation has a higher value, so its position is classified as up (U). Ensuing observations are classified similarly. Once all observations are classified, the runs are identified by checking the consecutive patterns. In this example, the second observation is a stand-alone run. The next three observations are classified as up and constitute another run. The third run is a down run containing four observations. In total, there are five observed U/D runs in this example.

Control chart patterns identified by runs require statistical testing of whether the runs are within expectations and hence the patterns are random, or beyond expectations and hence nonrandomness is present. It has been shown that runs are distributed approximately normally (Stevenson, 2002, p. 436) and using the z -test the significance of too few or too many observed runs can be determined as follows:

$$z = \frac{\text{Observed runs} - \text{Expected runs}}{\text{Standard deviation of runs}}. \quad [12.15]$$

A z -value within ± 2 , which provides 95.5 percent confidence level, would show that the runs are random; however, beyond these values $\leq \pm 2 \geq$, a nonrandom presence would be shown. We already know how to determine observed runs, from an earlier discussion (Figure 12.8). It is necessary to calculate the expected runs and their standard deviations. The formulas for expected A/B or U/D runs and their standard deviations are as follows:

$$E(\text{run})_{A/B} = \frac{N}{2} + 1 \quad [12.16]$$

$$\sigma(\text{run})_{A/B} = \sqrt{\frac{N-1}{4}} \quad [12.17]$$

$$E(\text{run})_{U/D} = \frac{2N-1}{3} \quad [12.18]$$

$$\sigma(\text{run})_{U/D} = \sqrt{\frac{16N-29}{90}}. \quad [12.19]$$

EXAMPLE 12.6

Determine the presence/absence of nonrandomness for the example presented in Figure 12.8, with 95.5 percent confidence limits.

Solution: The example has twelve observations, so $N = 12$. Using the formulas [12.15] through [12.19] above, we get:

$$E(\text{run})_{A/B} = \frac{12}{2} + 1 = 7.0; \sigma(\text{run})_{A/B} = \sqrt{\frac{12-1}{4}} = \sqrt{\frac{11}{4}} = \sqrt{2.75} = 1.66;$$

$$E(\text{run})_{U/D} = \frac{(2 * 12) - 1}{3} = 7.67;$$

$$\sigma(\text{run})_{U/D} = \sqrt{\frac{(16 * 12) - 29}{90}} = \sqrt{\frac{163}{90}} = \sqrt{1.81} = 1.35.$$

$$z_{A/B} = \frac{6 - 7}{1.66} = -0.60; \text{conclude that the A/B runs exhibit randomness.}$$

$$z_{U/D} = \frac{5 - 7.67}{1.35} = -1.98; \text{conclude that U/D runs exhibit randomness.}$$

However, this particular case is a close one, the quality manager should be on the lookout in the future, and compute the z -test again after collecting more observations. ■

Zone Tests. An alternative method that is often used by quality control software packages is called the “zone test.” The essence of the zone test rests on deviation from the center line by one-sigma, two-sigma, or three-sigma limits. Zone C, Zone B, and Zone A are identified by these limits, respectively. To create the zones, the formulas for constructing mean chart with range approach, [12.11] and [12.12] are used. Those formulas, presented earlier, use A_2 from Table 12.1, and the values for this table were calculated for three-sigma levels (or 99.7 percent confidence level). Thus, in constructing the zones, one must reduce the A_2 factor proportionately, according to the sigma level. Since A_2 is designated for three-sigma, for two-sigma $2/3$ of A_2 , and for one-sigma $1/3$ of A_2 would be appropriate. The zone formulas can be written as:

$$\text{Zone A} = \bar{\bar{x}} \pm A_2 \bar{R} \quad [12.20]$$

$$\text{Zone B} = \bar{\bar{x}} \pm \frac{1}{2} A_2 \bar{R} \quad [12.21]$$

$$\text{Zone C} = \bar{\bar{x}} \pm \frac{1}{3} A_2 \bar{R}. \quad [12.22]$$

FIGURE 12.9. ZONE TEST.

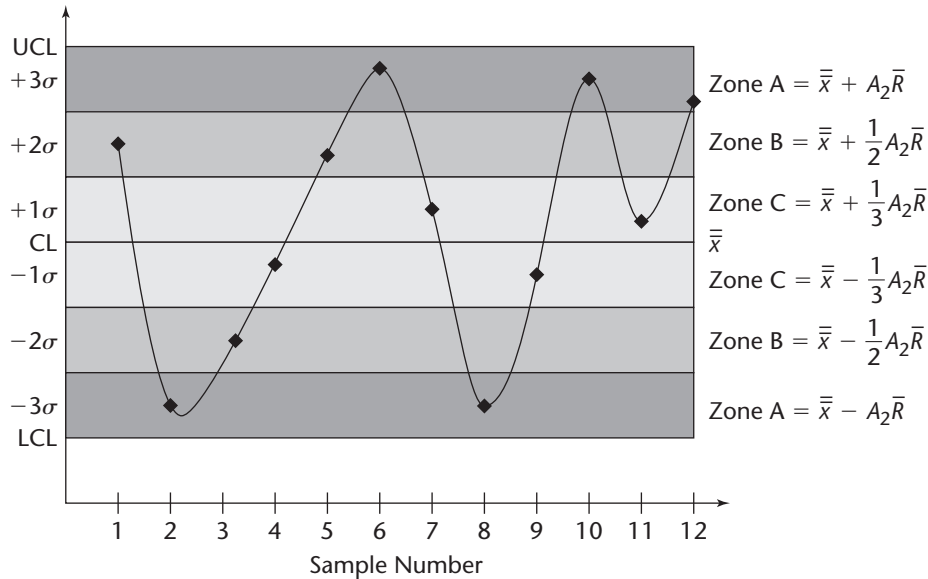


Figure 12.9 displays the zones constructed this way. After determining the zones, quality managers may use various guidelines associated with the zones to determine whether there are any nonrandom patterns in the control chart.

Sensitizing Rules for Control Charts. These rules determine whether the process is statistically out of control. The most commonly suggested rules for detecting nonrandom patterns are:

1. Single point outside of three-sigma limits.
2. Two out of three consecutive observations above two-sigma limits.
3. Four out of five consecutive observations above one-sigma limits.
4. Eight consecutive observations are one side of the center line.
5. Eight consecutive observations are in up or down pattern.
6. Fourteen points alternating up and down.
7. Single observation jumps four-sigma (Russell and Taylor 1995, p. 150; Chang, 2004).

EXAMPLE 12.7

Apply the pattern rules to the observations displayed in Figure 12.9.

Solution:

Rule 1: no violation.

Rule 2: violation: samples #10 and #12 are over 2-sigma limits in Zone A.

Rule 3: no violation.

Rule 4: no violation.

Rule 5: no violation.

Rule 6: no violation.

Rule 7: violation: sample #2 is down by 4-sigma, from Zone B above CL to Zone C below CL.

According to the pattern rules there are two violations, and nonrandomness may be present. Hence an investigation is required. ■

Process Improvement

Health care quality managers often face circumstances that require improvement or reengineering of care processes. Methods and tools used in reengineering processes are available to accomplish difficult and costly improvement tasks. One group of methods is for generating new ideas. Another group of tools are used to measure and display the findings, for decisions on actions.

Methods for Generating New Ideas

The 5W2H Approach. This approach takes its name from five questions starting with “W” and two questions starting with “H.” Health care managers can generate questions related to quality problems by asking “What?” (subject); “Why?” (purpose); “Where?” (location); “When?” (timing sequence); “Who?” (people); “How?” (method); and “How much?” (cost) (Stevenson 2002, pp. 487–489). The answers to the questions can be sought using such methods as brainstorming or quality circles and such tools as cause-and-effect diagrams or Pareto charts, all of which are discussed below.

Brainstorming. This is a group process: discussion to generate free-flowing ideas that might identify causes and generate solutions to a problem. The guidelines are that each member of the group expresses her or his ideas without receiving criticisms from the others, and that no member should be allowed to dominate the discussion. This approach works by focusing on a problem, and coming up with very many radical solutions. Ideas should be developed as fast as possible, to facilitate generating a wide spectrum, and should be very odd. The generated ideas can be evaluated after the brainstorming session, perhaps by using nominal group technique.

Nominal Group Technique. This technique is similar to brainstorming, but the session is led by an assigned moderator who presents the topic (problem) to session participants. Participants may ask questions, and briefly discuss the topic; then they think of ideas and write them down. The moderator asks each participant to read and elaborate on one of their responses. The responses usually are summarized on a flip chart. After everyone has given a response, participants are asked for second and then third responses, until all their ideas have been recorded on flip chart sheets posted around the room.

In the next step the moderator, working with the participants, eliminates redundant or similar responses. Session participants are then asked to choose five to ten responses that they feel are the most important and rank them according to their relative importance. If necessary, the moderator can give the results back to the participants to stimulate further discussion for a possible readjustment of the overall rankings of the responses. That is done, however, only when consensus about the ideas' ranking is important to the topic or the problem. The nominal group technique is an alternative to both the focus group and the Delphi techniques. It has more structure than the focus group does, but still takes advantage of the synergy created by group participants.

Interviewing. Keeping patient satisfaction as a goal, rich information about quality defects can be obtained from interviews of patients, in addition to satisfaction surveys. Benchmarked provider staff also can be interviewed for their insights about the quality of care.

Focus Groups. Focus groups are in-depth, qualitative interviews of small groups of carefully selected people who have been brought together to discuss a problem. Unlike a one-to-one interview, focus groups generate data through the give-and-take of group discussion, as people share and compare their different points of view. The focus group participants not only express what they think about the problem, but explain why they think that way. The composition of a focus group is usually based on the homogeneity or similarity of the group members. Bringing people with common interests or experiences together makes it easier for them to carry on a productive discussion. When there are different issues, different groups should be used for each issue.

Quality Circles "Kaizen Teams." As for a focus group, a group of employees in a health care organization come together to address issues about quality in their facility. Their focus in the health care organizations is to improve processes so that the best quality of care can be achieved. The strategy involved is to bring the employees' own ideas into play to improve quality. The group works as a team

(the term Kaizen Teams was adopted from Japanese management practice), and its results are based on consensus. The employees joining the team do so voluntarily, and participate under the leadership of their supervisor during normal work hours. The team meets regularly and makes recommendations to management. There are no formal rules for organizing a quality circle. However, meetings should take place away from work areas to minimize distractions, and should be held for at least one hour per week with clear agendas and objectives. The quality circles must be of manageable size. When needed, outside experts can be brought in (for example, a quality circle member from a different provider).

Benchmarking. The purpose of benchmarking is to identify the best in health care processes and try to match that level. Examining the processes of the best providers reveals invaluable information for health care managers trying to improve their own organizations. As mentioned above, Six Sigma quality, which many industries have adopted as a benchmark goal, has now been applied in health care as well.

Tools for Investigating the Presence of Quality Problems and Their Causes

Health care managers who are responsible for the quality of care and their team can use the approaches explained above to begin to understand a problem, but they also need tools to develop a detailed analysis of it. That effort requires quantification, and visualizations to develop alternative plans for a solution. The following are tools that are essential for the effort.

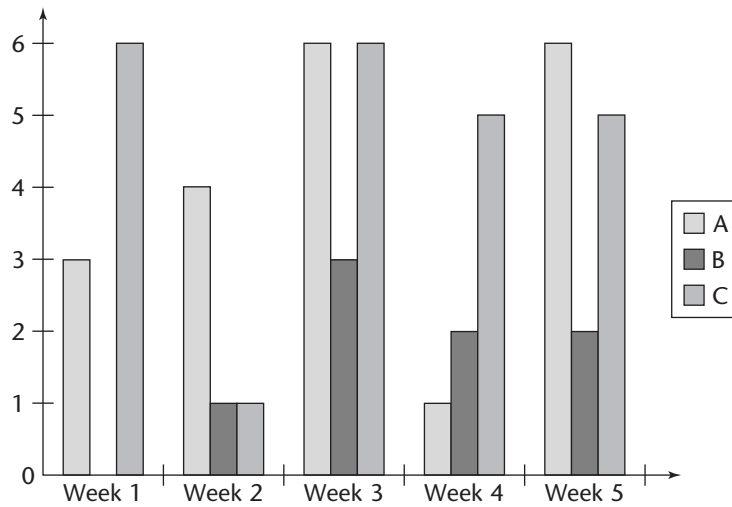
Check Sheet. This is a tallying tool used for fact finding or problem identification. It provides a format for health care managers to count the defects in the process for a list of the causes such as have been identified earlier while generating the ideas. For example, in an emergency room, long waiting times are recognized by the patients as defects in quality. However, the cause of the delays may arise from 1) the wait time for registering; 2) the registration process itself; and/or 3) the wait time to see a doctor. Figure 12.10 illustrates a check sheet developed to investigate the causes of long emergency room wait times.

Histogram. This is a chart that displays empirical (collected) data, the frequency distribution of a process. Examining the chart, health care managers can identify extremes (outliers at tail ends), as well as peak occurrences (mode) in the data. Histograms can be used to display the count data from check sheets.

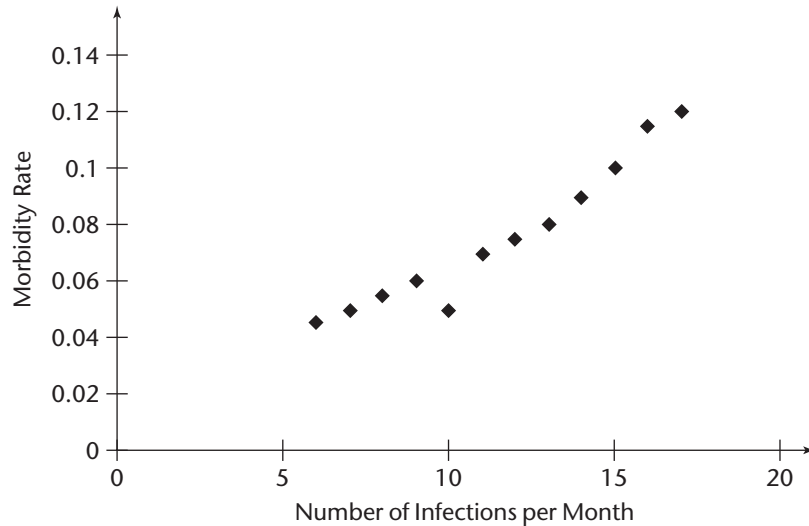
Scatter Diagram. This diagram displays the possible relationships between two variables, to identify a pattern that constitutes a problem for the quality of care.

FIGURE 12.10. A CHECK SHEET AND CORRESPONDING HISTOGRAM FOR EMERGENCY ROOM WAIT TIMES.

Weeks	A Wait Time to Register > 10 Minutes	B Registration Time > 5 Minutes	C Wait Time for MD > 15 Minutes
1	///		//////
2	////	/	/
3	//////	///	//////
4	/	//	////
5	//////	//	////



For example, medication errors or infection rates may correspond to hospital mortality or morbidity rates. Figure 12.11 displays a scatter diagram illustrating the correspondence between the number of infections per month and the hospital's morbidity rate.

FIGURE 12.11. SCATTER DIAGRAM.

Flow Chart. As also discussed in Chapter Six, flow charts could provide a chronological execution of processes in which a decision point—shown by a diamond symbol—may indicate a bottleneck in the process. Rectangular shape shows procedures, and arrows show the flow of the process. A good process would minimize the decision points without sacrificing necessary auditing requirements. Figure 12.12 is an example of a flow chart for the x-ray order process in an emergency department.

Cause-and-Effect Diagram. Also known as a fishbone diagram or an Ishikawa chart, a cause-and-effect diagram displays the structured results of the ideas generated from brainstorming, the nominal method, interviewing, focus groups and quality circles. The main causes of the problem are displayed on ticker lines or bones (such as methods or processes); then specific causes are displayed within on thinner lines (such as, too many steps).

Pareto Chart. The next step in analyzing the problem is a Pareto chart. Quality managers using nominal technique can prioritize the importance and/or contribution of each cause to the problem. The aim is to identify 80 percent of the causes and start working on the solutions. Figures 12.13 and 12.14 show a cause-and-effect diagram and the corresponding Pareto chart, respectively.

FIGURE 12.12. A FLOW CHART FOR THE X-RAY ORDER PROCESS IN AN EMERGENCY DEPARTMENT.

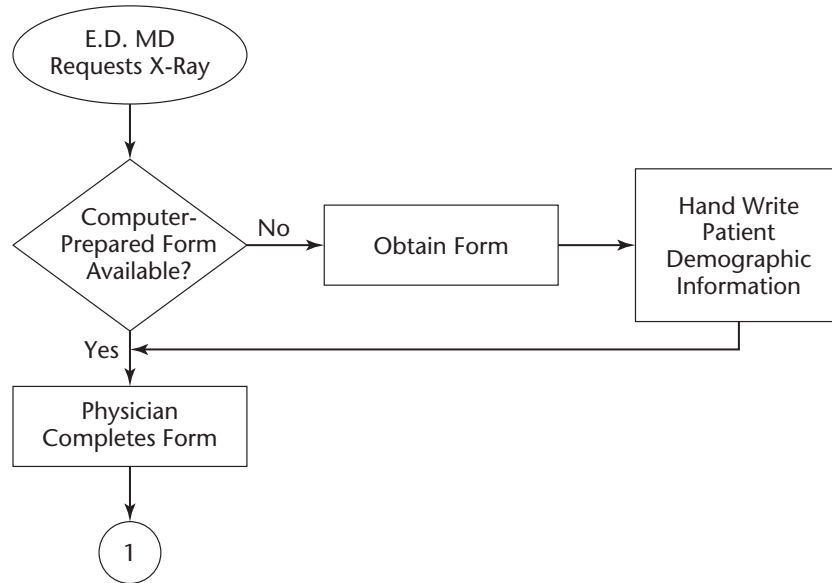


FIGURE 12.13. CAUSE-AND-EFFECT DIAGRAM.

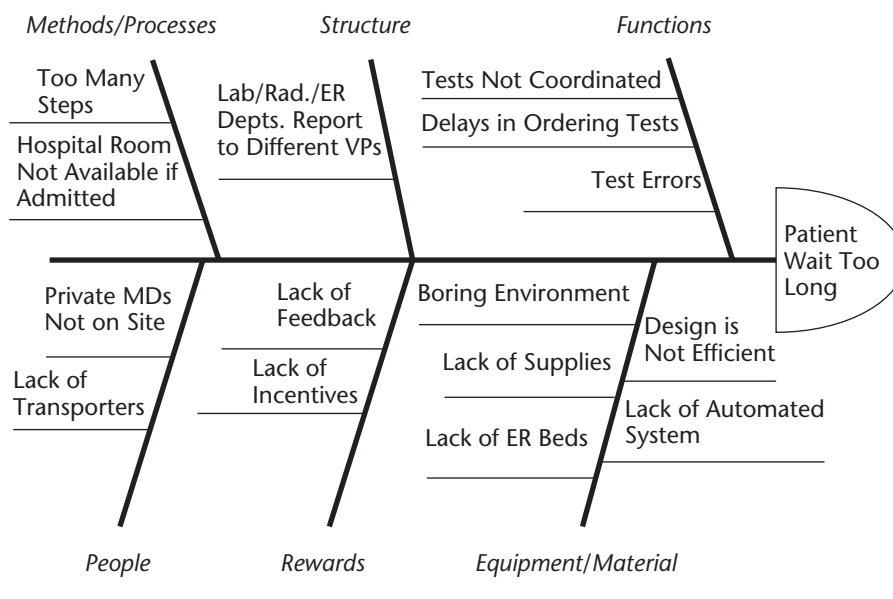
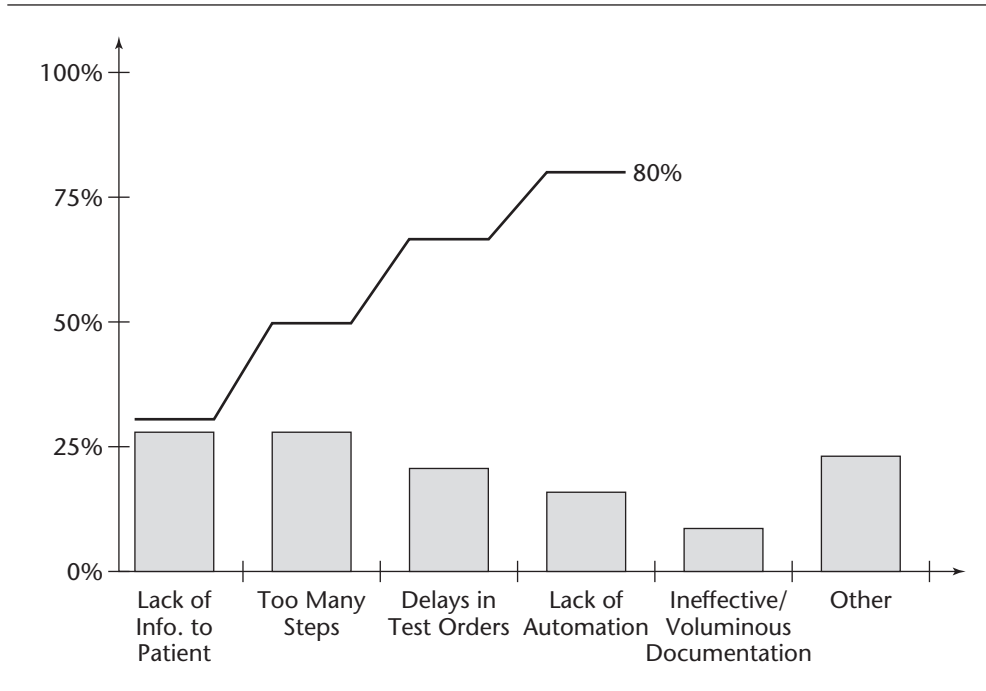


FIGURE 12.14. PARETO DIAGRAM.



Summary

Quality in health care is evaluated from differing perspectives of recipients and third-party payers. A health care system that has less than acceptable patient satisfaction reports, repeated morbidity, and unacceptable mortality must examine its conversion process. That is, the health care managers must investigate what mistakes and errors were committed systematically to produce the undesirable outcomes.

To comply with known standards or to establish new benchmarks, health care providers can implement well known quality methods to improve or overhaul their clinical care and management processes. As noted such methods include quality control, total quality management and continuous quality improvement as well as the more contemporary Six Sigma programs.

In health care delivery, to detect noteworthy variations in process, or tendencies that may cause unacceptable levels of errors, health care managers must monitor the processes for quality, using various charts. If they encounter repeated anomalies in the process, health care quality managers should take steps to improve or

reengineer the care processes. As discussed in this chapter, there are many methods and tools available to health care managers for generating new ideas, measuring and displaying the findings, and for making decisions to improve quality of care.

Exercises

Exercise 12.1

The Chief Nursing Officer (CNO) is concerned about medication errors in two hospital units. Collection of data over a year resulted in Table EX 12.1.

TABLE EX 12.1

Medication Errors	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Unit A	4	6	2	4	3	6	3	4	5	3	4	4
Unit B	3	3	6	5	4	7	3	4	6	4	5	4

- Using a 95.5 percent confidence level, calculate the UCL and LCL for an appropriate control chart for each unit.
- Construct the charts and identify the observations that are beyond the control limits.

Exercise 12.2

The data in Table EX 12.2 records the patient falls in three care units over a fifteen-week period.

TABLE EX 12.2

Patient Falls	Unit-I	Unit-II	Unit-III
Week 1	2	1	3
Week 2	1	2	1
Week 3	2	3	0
Week 4	2	2	2
Week 5	3	1	2
Week 6	1	0	1
Week 7	2	2	2
Week 8	1	0	1
Week 9	0	1	4
Week 10	1	1	3
Week 11	2	2	1
Week 12	1	0	2
Week 13	0	1	1
Week 14	2	2	2
Week 15	2	1	0
Week-14	1	0	2
Week-15	2	1	3

- For each unit, calculate LCL and UCL for an appropriate control chart, using 95.5 percent confidence limits.
- Construct a control chart for each unit.
- Are any observations in violation of the control limits for the unit?

Exercise 12.3

Using samples of 200 observations each, a quality inspector found the results shown in Table EX 12.3.

TABLE EX 12.3

Sample	1	2	3	4	5	6
Number of defectives	4	2	5	8	6	5

- Determine the fraction defective in each sample.
- Estimate the mean and standard deviation of the sampling distribution of fractions defective.
- Determine the control limits that would give an alpha risk of .025 for this process.
- Construct an appropriate control chart and identify any observations that are not within control limits.

Exercise 12.4

A medical center routinely conducts patient satisfaction surveys upon discharge and follows up with another survey within three months. The discharge and follow-up surveys, conducted on samples of five hundred discharges per month and identifying the number of patients dissatisfied with their care, are shown in Table EX 12.4.

TABLE EX 12.4

Dissatisfied Patients	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
At discharge	24	44	36	18	16	19	17	18	27	26	29	26
3-month follow-up	17	24	15	8	11	7	11	9	10	15	12	11

- Determine the fraction of dissatisfied patients at discharge and on follow-up, for each month.
- Estimate the mean and standard deviation of the sampling distribution of dissatisfied patients at discharge and at follow-up.
- For both surveys, determine the control limits for 95 percent confidence limits.
- For both surveys, construct appropriate control charts and identify any observations that are not within the control limits.

Exercise 12.5

Complaints of late responses to patient calls in a nursing unit trigger a study by the decision support department, requested by the nursing manager. A time study team made observations and compiled the data in Table EX 12.5.

TABLE EX 12.5

Observation	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	3	6	2	4	5	3	4
2	6	5	3	7	3	4	1
3	4	2	5	3	5	3	6
4	7	6	5	9	2	5	4
5	8	3	3	3	4	3	2
6	12	8	4	2	3	7	6
7	5	6	5	6	5	7	4
8	6	4	8	5	8	4	7
9	8	7	6	4	3	6	2
10	9	6	2	3	4	11	2
11	6	3	3	8	4	4	5
12	4	7	4	3	3	2	9
13	7	2	5	5	5	3	3
14	11	4	7	3	2	1	3
15	7	6	3	2	3	4	2

The measurements are recorded in minutes (rounded to the nearest minute) of response time once the patient has pressed the call button.

- Using the standard deviation approach, construct 99.7 percent confidence limits for patient call response times.
- Develop an appropriate control chart for the days.
- Are there any days in violation of the confidence limits?

Exercise 12.6

Using the information in Exercise 12.5:

- Calculate the range for each day and calculate LCL and UCL for a mean chart, using the range approach.
- Construct a corresponding control chart and identify any violations of the limits.

Exercise 12.7

Using the information in Exercise 12.5:

- Calculate LCL and UCL for a range chart.
- Construct a corresponding control chart and identify any violations of the limits.

Exercise 12.8

Consider the control chart in Exercise 12.1, part “b”:

- a. Perform a median run test and an up/down run test, using 95.5 percent confidence intervals.
- b. Are the medication error patterns random?

Exercise 12.9

Consider the control chart in Exercise 12.2, part “b,” for Unit-III:

- a. Perform a median run test and an up/down run test, using 95.5 percent confidence intervals.
- b. Are the patient fall patterns random in this unit?

Exercise 12.10

Analyze the control chart in Exercise 12.3, part “c”, using a median run test and an up/down run test. What can you conclude?

Exercise 12.11

Consider the control chart in Exercise 12.4, part “d”:

- a. Perform a median run test and an up/down run test, using 95.5 percent confidence intervals.
- b. Are the dissatisfaction patterns random?

Exercise 12.12

Consider the control chart in Exercise 12.5, part “b”:

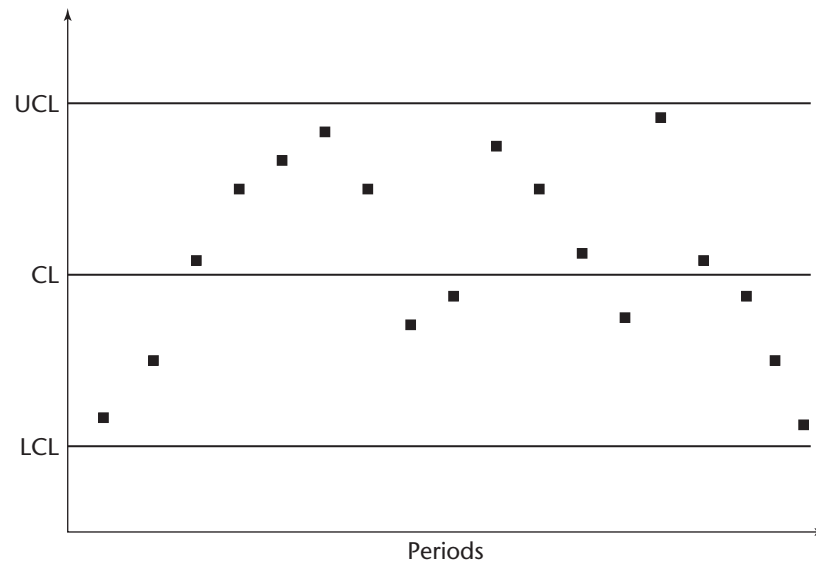
- a. Perform a median run test and an up/down run test, using 95.5 percent confidence intervals.
- b. Are the response patterns to patient calls random?

Exercise 12.13

The graph in Figure EX 12.13 represents sample means of delays on laboratory reports at periodic intervals, plotted on a control chart.

- a. Is the output random? Why?
- b. Perform run tests for randomness, using a 95.5 percent confidence interval, and interpret the results.

FIGURE EX 12.13

**Exercise 12.14**

A hospital has identified nonrandom variations in medication errors. These errors can emanate along a process from prescription orders to delivery to a patient. Hence, consider the departments involved in the process such as nursing, pharmacy, and others as appropriate, to:

- Draw a flow chart for the medication process.
- Construct a cause-and-effect diagram showing the potential causes of errors.
- Develop a Pareto chart to prioritize the causes (problems), for planning to solve them.

Exercise 12.15

A hospital has identified nonrandom variations in patient falls.

- Draw a flow chart showing under what circumstances a patient might fall.
- Construct a cause-and-effect diagram showing the potential causes of falls.
- Develop a Pareto chart to prioritize the causes of falls for planning to solve the problem.