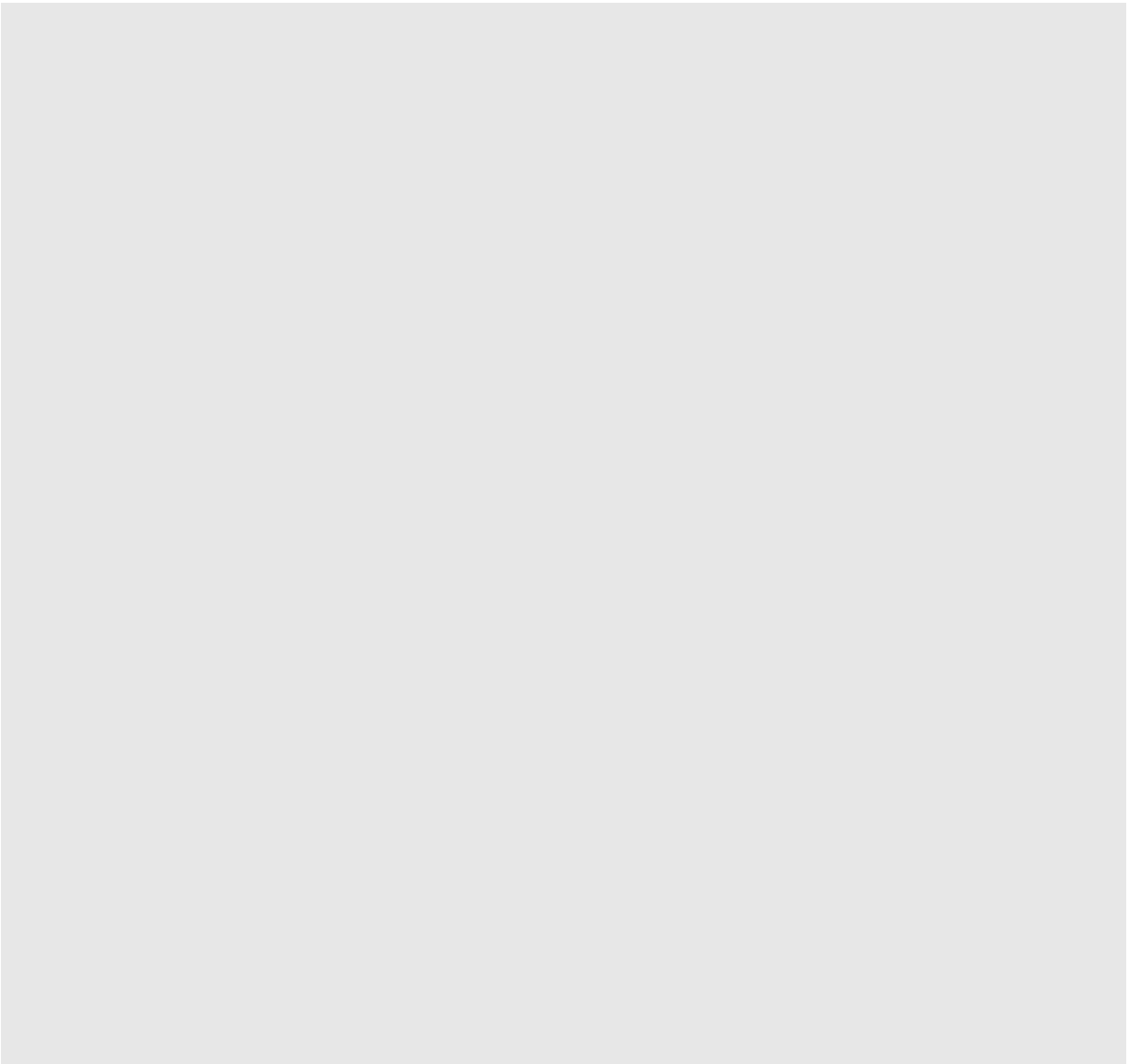


The Quality Imperative: Implementation



Chapter Outline

- Undertaking Process Improvement
- Other Improvement Methodologies
- Barriers and Facilitators to Improvement
- Improvement and Problem Solving
- Statistical Process Control
- Tools for Improvement
- Productivity and Productivity Improvement
- Physicians and CQI
- Patient and Worker Safety in Healthcare
- Quality Improvement Structures/Processes Useful in Patient/Worker Safety
- Overlapping Safety Issues for Patients and Workers

The section on Patient and Worker Safety in Healthcare was written by Mary Mohyla, RN, CIC, Director, Infection Control, Employee Health and Accreditation Services, Holy Cross Hospital, Silver Spring, Maryland.

Quality improvement (QI) focuses on doing the right things and doing the right things right. This chapter builds on the theory of quality/productivity improvement (Q/PI) discussed in Chapter 7 and introduces a continuous quality improvement (CQI) process improvement model. The chapter also discusses the relationship between problem solving and the use of teams in process improvement. The applications of benchmarking, six sigma, lean manufacturing, and reengineering are discussed. Accreditation and registration, through organizations such as the Joint Commission on Accreditation of Healthcare Organizations (The Joint Commission) and the International Organization for Standardization (ISO), respectively, are addressed. Productivity improvement¹ (PI) methods to improve work systems and job design; capacity and facilities layout; and production control, scheduling, and materials handling are described. Also addressed are the necessity for and means of achieving physician involvement in

quality improvement. The chapter concludes with a discussion of patient and worker safety.

Undertaking Process Improvement

Quality improvement begins by selecting a process to improve and choosing the members of the quality improvement team (QIT). Improving quality consumes significant staff time, both for team members and for those who provide support. This means that the health services organization (HSO) is best served if high-value processes are improved first. Success in improving simple but important processes—picking the low-hanging fruit—will produce results quickly, demonstrate the value of CQI, and help convince skeptical staff of the usefulness of CQI.

Figure 8.1 shows the flow of QI activities. Data sources (many of them outcome indicators) focus the attention of the quality improvement council (QIC), which is the coordinating body. As noted in Chapter 7, the QIC approves (sanctions) formation of cross-functional QITs to analyze processes and recommend changes to improve them. Intradepartmental and functional QITs are established by departments and/or those who are part of the functional area(s), monitored locally. In addition, departments or functional areas may assign individual staff who may be process owners to monitor and improve processes. Although unlikely, the QIC may have authority to approve changes and expenditures resulting from QIT recommendations. More likely corporate executive officer (CEO) and/or governing board (GB) approval will be required.

QITs

The basic component for undertaking quality improvement is the QIT, sometimes known as a process improvement team (PIT), despite the latter's less-than-desirable acronym. As noted, QITs may be internal to a function or department or may be cross-functional. The PDSA cycle described in Chapter 7 is the basic methodology applied by the QIT.

QITs are composed of persons who have process knowledge and who can document the process as it functions *currently*. Understanding the process in its current state is essential. Processes tend to succumb to entropy over time, which is to say that they devolve to a lower level of performance than that intended in the Quality Planning phase as described by Juran. The QIT identifies the key quality characteristic (KQC) of the process—an outcome that can be used to measure quality, such as patient satisfaction, waiting time, or accuracy of medication. Sometimes, there is more than one KQC. Next, the QIT develops an understanding of the process. Flowcharts, also known as flow diagrams or process maps, are used to visualize and understand the process in its current state. To be useful this visualization must show the process in all its complexity. Process complexity and the handoffs from one step to the next are common sources of delay, error, and rework. Only by understanding the process in all its complexity can one effect improvement.

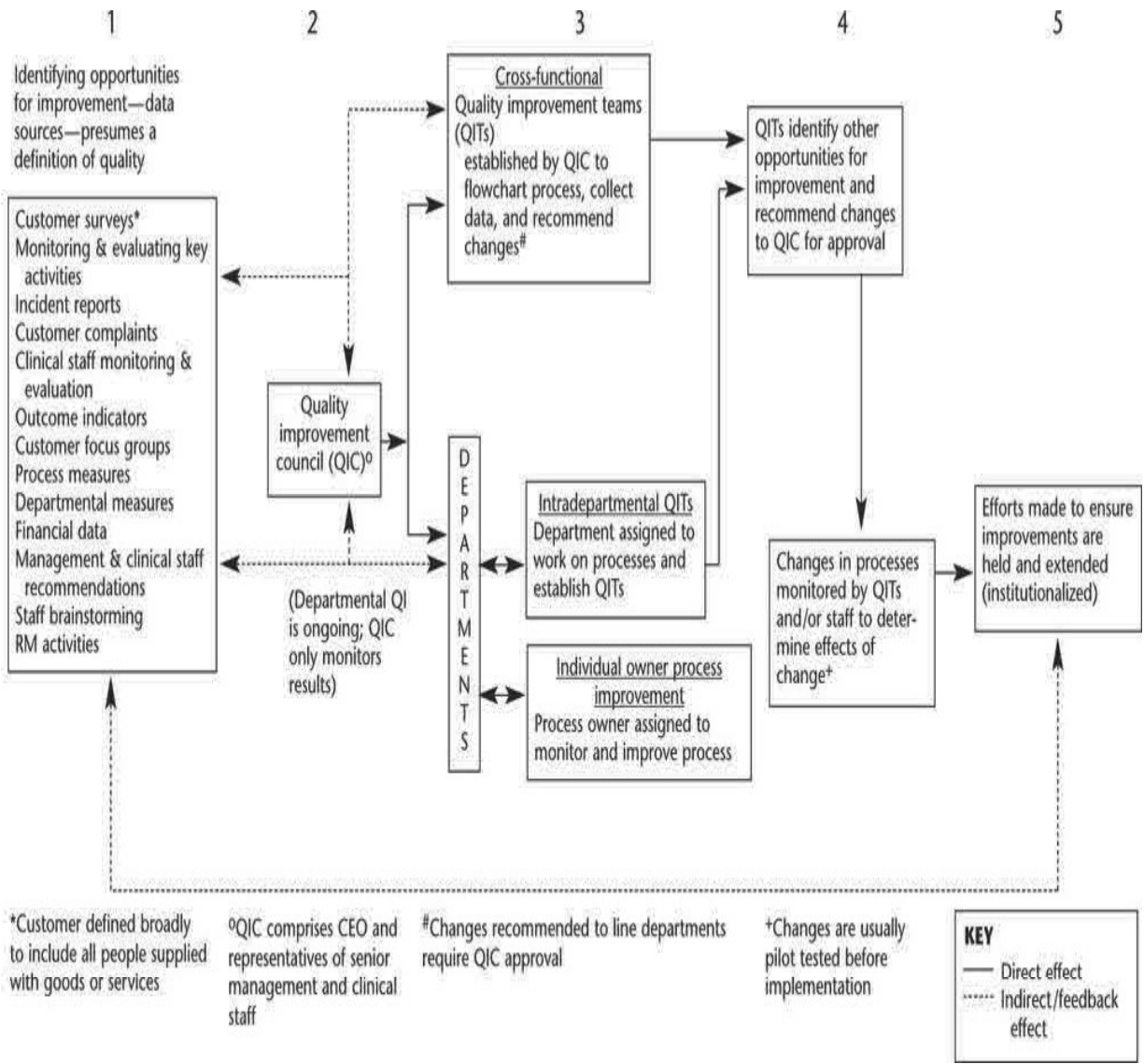


Figure 8.1. Steps in the process of QI.

QITs for processes that cross functional area lines or are interdepartmental must be sanctioned by the QIC. This is done because 1) it is likely that resource consumption will be greater; 2) it is almost certain that more than one department or process will be investigated for improvement; and, 3) the changes that will be recommended by the cross-functional team will have to be judged and possibly implemented. Thus, there is a need to obtain the *imprimatur* of the QIC.

After the process is completely understood, data can be collected to determine if the process is in control (i.e., only common cause variation

within 3 standard deviations [*SDs*]) is present. A process that is not in control must be brought into control. This means eliminating special cause variation, which is variation beyond 3 *SDs*. Shewhart termed variation beyond 3 *SDs* assignable variation. Once a process is in control, the key process variables (KPVs) can be identified and measured, and the data can be used to determine the points in the process at which to make change(s) to help the process meet the KQC(s). The process should be changed in only one way at a time so that the effects of a change can be measured. Data collected after the change measure effects of the change. Understanding cause and effect is key to further improvement. A pilot project or experimental design should be utilized so that change(s) in processes used elsewhere in the HSO can be understood before they are widely implemented. For example, changes in a nursing care process should be piloted (tested) in one unit before wider implementation.

Figure 7.3 shows that monitoring and evaluating are key to successful process improvement. Formal sources of data include routine reports, run and control charts, and customer and staff surveys. Informal sources include customer complaints and suggestions solicited from staff. These data must be organized to become information usable for decision making.

Other Improvement Methodologies

Since the concepts of CQI, including the Plan, Do, Study, Act (PDSA) cycle, were first applied to health services in the 1980s, there have been numerous permutations of its basic content. Some, such as the International Organization for Standardization (ISO) standards, predate the health services applications but do not predate the basic concepts, such as statistical process control (SPC), developed in the 1920s. Others are “old wine in new bottles,” meaning that they are posited as more useful or effective than CQI but are primarily repackaged variations on the same theme. This does not denigrate their usefulness, but only suggests that basic CQI and its corollaries are intrinsic to them. Someone well versed in the fundamentals of CQI will find a familiar landscape.

Lean And Six Sigma

The lean concept focuses on reducing waste and eliminating unnecessary steps to increase throughput speed and, thus, productivity. The six sigma methodology focuses on reducing variation to improve quality.² Typically, lean and six sigma are used as complements to one another.

Lean

The concept of lean is derived from the Toyota production system, or just-in-time production. Lean's antecedents can be traced to Eli Whitney's development of interchangeable parts for musket manufacturing in 1799 and Henry Ford's development of the assembly line for manufacturing the Model T in 1910. Ford may be considered the first practitioner of just-in-time and lean manufacturing. After World War II, Taichi Ohno and Shigeo Shingo began to apply Ford production, SPC, and techniques such as quality circles at Toyota.³

The true benefits of lean can only come from strategic planning. A lack of governing body and senior management commitment and knowledge is often to blame for failure of the transformation to lean. Short-term solutions are not the answer,⁴ a theme repeatedly sounded by Deming. In health services, the theories of lean can be applied effectively as the concept of lean processes.⁵

Lean's goal is to eliminate activities that do not add value, defined as something for which customers are willing to pay. Lean relies on various methods and tools, including problem-solving diagrams and statistical techniques, to find waste.⁶ Common sources of waste are processing, correction, overproduction, motion, material movement, waiting, and inventory. A common example in healthcare is the "work around" that occurs when nursing staff must go to another nursing unit to obtain supplies because the system is inadequate to meet their needs.

Preventive error proofing is needed because lean implementation frequently results in *reduction* of automation and an increase in manual labor, because for some processes automation is less flexible than an

operator performing a variety of tasks. The possibility that manual labor may be more effective than automation in a specific use is counterintuitive and requires adaptable thinking by managers. It must be borne in mind that reducing automation may increase the opportunity for error even if work is standardized.⁷ Fewer errors using automation assumes that the devices are calibrated properly and in good repair. Dr. Deming notes that devices (he called them gadgets) may increase variation in a process if they are constantly adjusting for the previous result—in effect a mechanical form of tampering.⁸

Staff empowerment is integral to lean because as the number of staff decreases, those remaining are challenged to find ways to overcome the deficiency. This approach allows the intellect of staff to be applied in problem solving, encourages buy-in, and allows self-actualization.

Six Sigma

Lean is often a precursor to application of six sigma, which is a statistical description of performance. Some literature combines the two as “lean–six sigma.” Six sigma originated with the work of mathematician Carl Frederick Gauss (1777–1855), who introduced the concept of the “normal curve.” Shewhart (and Deming) used *three sigma* to distinguish nonassignable from assignable variation and to guide decision making about actions to be taken. The term *six sigma* originated with Motorola engineer Bill Smith (1929–1993) and has been refined since the 1970s into a change-management and data-driven methodology focusing on business excellence.⁹ The objective of six sigma is to reduce process output variation so that, over time, there are no more than 3.4 defects per million opportunities (for defects). For example, a healthcare process with a sigma level between 5 and 6 is 5.4 deaths per million surgeries caused by anesthesia. A sigma level between 3 and 4 is 1% of a million hospitalized patients (10,000) injured by negligence.¹⁰ As the process sigma value increases from zero to six, the variation of the process around the mean value decreases. With a high enough value of process sigma, the process approaches zero variation and is known as zero defects. Decreasing process variation will increase the sigma of the process, resulting in higher

customer satisfaction and lower costs.¹¹ A framework to apply six sigma to reduce variation has the acronym DMAIC—for define, measure, analyze, improve, control—a method that is being used in health services quality and performance improvement.¹²

ISO 9000 and ISO 14000

The International Organization for Standardization (ISO), headquartered in Geneva, Switzerland, began developing voluntary technical standards for almost all sectors of business, industry, and technology in 1947. ISO 9000 and ISO 14000 are two families of generic management systems standards that can be applied in the health services field. *Generic* means that the standards can be applied to any sector of activity, whether product or service based; *management system* means what the organization does to manage its processes or activities. ISO 9000 is concerned with *quality management*, which means what the organization is doing to enhance customer satisfaction by meeting customer and applicable regulatory requirements and to continually improve its performance. ISO 14000 is primarily concerned with environmental management and what the organization is doing to minimize its activities' harmful effects on the environment and to continually improve its environmental performance.¹³ Their orientation makes ISO 9000 and ISO 14000 standards usable by HSOs. In 2009, ISO 9004 was released. Its focus is making quality management systems more effective. ISO 19011 was released in 2011. It provides a methodology to use ISO 9004 and ISO 14000 simultaneously to guide auditing of quality management systems.¹⁴

Once the standards are implemented, the organization seeks certification and is audited by an independent auditor, who determines whether the management system conforms to the requirements specified in the ISO standard. If the management system conforms, the certification is recorded by the auditing body, which constitutes registration of the management system.¹⁵ Like Joint Commission accreditation, the ISO 9000-compliant organization has met minimum standards with regard to a

quality system. ISO neither carries out certification to its standards nor controls the business aspects of certification activities.¹⁶

ISO 9000 standards do not define quality—the organization does that. However, the 150 guidelines in the standards provide the structure for developing and maintaining a quality system. Organizations that become registered must follow procedures in more than 20 areas, some of which are management responsibility, quality system, process control, inspection and testing, corrective and preventive action, control of quality records, training, and statistical techniques.¹⁷ Customers are aware that the organization is structured to produce consistent results. The organization may extend the quality system requirements backward and require ISO registration of its suppliers to ensure their conformance to requirements. ISO registration by suppliers helps ensure that the inputs HSOs receive have few defects, or are defect free. Higher quality inputs allow HSOs to perform their work with fewer quality problems.

The eight quality management principles of ISO 9000 in its year 2012 standards are as follows:

1. *Customer focus.* Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements, and strive to exceed customer expectations.
2. *Leadership.* Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
3. *Involvement of people.* People at all levels are the essence of an organization, and their full involvement enables their abilities to be used for the organization's benefit.
4. *Process approach.* A desired result is achieved more efficiently when activities and related resources are managed as a process.
5. *System approach to management.* Identifying, understanding, and managing interrelated processes as a system contribute to

the organization's effectiveness and efficiency in achieving its objectives.

6. *Continual improvement.* Continual improvement of the organization's overall performance should be a permanent objective of the organization.
7. *Factual approach to decision making.* Effective decisions are based on the analysis of data and information.
8. *Mutually beneficial supplier relationships.* An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.¹⁸

By the late 1990s, registration to ISO 9000 standards had made few inroads into the predominant position in health services accreditation enjoyed by The Joint Commission and accreditors such as the Community Health Accreditation Program and the National Committee for Quality Assurance. In 2012, only 40 U.S. hospitals were ISO certified.¹⁹ This is likely to change with increased recognition of ISO standards in the health services field. As noted in Chapter 1, Det Norske Veritas Healthcare, Inc. (DNVHC) has been recognized by the Centers for Medicare and Medicaid Services (CMS) as able to confer "deeming status," which allows health services providers to be reimbursed under federal programs. DNVHC uses a combination of the CMS "conditions of participation" (COPs) and ISO 9000:2000 quality standards. This alternative is a credible challenge to the status quo of accreditation in health services. The Joint Commission, which has been the preeminent voluntary accrediting body for almost 100 years, will be the most affected. The results will have far-reaching implications.

Reengineering

Reengineering is more technique, less philosophy, and can complement CQI. It is "plan" in the PDSA cycle, and quality planning in the Juran Trilogy. Both are described in Chapter 7. CQI and reengineering share a process orientation, a dedication to improvement, and an imperative that

one begins with the customer.²⁰ Reengineering is another approach in the continuum of improvement that builds on the principles and tools of CQI.²¹ It includes the additional features of radical change and process redesign.

Hammer and Champy defined reengineering as “the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance such as costs, quality, service, and speed.”²² Sometimes termed process innovation or core process redesign,²³ reengineering as applied to health services seeks fundamental and radical change in processes and in how healthcare is arranged and delivered, including time and place.²⁴

Outward-In, Right to Left

Creating quality and enhancing competitive position require an outward-in orientation. To obtain the high-quality service that enhances competitive position, reengineering directs HSOs and health systems (HSs) to work backward—thinking right to left—to improve processes. The CQI model in Figure 7.3 focuses on market changes and customer needs that result in an enhanced competitive position [5]. This is done through quality outcomes that conform to requirements and meet or exceed customer expectations [4]. CQI changes existing processes incrementally to improve quality.²⁵ A change in customers’ needs or in competition may cause a performance gap.

If the world has changed dramatically since the process was (or most recently [was]) redesigned, the current design may be fundamentally flawed and incapable of delivering the required performance. Reengineering is then called for. Reengineering does not merely enhance the individual steps of the process but entirely reconsiders how they are put together.²⁶

The transition from inpatient to outpatient care in HSOs,²⁷ including support mechanisms, apparatus, facilities, and staffing, is an example of a radical change in the process of patient care delivery. Formation of HSs is an example of redesigning integration and delivery of care among entities.

Because of a fundamental shift that increased the bargaining power of the payer, prospective pricing and managed care required rethinking how HSOs/HSs do business.

Elements

The following are critical elements of reengineering:

1. Outside-in, customer focus, putting the organization in the shoes of the customers to understand and meet their needs
2. Focus on cross-functional, end-to-end processes, versus intradepartmental processes
3. Understanding processes and customer requirements, leading to recognition of the weaknesses of the existing process and the performance requirements of the new one²⁸
4. Articulated vision of where the HSO/HS wants to be in the future, with that vision communicated and understood by all organization members
5. Top-down rather than bottom-up leadership initiated with committed senior-level management who elicit and obtain acceptance by process owners
6. Identifying and questioning underlying assumptions about processes
7. Design of new processes, including piloting (small-scale use) to see if they work, and redesigning and rolling out the new processes in rapid fashion
8. An organizational environment that supports reengineering, including communication throughout the organization, supportive leader personal behavior, measurements, rewards, and “selling the new way of working and living to the organization as a whole”²⁹

Additional elements to be implemented are senior management's commitment to and championing of the reengineering effort; identification of process owners—those with direct interest in and responsibility for processes—and empowering them to initiate change; formation of reengineering teams—groups that diagnose existing processes, oversee their redesign, and implement new processes; and use of a steering committee—“a policy-making body of senior managers who develop the organization's overall reengineering strategy and monitor its progress.”³⁰

What Reengineering Is Not (Reengineering and CQI)

A major criticism of reengineering is that it is a rationale to justify downsizing, which encompasses cost-reduction strategies of reducing labor costs, outsourcing work previously done in-house, replacing permanent employees with temporary employees,³¹ or discontinuing programs or services. Reengineering can be differentiated by what it is not. It is not automating, restructuring or downsizing, or reorganizing, delayering, or flattening the organization. However, these results often occur with use of the “clean sheet of paper” radical, cross-functional redesign with a customer focus. Further, reengineering is not the same as CQI. “Quality improvement seeks steady incremental improvement to process performance. Reengineering ... seeks breakthroughs, not by enhancing existing processes, but by discarding and replacing them with entirely new ones.”³²

CQI improves processes and performance on a consistent upward slope. At some point, however, performance gaps, such as diminished or weakened competitive position and changed customer needs and demands, necessitate replacement of some processes through reengineering, which may be conceptualized as a step increase, rather than a slope. Once reengineering occurs, CQI—improvement of the new, redesigned process—continues until external forces require another breakthrough change. This relationship is similar to the Juran Quality Trilogy (described in Chapter 7) of quality planning (reengineering), quality control (preparatory to CQI), and quality improvement (CQI).

The triggers or drivers of reengineering efforts may include a strategy of retrenchment because the HSO/HS no longer has a competitive advantage or market strength for a program or service (see Chapter 9); because of limited resources that can be allocated more effectively to other existing or new services; or because of changing needs of patients/customers, including shifts in market demand or composition. Examples include a decision to exit a product or service line, based on assessment of external threats and opportunities and internal strengths and weaknesses, or a situation in which the HSO/HS cannot maintain or cannot attain a comparative advantage. Reengineering as the organization's response to a changing marketplace can be viewed as strategic in nature, whereas CQI is tactical.³³

Applications

Various applications of reengineering in HSOs/HSs are described in the literature. Among them are service decentralization, clinical resource management, patient aggregation, skill-mix changes, and alterations to noncore processes. In their research based on interviews with 255 senior managers, physicians, and staff at 14 hospitals, Walston and Kimberly found that service decentralization occurred in 13 of the HSOs examined. They reported that ancillary services such as respiratory therapy, physical therapy, and dietary, laboratory, and radiology services were segmented departments in hospitals. To decrease multiple patient handoffs and “throwing services over the wall” to other departments, which resulted in scheduling complications and increased waiting time, a redesign was undertaken that resulted in initiating responsibility for some support services, such as phlebotomy and respiratory services, on the nursing unit. “Housekeeping, dietary, and EKGs were often combined into new patient services positions titled patient care associates, patient care partners, or support partners.”³⁴ Clinical resource management initiatives involved the creation of clinical protocols to lessen treatment variation and to provide a day-to-day schedule for each different type of patient by diagnosis using physician “best practices.” Only modest success was reported, however.³⁵

Patient aggregation and process redesign involves grouping patients with similar skill and resource needs. Homogeneous patient populations that require similar clinical resources enable dedicated delivery teams to enhance their skills, provide for coordination and continuity of care, decrease unnecessary clinical variation, and enhance outcomes of quality and customer satisfaction.³⁶ Skill-mix changes reported included using nursing assistants rather than licensed practical nurses, and abandoning primary nursing. Nonpatient care reengineering examples were increasing charge capture, improving materials contracts, and modifying employee benefits.³⁷

Finally, although advocates of reengineering indicate that downsizing and de-layering are not its focus, Walston and Kimberly report “it was our experience that downsizing through layoffs was specifically a focus of many executives,”³⁸ in part because of situations of decreased inpatient census and diminished competitive position. Others are critical of reengineering, citing its use to absolve HSOs from blame when layoffs are perceived negatively.³⁹

Barriers and Facilitators to Improvement

Change is threatening. CQI and PI require change, and managers must recognize the necessity of change if improvement is to occur. Resistance to change may be political, or it may come from those who will be adversely affected, have low tolerance for change and prefer the status quo, or are unconvinced that change is needed. Resistance may be overt and explicit or covert and indirect. Managers should uncover resistance to change, understand the motivation, provide incentives for accepting and disincentives for not accepting change, and address people’s concerns.⁴⁰

Table 8.1. Reengineering facilitators and barriers

Facilitators	Barriers
Establish and maintain a constant, consistent vision	Lack of continuity of vision/purpose Disconnection of vision with environment
Prepare smooth transitions for the reengineering effort	Poor transition between project phases Planning to implementation Implementation to a continued process
Prepare and train for reengineering changes	Inadequate administrative skills Inadequate clinical/technical skills
Establish continual, multiple communication methods	Historical practices Lack of continuity of communication Little or inadequate feedback Perceived dishonest communication
Establish strong support and involvement	Inconsistent support and involvement Lack of consistent and even administrative support Lack of equitable departmental participation
Establish mechanisms to measure reengineering's progress and outcomes	Inability to measure progress Complexity of changes without understanding causal mechanisms
Effectively establish both new authority and responsibility relationships	Inadequate authority/responsibilities assigned
Find methods to involve physicians	Lack of time and interest

From Walston, Stephen L., and John R. Kimberly. "Reengineering Hospitals: Evidence from the Field." *Hospital & Health Services Administration* 42 (Summer 1997): 153; reprinted by permission from Health Administration Press.

Vision, organizational philosophy, senior-level management commitment, physician participation, process design and implementation, and performance measures will help ensure success of reengineering. Complete and open communication lessens fear and dispels uncertainty; employee involvement can lead to co-optation and accepting ownership. Chapter 9 discusses resistance as a natural reaction to change. Table 8.1 shows facilitators and barriers to reengineering. This depiction mirrors facilitators and barriers to CQI initiatives.

Improvement and Problem Solving

Process improvement problem solving uses the problem-solving model in Figure 6.4. Conditions that initiate problem solving are deviation (actual results inconsistent with desired results), crisis, opportunity or threat, and

improvement (see Figure 6.3). As with the other categories, problem solving under the condition of improvement involves 1) problem analysis, including stating the problem, 2) developing assumptions, 3) identifying tentative alternative solutions, 4) developing and applying decision criteria, 5) selecting the alternative that fits the criteria best, 6) implementing the solution chosen, and 7) evaluating the solution. Postchange performance is compared with the results desired.

The PDSA cycle is conceptually similar to the steps of problem solving. CQI can also involve problem solving under the condition of deviation, as when special cause variation is investigated. However, CQI enhances performance primarily by improving processes. The situation analysis step is different when the problem-solving model is applied to opportunities for improvement. It involves collecting and evaluating data about a process that is “in control” so that improvement opportunities can be identified. The purpose is to make the acceptable better. Improvement problem solving for Deming is reducing common cause variation; for Juran, moving a process to the new zone of quality control; and for Crosby, moving toward the goal of doing it right the first time.

In Chapter 6 the discussion of making assumptions states that narrow, overly restrictive structural, personal, and problem-centered assumptions result in lower-quality solutions. Less adequate solutions result because restrictive assumptions limit the range of alternatives that can be considered. The same concern arises in process improvement.

The advantages of group problem solving discussed in Chapter 6 are even more applicable to process improvement. Participation of persons with process knowledge is essential for a QIT to be effective.⁴¹ In addition, QIT members learn new tasks and become aware of others' problems and more attuned to the triple role of customer, processor, and supplier, Juran's triple role of the worker is shown in Figure 7.1. Team members will be more eager to assist each other in solving problems, team spirit will develop, and motivation and a sense of worth will be enhanced.⁴² An important benefit, especially for cross-functional QITs, is that staff will see more clearly how their work fits into the whole system of delivering services and how what they do can help optimize the system.

Management must show its commitment to CQI by allocating resources for education, staff, and computer software, implementing a participative philosophy, and encouraging employee team building. Deming, Juran, and Crosby advocated giving employees the authority to act. Others call it empowerment.⁴³ The knowledge of QIT team members allows systematic dissection of a process so it can be fully understood, as requisite to improvement.

Statistical Process Control

Life teaches that there is variation in everything, everywhere. Examples are the time it takes to commute to work and return home, or the lengths of time needed to perform a repetitive task. It takes but a bit of imagination to apply the same concept of variation to any process in the workplace. Further, one can easily understand how variation in a process contributes to output of a lesser quality. A classic question for managers has been to whom, or what, are to be attributed the quality issues that arise in the output from a process. Historically, the answer has been that the worker is responsible for what is produced. The process is fine—after all it was developed and implemented by management. It is the worker working in the process who causes poor quality. That was to begin to change in the 1980s.

Deming and Juran asserted that poor quality is almost always caused by processes, not by workers. They emphasized use of statistical methods for quality control and the need to identify sources of process variation.⁴⁴ Deming was adamant that variation in processes causes poor quality. There is ample empirical evidence that he was correct. Many consider the world's finest violins to be those crafted by Antonio Stradivari in the 17th and 18th centuries. These instruments were made to a perfect thickness in all parts; the result, even centuries later, is an incomparable quality of sound. The seven-time world champion Formula One driver, Michael Schumacher, best known as a driver for Ferrari, determined the fastest line around a race track at practice. During the race, he deviated from that line

as little as possible, thus earning him the best time and, ultimately, 91 victories.

For the purposes of SPC, Deming defined variation as “performance within three standard deviations of the mean—a generous amount of variation, although management can set more stringent limits.”⁴⁵ Depending on the process and the amount of variation in it, HSOs/HSs may set control limits at two standard deviations. Narrowing control limits risks increasing the number of false positives—common cause variation (caused by unknown factors) that appears to be special cause variation (caused by known factors), but is not. Thus, management may undertake to find the source of the “special cause” variation, which will be impossible because the false positive is actually common cause variation that is, by definition, nonassignable to any source.

Variation within control limits is common cause variation and produced by the process itself. Variation beyond the control limits is special cause variation. Shewhart called special cause variation “assignable” because it could usually be attributed to a cause from outside the process. Special cause variation may be negative or positive. Reasons for negative special cause variation must be identified and prevented, if possible.⁴⁶ Examples are an act of nature, such as a hurricane, or delays in service because of an unanticipated surge in arrivals in the emergency department (ED). Special cause variation for Juran is the “sporadic spike,” which causes the process to not be “in control.” Deming and Juran asserted that only processes “in control,” meaning those affected only by common cause variation, can be improved. Juran referred to this process improvement as moving to the “new zone of quality control.” Deming termed this improving the process by decreasing common cause variation around the mean. For Crosby, it meant moving through the organizational maturity stages toward certainty and striving for the goal of “do it right the first time.” Deming used control charts to determine whether a process was stable and, therefore, its performance was predictable and process improvement could be undertaken.

The most important reason for process improvement is to reduce common cause variation around the mean in a process that is in statistical control. To be in statistical control means that, in a control chart with

control limits of ± 3 standard deviations, there is a 99.74% probability that the next data point (process output being measured) will fall within the control limits, even though it is impossible to know exactly where within the control limits the data point will fall.

Deming asserted that all processes in control can be improved and that initiatives to reduce variation will result in higher quality, which in turn means improved productivity. Juran called this moving to the new zone of quality control. For Crosby, this is moving toward the goal of zero defects.

Tools for Improvement

Control Charts

Control charts are essential to SPC and successful Q/PI. Chapter 7 presented the theoretical bases for control charts when SPC was discussed. Control charts are essential to distinguishing common cause variation from special cause variation, an ability indispensable to effectively managing. Special cause variation *cannot* be identified only by looking at a set of numbers, even if arrayed on a run chart. Control limits *must* be calculated.

Run charts are a simple data collection tool. Figure 8.2 is a run chart of data that shows performance of one aspect of inpatient food service on a nursing unit. Run chart data are used to calculate the standard deviation. As already noted, 3 *SD* are commonly used in SPC. Drawn on the run chart, the upper and lower control limits of 3 *SD* transform it into a control chart such as Figure 8.3. Thus, the process itself establishes the limits that distinguish common cause from special cause variation. As a corollary, it is wrong to set an arbitrary number that the process (and its workers) is expected to produce. Process capability—the capacity of the process—is inherent in it and necessarily limits performance of the process.

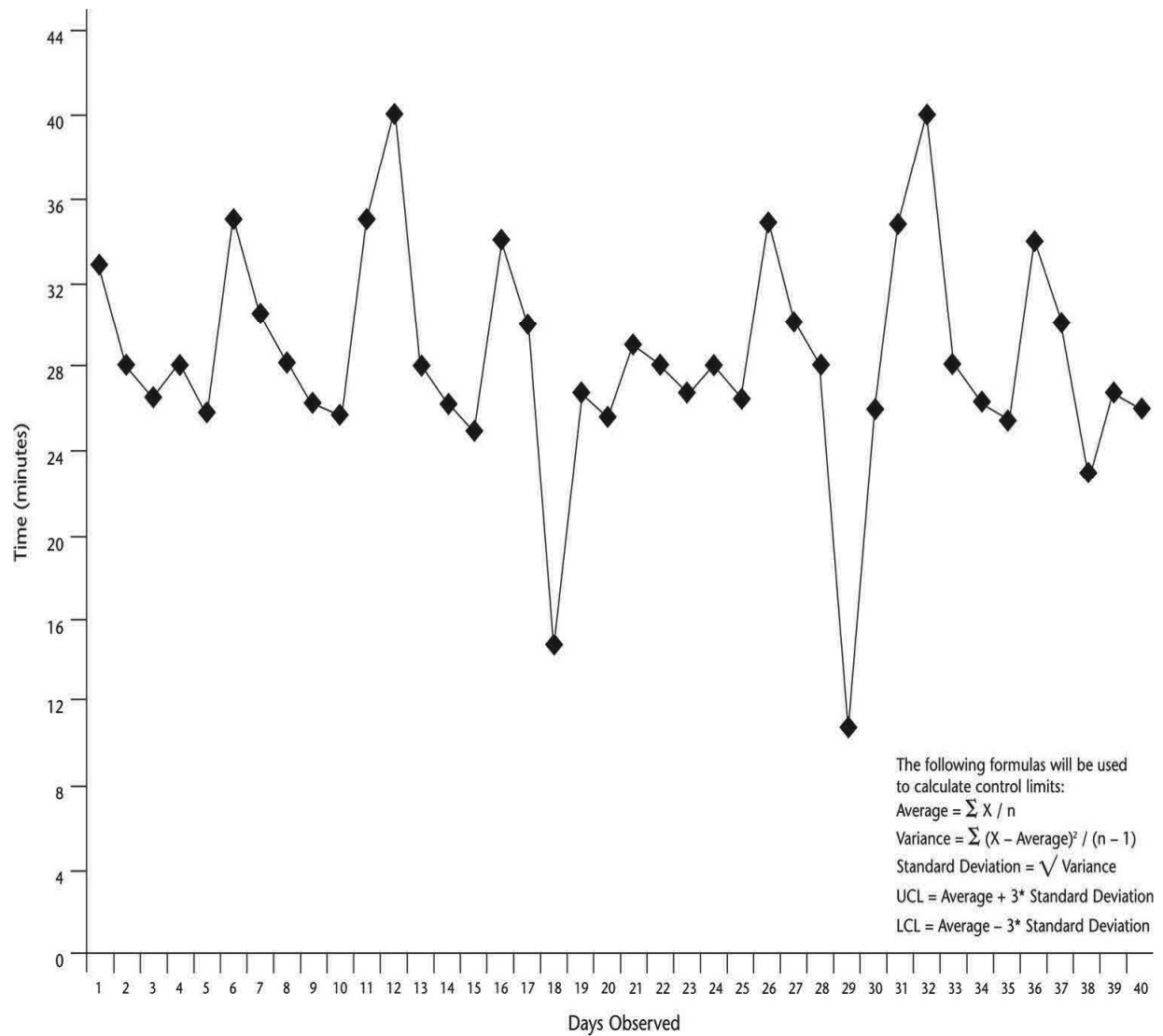


Figure 8.2. Run Chart: Time elapsed between noon meal food trays leaving kitchen and first patient receiving tray on unit 2W, by day, in minutes. Source for formulas: Dunn, Oliver Jean. *Basic Statistics: A Primer for the Biomedical Sciences*. New York City: John Wiley & Sons, Inc., 1964, 38.

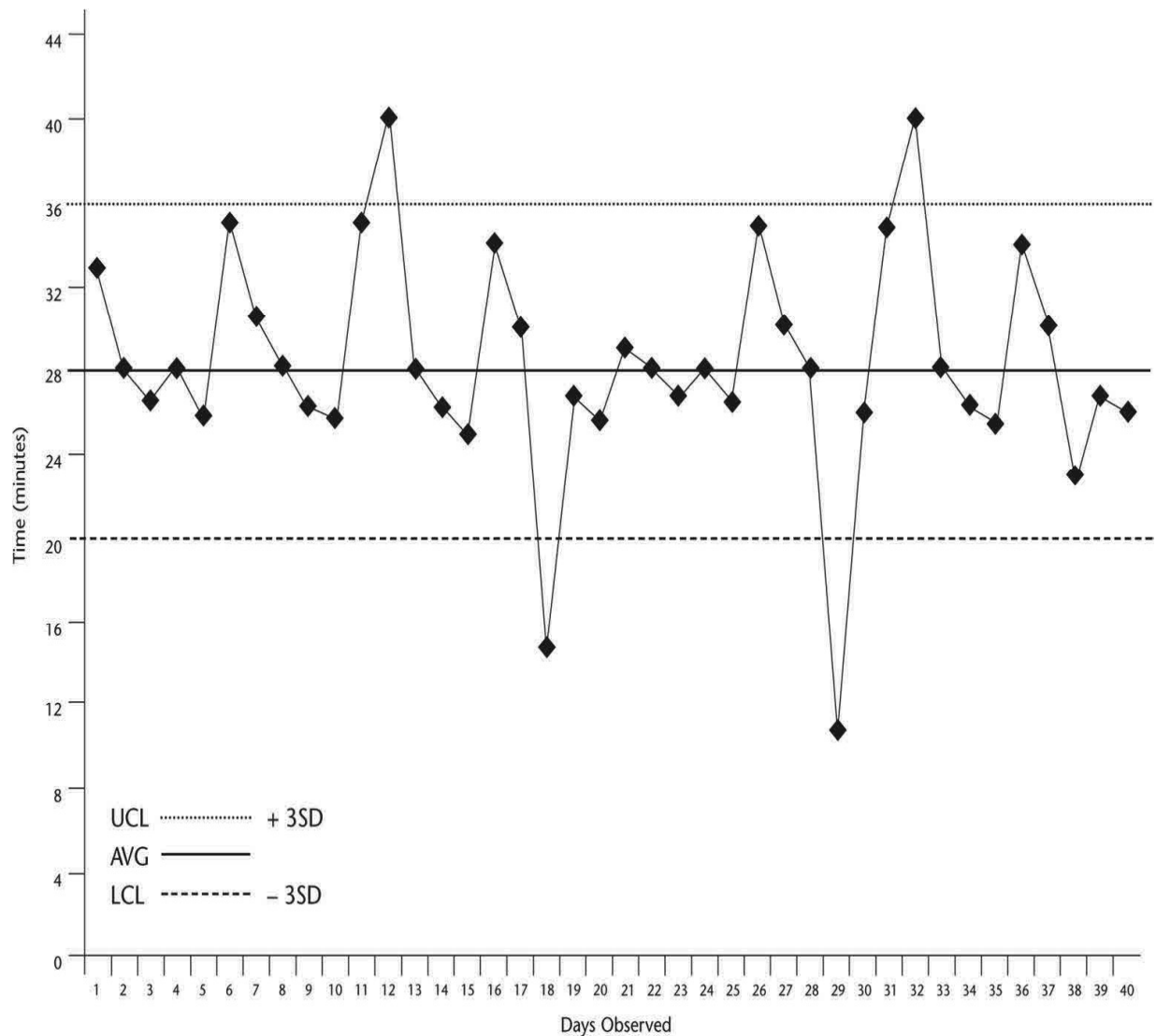


Figure 8.3. Control Chart: Time elapsed between noon meal food trays leaving kitchen and first patient receiving tray on unit 2W, by day, in minutes. UCL, upper control limit; LCL, lower control limit.

Both run charts and control charts array data on two axes: The vertical axis is the performance being measured; the horizontal axis shows time. Control charts can be used to monitor any process, such as customer waiting time in patient admitting, units of laboratory output, or utilization of diagnostic equipment.

The control chart in Figure 8.3 shows that the average time between when noon meal food trays leave the kitchen and receipt of a tray by the first patient on unit 2W is 28 minutes. There is wide common cause

variation around the mean, however, with a range of 23 to 35 minutes. This process is not “in control,” because there are four special cause variation data points—two well below the lower control limit (LCL) and two well above the upper control limit (UCL). As a first step, SPC requires that the process must be brought into control by investigating special causes of variation to determine their sources. Delivery times of 40 minutes will almost certainly diminish customer satisfaction. Negative special causes should be identified and eliminated, if possible, or if not, their effects on the process must be minimized. Positive special cause variation is present in delivery times that were much shorter than the mean of 28 minutes. Early delivery times are not necessarily better, because nurses and patients might not be ready. They do, however, show that faster delivery is possible. Reasons for the positive special cause variation should be identified and, if possible, incorporated into the process because it is almost certain that food delivered sooner will be more palatable, likely of higher quality, and, thus, more likely to meet the patient’s (customer’s) expectations. Once the process is in control, process improvement can be undertaken to reduce variation around the mean and, if desirable, move the mean toward a shorter delivery time.

Because nursing is involved in delivering trays to patients, one KPV will be predictability. If nurses know that trays will arrive within a narrow range of variation, they can be ready to serve meals to patients. This will invariably lead to greater customer satisfaction. In this process, both nurses and patients are customers.

Fishbone, or Ishikawa Diagram

Often, a QIT’s first step is to brainstorm perceived causes of problems in a process and develop a cause-and-effect diagram like that shown in Figure 8.4. The cause-and-effect diagram is also known as the fishbone diagram, because of its shape, or the Ishikawa diagram, after its originator Kaoru Ishikawa. An effect is a desirable or undesirable situation, condition, or event produced by a system of causes. Figure 8.4 shows reasons for laboratory test delays for patients in an ED. Primary process variables (components) are shown by the long arrows; minor process variables are

shown by the short arrows and are elements of the primary variables. Brainstorming to identify the problems perceived to be present in a process suggests the directions for collecting confirmatory data. In turn, the data will suggest solutions to the problem(s).

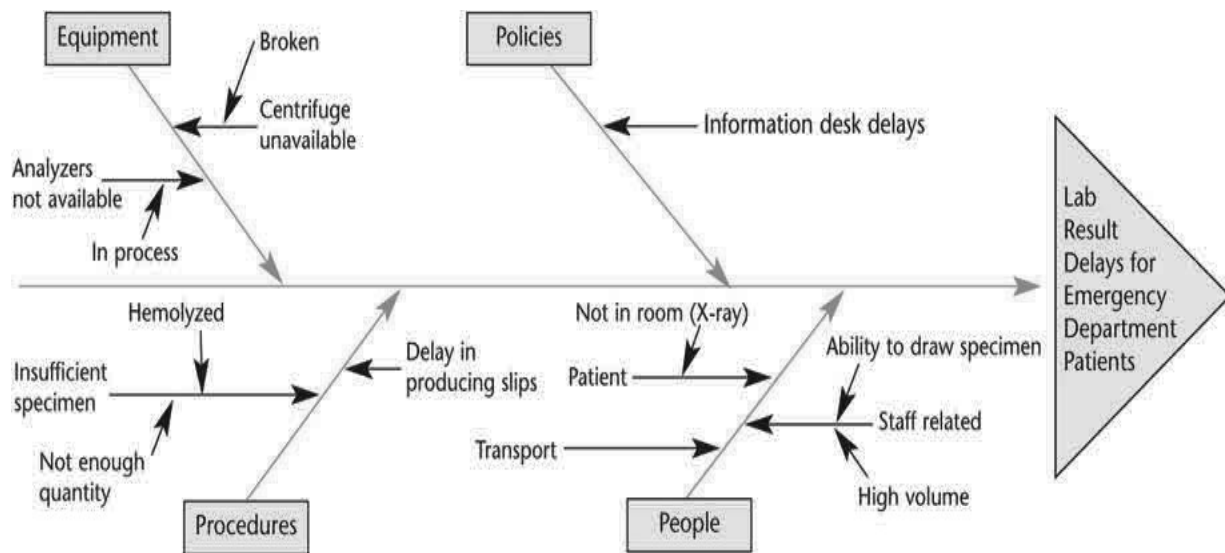


Figure 8.4. A fishbone, or cause-and-effect, diagram examining reasons for delays in laboratory test results for emergency department patients. The fishbone diagram is drawn after a brainstorming session. The central problem is visualized as the head of the fish, with the skeleton divided into branches showing contributing causes of different parts of the problem. (From Merry, Martin D. “Total Quality Management for Physicians: Translating the New Paradigm.” *Quality Review Bulletin* 16 [March 1990]: 102; reprinted by permission. Copyright 1990 by Joint Commission Resources.)

Pareto Analysis

Another contribution of Juran was discovering the work of an Italian economist, Vilfredo Pareto. Often cited as separating the “vital few” from the “trivial many,” Juran came to realize that the many are still useful and cannot be ignored.⁴⁷ Also known as the 80/20 rule, the Pareto principle is commonly applied in marketing where, for example, 80% of sales are derived from 20% of products or services. In QI, it means that 80% of defects—errors, delays, rework, and the like—are typically caused by 20% of the variables in a process. Applied to a hospital operating room’s (OR’s) schedule, Pareto analysis might find that 80% of delays are caused by 20%

of surgeons. The 80/20 ratio is neither fixed nor magical; rather, it helps decision makers understand relationships. Pareto analysis can show the relative importance of variables in a process and their contributions to a result, thus assisting to develop priorities in CQI. The Pareto diagram in Figure 8.5 shows that physicians' untimed routine and discharge orders are the two areas in which most improvement can occur. QITs should focus there.

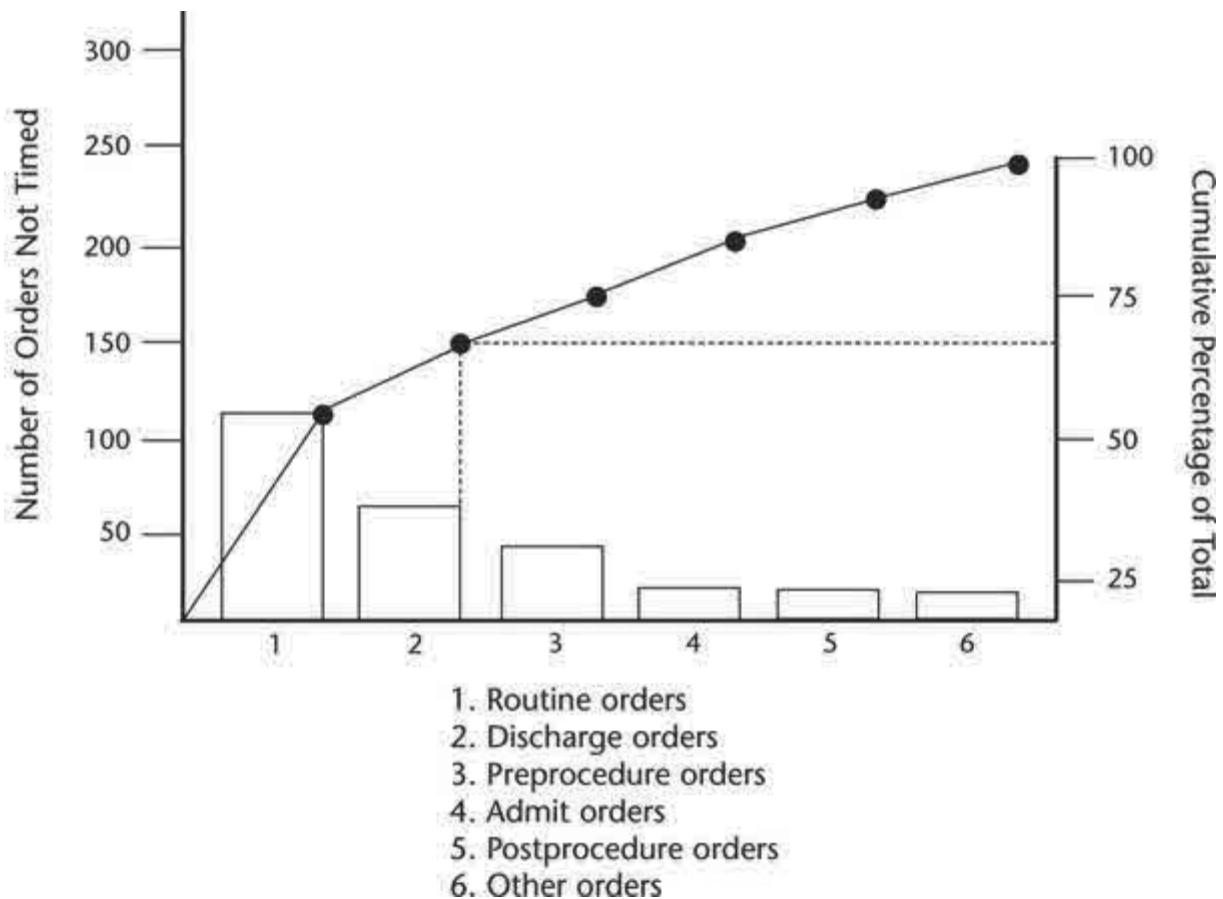


Figure 8.5. Pareto diagram showing the rank order of untimed physicians' orders in a major hospital. This diagram ranks classes of orders that failed to be timed with a plot line showing that the correction of the first two classes of orders would lead to a greater than 50% improvement in all untimed orders. (From Re, Richard N., and Marie A. Krousel-Wood. "How to Use Continuous Quality Improvement Theory and Statistical Quality Control Tools in a Multispecialty Clinic." *Quality Review Bulletin* 16 [November 1990]: 394; reprinted by permission. Copyright 1990 by Joint Commission Resources.)

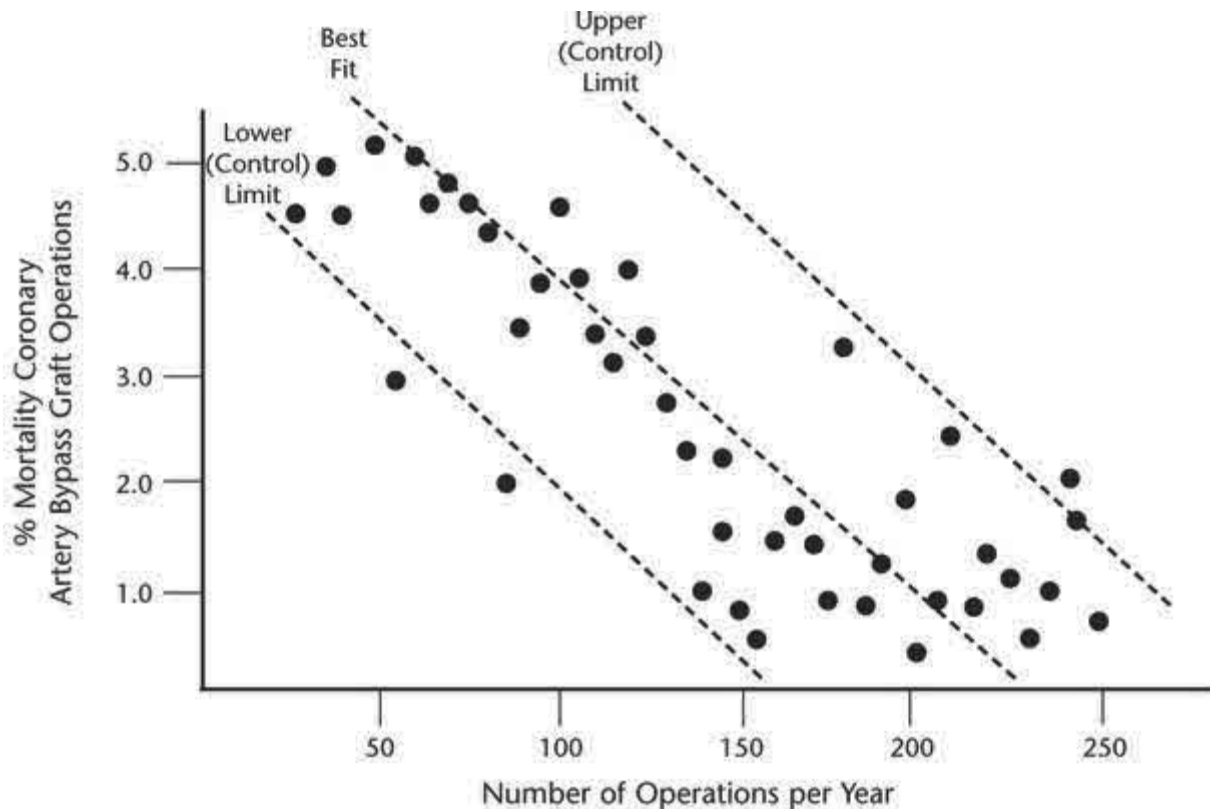


Figure 8.6. Scatter diagram used to determine a possible relationship between two variables: the mortality rate for a surgical procedure and the number of times the procedure is performed during a 12-month period. (From Merry, Martin D. “Total Quality Management for Physicians: Translating the New Paradigm.” *Quality Review Bulletin* 16 [March 1990]: 103; reprinted by permission. Copyright 1990 by Joint Commission Resources.)

Scatter Diagrams

Scatter diagrams, also known as scatter plots, show the relationship between two variables. Figure 8.6 depicts the relationship between the number of coronary artery bypass grafting (CABG) surgeries per year on the horizontal axis and the percent of operated patients who died (mortality)—a strong indication of quality—on the vertical axis. The data show an inverse relationship between mortality and the number of CABG procedures. The learning, or experience, curve for surgeons and staff is often cited as the reason for this relationship.

The statistical technique of least squares linear regression can be applied to scatter diagrams to show a “best fit line.” UCLs and LCLs are

calculated using the variation of data points from the best fit line. Control limits of 3 *SD* mean that there is a 99.74% confidence level that a data point beyond the UCL or LCL is not due to chance alone. Figure 8.6 shows one data point above the UCL and two below the LCL. These points comprise Deming's special cause variation, Juran's sporadic spike, and Shewhart's assignable cause. All three data points showing special cause variation are of interest. The cause of the data point above the UCL should be determined so that recurrence of this undesirable result can be prevented. Data points below the LCL should be investigated to understand why these positive results occurred so they can be studied and replicated to the extent possible. For example, a surgical team with superior results (positive special cause variation) should be studied and the lessons applied to other surgical teams. Positive special cause variation may result from input differences such as surgeons' skills and training, or the acuity levels of patients on whom surgery was performed. Or, the process of performing the surgery may be the cause of positive special cause variation.

Failure Mode Effects Analysis

Failure mode effects analysis (FMEA) was developed by the National Aeronautics and Space Administration (NASA), the civilian agency of the federal government responsible for space travel. The complexities of NASA's systems required a technique to identify the root causes of potential problems so that they could be designed out of processes or processes could be modified to prevent them from occurring. FMEA is proactive because it prevents problems—the failure mode—from occurring when the process becomes operational. This makes FMEA part of Juran's quality planning. FMEA can be applied after problems arise, as well.

FMEA is generally applicable to HSOs. It uses a template that enables team members to work through the failure mode and its effect. After identifying a service feature or a process, the team brainstorms to identify potential failure modes, the potential effect of each failure, the severity rating for each potential failure, the potential causes of failure, the

likelihood of the failure occurring, and the likelihood of detection by current process controls. Finally, the team assigns priority numbers to identify the issues that should receive the most attention. The second half of the template addresses how the potential problems will be prevented.⁴⁸ Applications of FMEA in health services have included the blood product transfusion process.

Crew Resource Management

Crew resource management (CRM) is a generalized application of cockpit resource management, a concept developed jointly by the Federal Aeronautics Administration and the airline industry in the 1980s to enhance the quality of responses to emergencies involving the crews of commercial aircraft. The study of human factors in aviation emphasizes the role of human beings in high-stress, high-risk environments. An estimated 80% of airplane accidents are caused by human factors. The purpose of CRM is to develop techniques and procedures to catch mistakes before they cause problems.⁴⁹ The similarities between the cockpit of a commercial aircraft and a hospital's OR or ED are striking. CRM can be applied to any area in which a team provides care.⁵⁰ Since the late 1990s, CRM has been applied in hospital EDs, ORs, and intensive care units. Unlike CQI, CRM is not data driven.

CRM seeks to enhance patient safety and quality of care by improving teamwork through better cooperation, coordination, and communication. Techniques include presurgical briefings, preoperative assessments, and methods to ensure that handoffs from one part of the process or staff member to another are effective. These safety measures (tools) ensure the staff's daily use of the teamwork and communication skills learned in the training classes. The purpose is to achieve a permanent change in behavior.⁵¹ Specific examples of applying safety tools in the OR include the OR time out, which requires confirming vital information about a patient, and surgical site verification, which confirms the surgical site before surgery begins and may include asking a patient to state what is to be done.

Hospitals that have applied CRM report significant positive results, including lower costs of malpractice, higher staff satisfaction levels and less turnover, and far fewer “wrong” surgeries—wrong patient, wrong site, wrong device.⁵² These wrong surgeries are known as never events because they should never happen. The evidence of CRM’s value remains anecdotal, however. It has been argued that CRM is worth further investigation in healthcare, but it is premature to conclude that it can reduce medical errors.⁵³ Others have raised questions about the extent of behavior change⁵⁴ and the link between attitudes about teamwork and patient outcomes.⁵⁵

Benchmarking

Organizationwide or macro-level data collection permits management to prioritize the order in which processes will be improved. Micro- or process improvement-level data collection enables QITs to measure process variables, which is requisite to improvement. Benchmarking allows comparisons by providing norms, standards, and measures for various processes and outcomes such as patient admitting, customer satisfaction, quality of care, and financial performance.

There are several types of benchmarking. Internal benchmarking compares similar activities or processes within the HSO. External benchmarking compares the HSO’s performance with similar activities and processes in comparable organizations both in- and outside health services. Competitive benchmarking involves comparisons with competitors who provide the same service in similar markets. Its most aggressive application identifies the “best patient outcomes for each service measured by such factors as mortality rates, nosocomial (HSO-acquired) infections, [and] patient mobility” as well as the practice patterns and resource consumption profiles of competitors.⁵⁶ World-class benchmarking compares the HSO/HS to organizations in- or outside the health services industry that excel in using similar processes. Examples

common to a wide variety of organizations are order fulfillment, supplier relations, and billing and collection processes.⁵⁷

It must be understood that benchmarks are only guidelines. Achieving the same results as a world-class performance benchmark, for example, requires that the HSO have an exact replica of everything that is present in the benchmark organization, including its culture. Regardless, knowing what can be accomplished might stimulate the HSO to achieve higher quality or even to achieve at a level higher than the benchmark.

Benchmarking includes determining what to benchmark, collecting internal and external data, and applying the conclusions reached to improve existing processes. Examples of processes that HSOs benchmark are admitting, billing, patient transport, and surgical scheduling and OR use. Control is another application of data obtained about other HSOs/HSs. Chapter 11 identifies databases that contain peer organization performance and financial outcomes and resource consumption data.

The data provide comparative benchmarks for “best in class” performance and allow HSOs/HSs to understand the extent to which improvement in competitive position is possible, if resources are adequate. Chapter 9 considers external environmental analysis that enables the HSO to attain and sustain competitive position by knowing its competitors’ performance levels.

Productivity and Productivity Improvement

Cost-efficiency and PI result from CQI. Figure 7.3 suggests that process improvement [2] leads to higher quality outputs [3], which lead to PI and better resource use [4] and, thus, enhanced competitive position [5]. The Deming Chain Reaction shown in Figure 7.4 connects improved quality, decreased costs, improved productivity, and the organization’s ability to decrease prices, increase market share, and stay in business. CQI and PI are integral and inseparable. Similarly, input resource costs and quality are

conjoined with output quality; neither can be considered in isolation from the other.

Productivity is the index of outputs relative to inputs.⁵⁸ Alternatively, productivity is the results achieved relative to resources consumed⁵⁹:

$$\text{Productivity} = \frac{\text{Outputs}}{\text{Inputs}} = \frac{\text{Results achieved}}{\text{Resources consumed}}$$

Productivity is increased by any change that increases the ratio of outputs to inputs, which is achieved by altering either the conversion process (structure, tasks/technology, people; see Figure 5.7) or the inputs. For example, fewer nurses caring for the same number of patients increases productivity: fewer inputs (lower costs), but the same output. More radiographic procedures per day with the same staff and equipment have the same result. If, however, productivity (output) is increased without maintaining or enhancing quality (defined as conformance to requirements and patient satisfaction) a lower quality of higher output will actually cause a diminution in productivity because it results in errors, rework, and dissatisfaction among customers and staff. Producing poor quality radiographs or performing unnecessary radiographic procedures (nonconformance output) is not productivity improvement. Neither is decreasing the number of surgical assistants and increasing patient and physician wait times, because they lessen customer satisfaction. Productivity improvement occurs only when the index ratio of outputs to inputs increases and conformance and expectation quality is maintained or enhanced. This is denoted in the following formula:⁶⁰

$$\text{Productivity improvement} = \frac{\text{Outputs}}{\text{Inputs}} = \frac{\text{Quantity}}{\text{Inputs}} + \text{Quality} = \frac{\text{Results achieved}}{\text{Resources consumed}}$$

CQI and PI

Figure 8.7 shows the relationship of the PI triangle to CQI. PI occurs only when lowest costs (inputs) are consistent with appropriate quality

(outputs). The original *Quality Measurement and Management Project* report termed this the “value of healthcare.”⁶¹ Because PI focuses on the relationship of inputs and costs to outputs and quality, both inputs and processes are investigated in PI, as they are in CQI.

HSOs are service organizations that have high levels of customer interaction. Some, such as acute care hospitals, must have flexible capacity to meet surges in demand. At the other end of the spectrum, HSOs such as nursing facilities have little need for flexible capacity because their customers are usually long-term residents and occupancy is usually near 100%.

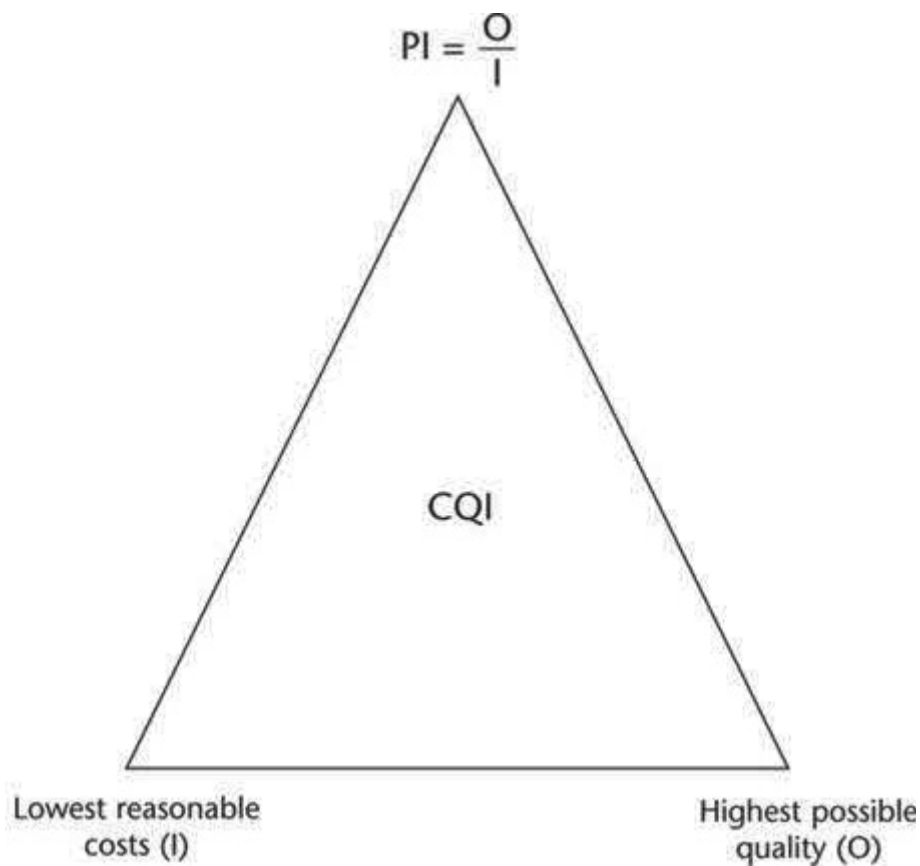


Figure 8.7. Productivity improvement (PI) triangle.

CQI focuses on improving processes (see Figure 7.3), which necessitates evaluating inputs. For example, the QIT may determine that higher quality will result from a process if better-skilled (more expensive)

employees are recruited or if employees are cross-trained so work assignments can be more flexible as workloads change. Enhancing technology inputs can improve work systems and may be able to substitute equipment for people. Magnetic resonance imaging improves clinical diagnosis, and personal computers enhance accuracy and productivity in billing and admitting. Other techniques may be used to add efficiency to inputs: increasing the quality of materials and supplies by working closely with suppliers (Deming advocated developing long-term relationships with suppliers and even suggested that sole-source suppliers will improve quality); using a just-in-time inventory system to eliminate inventory other than that needed for safety stock; and using ABC inventory analysis,⁶² which is similar to Pareto analysis, to identify the supplies that are most expensive or critical and that require special attention. Management information systems provide data for control and utilization evaluation; successful forecasting enables managers to anticipate demand and alter capacity. Use of work measurement to monitor employee utilization and workloads and information from a patient acuity classification system permit efficient nurse staffing patterns.

Productivity may be improved in numerous ways other than by analyzing inputs. Examination of a process or work system in a CQI framework should ask questions such as Is what we do really necessary? Are we doing the right things? Can the work be done another way with the same or better quality? How are the work results of one job interdependent with other jobs, materials, or processes? Can we improve the process with a different mix of resources that will improve quality, decrease costs, or both? These questions can be answered by the following methods: 1) analysis and improvement of work systems and job design; 2) capacity planning and facilities layout; and 3) production control, scheduling, and supply chain. Inputs are integral to each. These methods are described next.

Work Systems (Processes) and Job Design

Analysis and improvement of work systems and job design are integral to CQI process improvement and will lead to PI. The basic objectives are to find better ways to work in general, improve specific jobs in particular, and increase the ratio of quality relative to costs—with the same, fewer, or a less costly mix of inputs.

Work systems (processes) are interrelated jobs that form an integrated whole. Hospitals, for example, have hundreds of systems and subsystems: nonpatient care systems include admitting, discharge, accounts receivable and accounts payable, transportation, inventorying and distributing material, patient food delivery, and medication order fulfillment; direct patient care systems include nursing service, clinical support services (e.g., laboratory, radiology, and respiratory therapy), and therapeutic activities such as perioperative services. Analysis of a system can be exclusive (how it functions) or inclusive (how it interrelates with other systems). The purpose is to improve systems to enhance output quality and productivity. Process and methods analyses are techniques used to evaluate systems.⁶³ Health services processes are the operations, steps, or activities through which patients, material, or information flow. Documenting this flow permits evaluation of each activity in the sequence.⁶⁴ This in turn makes it possible to determine if altering the flow, combining or eliminating operations, or methods redesign will result in higher-quality outputs and PI.⁶⁵ As noted, one of the first activities of a QIT is to prepare a flow diagram (process map) of the process.

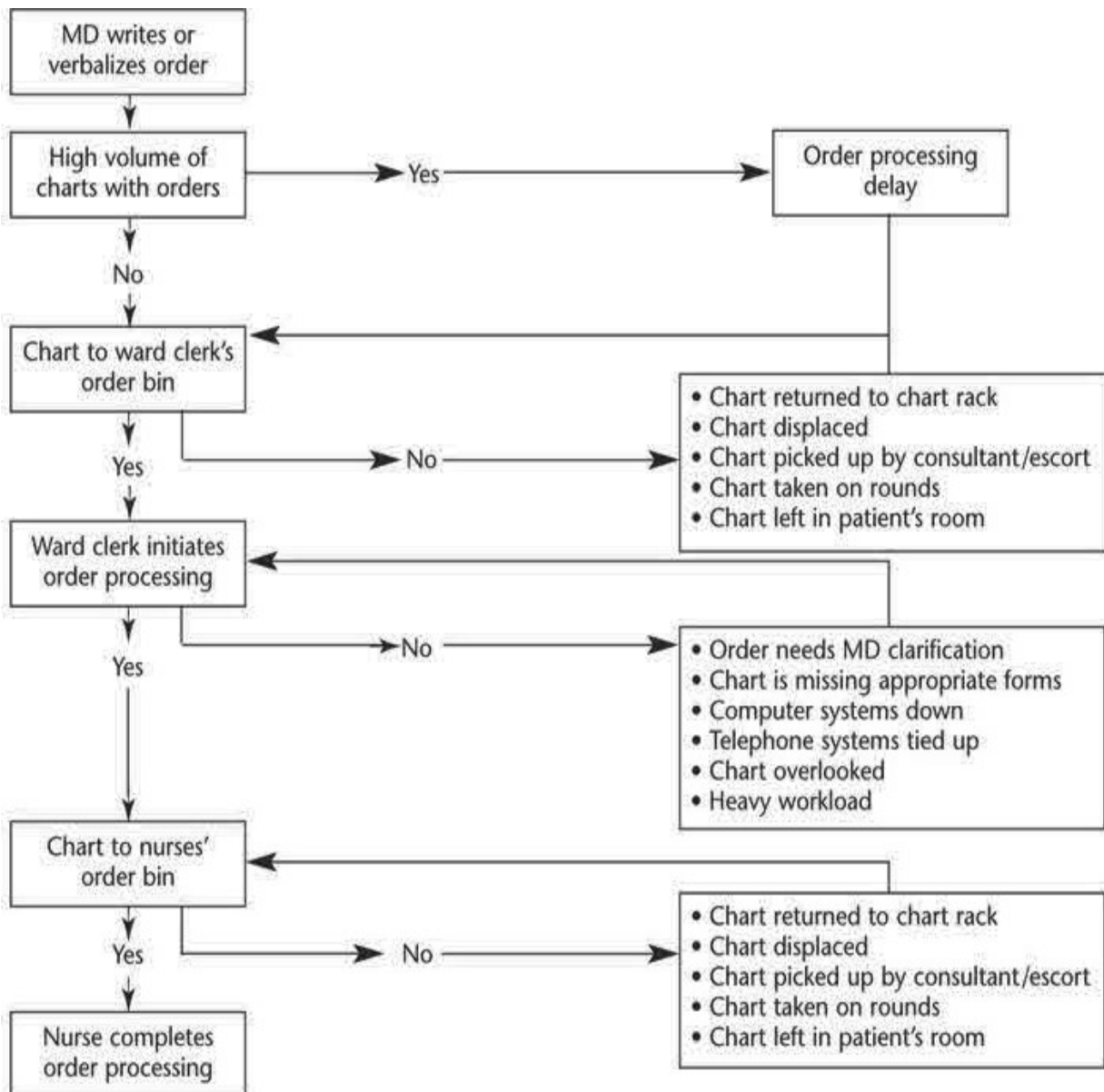


Figure 8.8. Flow chart outlining the initial steps in implementing physicians' orders, clearly identifying points of consumer–producer interchange (e.g., the interaction of physician and ward clerk) and sites of possible system failure or delay. (From Re, Richard N., and Marie A. Krousel-Wood. "How to Use Continuous Quality Improvement Theory and Statistical Quality Control Tools in a Multispecialty Clinic." *Quality Review Bulletin* 16 [November 1990]: 393; reprinted by permission. Copyright 1990 by Joint Commission Resources.)

Figure 8.8 is a flowchart (flow diagram) that outlines the process used to implement physicians' orders. Understanding the steps in a process will show that improvements can be made by eliminating bottlenecks, delays,

or even steps. Flow analysis is used for processes with high customer interaction to indicate where and how interactions may be enhanced or lessened, whichever is likely to result in higher patient satisfaction.

HSO work systems are interdependent, and multisystem process flow analysis is necessary to identify areas for improvement. For example, timely reading and reporting of test (imaging, electrocardiography, electroencephalography, and laboratory) results positively affect patient care and shorten lengths of stay; delayed reading or reporting negatively affects patient care and increases lengths of stay. Staff knowledge about and improvement of system or process outputs that become inputs elsewhere in the HSO positively affect productivity.

Methods analysis involves evaluating how work is done—the specific operations, steps, or activities performed. Such analyses include evaluating appropriateness of the operations, steps, or activities; considering alternative inputs, such as personnel and equipment substitution or redesigning jobs; or evaluating information flow and the media used.

At a micro-level, job design improvement evaluates the tasks in a job or a cluster of jobs that constitute an operation or activity in a process. Included is the sequence of job tasks, design of physical layout, and person–machine relationships (ergonomics), as well as the equipment, material, and supplies used. Job design improvement or a variant, work simplification—organizing work into specific tasks to make it easier—is used to eliminate unnecessary tasks, reduce time between tasks, reallocate tasks among different jobs, combine jobs, or centralize common tasks in one job through specialization.

Finally, work simplification is a way to evaluate and improve jobs and enhance work results. User-friendly, menu-driven computers in the admissions department enable employees to admit patients faster, with greater accuracy; both improvements increase quality, productivity, and customer satisfaction.

Capacity Planning and Facilities Layout

Facilities analysis is an important dimension of process improvement. It focuses on the physical aspects of a process, the need for flexibility in meeting variable demand, and balancing timeliness of service and idle resources. Facility layout is the arrangement of equipment and work areas. Facilities, process flow, equipment, and workstations may be rearranged to improve sequence and flow, decrease unnecessary worker movement and materials transportation, and eliminate bottlenecks and congestion. The result is faster patient throughput. Layout analysis can be accomplished by using drawings, proximity charts, templates, or three-dimensional models. Computer simulation can be used to design the physical layout of a facility within predetermined constraints and assumptions.

The analysis of traffic patterns and material flows consists of observing and recording movement to decrease travel, eliminating or reducing delays, or substituting alternate material handling or delivery methods. For example, analysis of traffic patterns may reveal that restricting use of certain elevators to patients, staff, and movement of equipment reduces delays in clinical activities. Similarly, a materials and supplies flow analysis may justify an exchange cart system to improve logistics, decrease inventory and staffing, and ensure that patient care supplies and medications are on units when needed.

Production Control, Scheduling, and Supply Chain

Production control in HSOs involves matching workload with capacity through work scheduling and is applicable to areas such as admitting, ORs, diagnostic testing, clinics, physician offices, and outpatient services. Production-smoothing techniques are used to spread the workload throughout a shift. For example, if all inpatients are brought to radiology at about the same time, or all outpatients arrive at 9:00 a.m., waiting lines build, staff is overloaded, and the increased waiting time will reduce patient satisfaction. By comparison, in the afternoon, staff is underutilized. Workload spread throughout the day minimizes patient waiting time, and staff is productive during an entire shift. If demand cannot be controlled through scheduling, part-time staff can be used or other adjustments made to meet peak load demands.

Workload balancing by scheduling demand or capacity ensures that staff, equipment, and facilities are used efficiently and customer waiting time is lessened. Manual and computerized scheduling techniques are available, including short-interval scheduling, multiple-activity charts, and work distribution analysis. Another technique, simulation, is discussed in Chapter 11.

Effective supply chain management and timely distribution of materials and supplies are essential to downstream processes. Improvement techniques may be as simple as using exchange carts to deliver supplies to nursing units. On alternate days, one cart is filled and the other is used. Once a day, carts are exchanged. A case cart system may be used in ORs. Each surgeon has a list of instruments, devices, and supplies needed by type of procedure. Before surgery, the case cart for that procedure is packed and delivered to the OR. The unit dose system can be used to distribute drugs. Medications are purchased individually prepackaged or are packaged in the pharmacy and distributed to nursing units. Costs are higher, but the risk of medication errors is reduced because each dose is available as needed by the patient.

Physicians and CQI

HSOs/HSs are unique because they are structural blends of administrative and patient care activities in which clinicians are accorded significant autonomy. Historically, the blended structure created conflict between the two. The quality philosophy is changing this relationship, however; it demands greater shared managerial and clinical accountability for quality, more collaborative participation in quality initiatives, and a mutual interest in both retrospective and concurrent process performance.⁶⁶ Both HSO/HS managers and physicians realize they must respect each other's competencies, and they must collaborate to succeed in providing quality services and introducing organizational change, such as improved processes, reengineering, or strategic quality planning. One such change has been widespread use of practice guidelines.

Practice Guidelines

Practice guidelines have been developed by various public and private organizations. “Practice parameters (guidelines) is a generic term for acceptable approaches to the prevention, diagnosis, treatment, or management of a disease or condition, as determined by the medical profession based on the best medical evidence currently available.”⁶⁷ This means practice guidelines are derived from evidence-based medicine. Various names are used to express the concept of practice guidelines: critical paths, practice parameters, clinical guidelines, clinical protocols or algorithms, care maps or target tracks, case management, and clinical pathways. The names differ, but all are meant to assist physicians and other licensed independent practitioners (LIPs) in clinical decision making. HSOs/HSs may define practice guidelines differently and with various degrees of precision. Implementing them is stimulated by a commitment to improve quality and lessen costs by reducing *unnecessary* variation in clinical decision making. This is not “cookbook medicine,” as opponents of practice guidelines sometimes allege, because deviations can and must be made *if* they are clinically justifiable. Justifying the deviation lies with the LIP.

Practice guidelines are not the same as clinical indicators, but they lead to measurable indicators. Practice guidelines describe what should be done; indicators measure what *was* done.

The American Academy of Pediatrics developed the first practice guidelines in 1938. It was not until the late 1970s that such efforts gained momentum, however. By 1990, 26 physician organizations had practice guidelines for their specialties.⁶⁸ By 1995, approximately 1,800 medical practice guidelines had been cataloged.⁶⁹ In 2007, the National Guideline Clearinghouse (NGC) had over 2,000 practice guidelines. In the late 1990s, 81% of hospitals were using practice guidelines; many others were planning to use them.⁷⁰ By 2012, the NGC included over 2,500 practice guidelines. In the 2000s, 87% of hospitals were using practice guidelines; many others were planning to use them.⁷¹ There is significant evidence,

however, of poor adherence to clinical guidelines even after they are adopted.⁷²

Clinical CQI initiatives such as practice guidelines can reduce costs while improving quality. Both dimensions are especially important in a provider-at-risk environment that includes capitated and per case revenues, as well as managed care cost limits. Practice guidelines are also an analytical tool to identify optimal timing for clinical interventions by diagnosis and to obtain more effective resource use and better outcomes.⁷³ By reducing variation around the mean, practice guidelines will result in more consistent clinical decision making. Better clinical decision making and less unnecessary variability in diagnosis and treatment will enhance quality initiatives regarding inputs consumed and outcomes attained.

The clinical practice guideline in Figure 8.9 suggests hospital-based ED treatment responses for mild exacerbation of asthma in patients older than 2 years of age. This guideline can assist LIP decision making at initial assessment and treatment and in continued assessment and treatment, as well as suggest alternatives ranging from discharge to treatment with a guideline for asthma of greater acuity. HSs that have multiple units providing services on the same continuum of care should monitor practice guidelines for “best practices” consistency.⁷⁴ Proof of the value of using practice guidelines is readily available. For example, practice guidelines for congestive heart failure developed by the U.S. Agency for Health Care Policy and Research resulted in fewer readmissions and decreased costs and lengths of stay by boosting the use of recommended post-hospital medications.⁷⁵ Practice guidelines for intraoperative monitoring (monitoring during surgery) developed by the American Society of Anesthesiologists are credited with virtually eliminating hypoxic (insufficient oxygen) injury lawsuits and significantly reducing medical malpractice insurance premiums.⁷⁶ Another important potential benefit of practice guidelines is major reductions in losses per malpractice claim in high-risk areas such as EDs, obstetrics, and ORs. One study reported a 96% reduction when practice guidelines were used in all three areas.⁷⁷

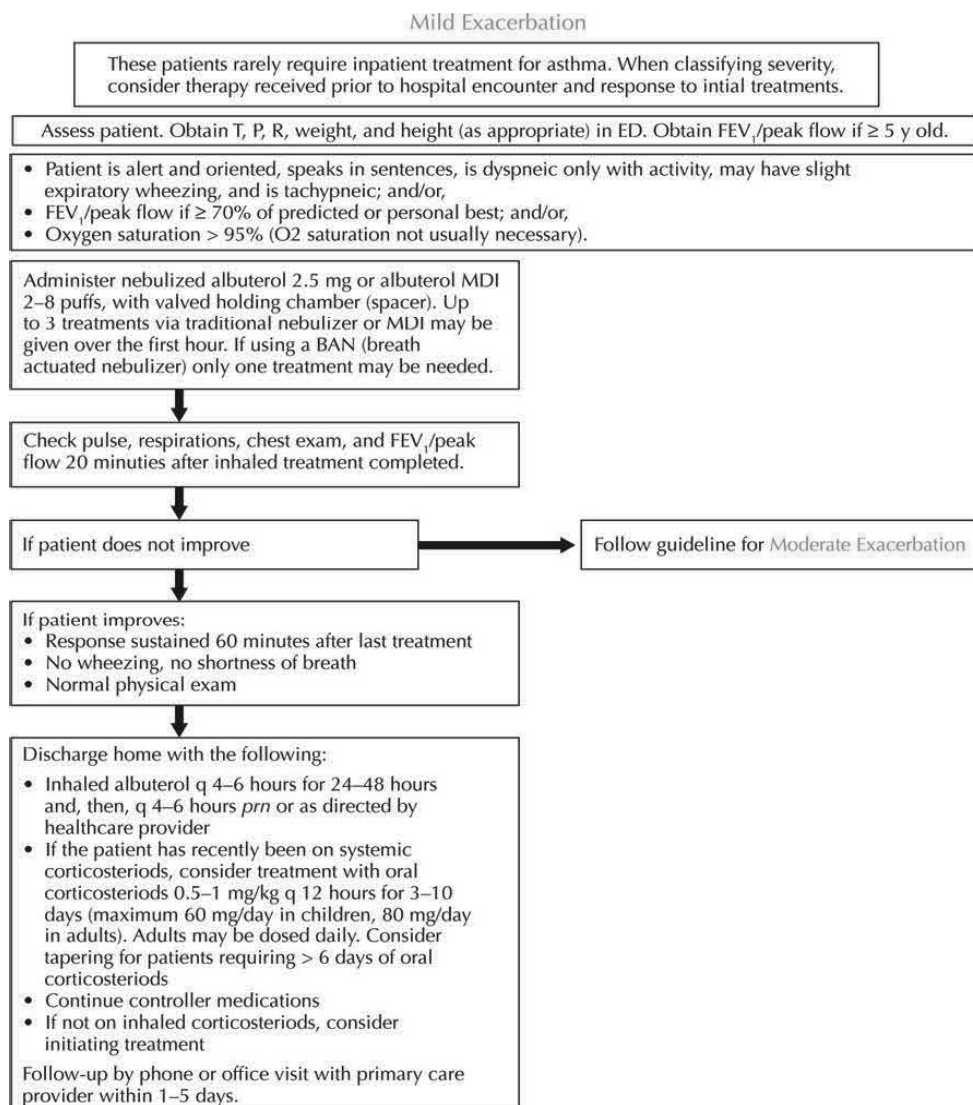


Figure 8.9. Asthma—ED Clinical Practice Guidelines, Mild Exacerbation. (From “Asthma—ED Clinical Practice Guidelines, Mild Exacerbation.” Retrieved August 6, 2013, from http://www.bbch.org/clinicians/Documents/Asthma_ED.9.08.pdf)

Beyond offering guidance to physicians and other LIPs, practice guidelines will help establish the legal standard of care. During litigation, physicians will be able to explain deviations from practice guidelines. Deviations are likely because practice guidelines are meant to assist providers, not replace individualized patient treatment plans.⁷⁸ It is possible, however, that practice guidelines will become presumptive of the standard of care and that this will shift the burden of proof to the LIP to show that the deviation(s) were justified.

Involving Physicians and Other LIPs⁷⁹

Physicians are most likely to support clinical CQI if they are involved and have ownership.⁸⁰ Physician champions are needed and physicians must be convinced that such initiatives will enhance quality without inappropriately jeopardizing professional autonomy or the specific needs of individual patients.⁸¹

Brent James, MD, identified three general categories of work in HSOs: 1) support services, including admission/discharge, billing, medical records, and scheduling; 2) medical infrastructure, including services directly involved in patient care, such as blood bank, laboratory, radiology, and other ancillary services; and 3) clinical products—“the diagnostic and treatment processes that hospitals provide to patients. For example, normal obstetrical delivery, medical treatment of acute myocardial infarction (heart attack), and surgical treatment of appendicitis are all clinical products.”⁸²

James identified ways to increase physician involvement in CQI initiatives, which apply by extension to reengineering and strategic quality planning.⁸³ First, the principles of CQI are not new to physicians. They are trained in scientific, numbers-oriented investigation and reasoning. Management must educate physicians about the philosophy of CQI and train them to use CQI tools. “Quality improvement theory should be presented as a direct extension of the principles that the medical profession has always espoused.”⁸⁴ Clinical quality initiatives seek improvement in medical outcomes; physicians will be comfortable with their data-driven scientific approaches and process orientation. These initiatives will result in better mobilization and utilization of resources to meet the needs of patients and physicians.⁸⁵

Second, physicians are likely to distrust clinical measurement efforts unilaterally initiated by management.⁸⁶ Management must reassure clinicians and dispel any perception that quality projects are “thinly disguised efforts to reduce healthcare resource utilization, seemingly without regard for the potential impact of such actions on patients’

health.”⁸⁷ If trust is established, physicians and managers can work toward common goals in delivery of high-quality and cost-effective services.⁸⁸

Third, quality teams already exist for clinical products, and they should be involved in other quality initiatives. Quality assurance (see Chapter 7) includes peer review “typically organized through subspecialty medical staff groups and reports through an independent medical staff organization.”⁸⁹ CQI techniques can be incorporated into this process. Because of physicians’ independent self-interest in husbanding their time, James recommends structuring clinical improvement projects within staff meetings and allocating salaried physicians’ use of work time.⁹⁰ Management “should consider physicians’ self-perceived role as customers or providers as they plan physician involvement on quality improvement teams.”⁹¹

Fourth, physicians should be encouraged to become involved in clinical product quality initiatives with other organization members and given administrative support in this effort.⁹² This may include assigning staff to collect and analyze data and to support clinical QITs, as well as investing in real-time clinical/management information systems.⁹³

Fifth, clinical CQI requires stable diagnostic and treatment processes. Physicians determine when these processes are used. This means management must ensure that physicians participate in Q/PI initiatives, that physicians understand they can be, and commonly are, both customers *and* suppliers in a process, and that managers are vitally interested in improving processes. As James observed, “It is more important how you [managers] implement than what you implement. The aim is to manage clinical processes, not to manage the physicians.”⁹⁴

Sixth, a 2-year study to identify and assess attributes of successful CQI initiatives in acute care hospitals concluded that physician involvement on clinical QITs early in the CQI program is essential for success.⁹⁵ Similarly, CQI will stimulate use of process measures by physicians.⁹⁶

Management must train a nucleus of physicians at the outset of a CQI initiative to stimulate a sense of physician ownership.⁹⁷

Seventh, the focus should be strategically important clinical issues and procedures—those that are high cost and high volume and for which data are readily available and improvement opportunities are present.⁹⁸ It is suggested that management identification of these conditions will be an important motivating factor and will reinforce the HSO's commitment to improving areas of concern to physicians.⁹⁹ Those involved as champions should be physician leaders who have administrative appointments, as well as attending physicians who are highly respected by their peers.¹⁰⁰

Eighth, management must be both persevering and opportunistic¹⁰¹ and be prepared to respond to the “neutral” majority of physicians who identify a clinical problem or concern.¹⁰² When they do, management should be ready to show how CQI relates to those physicians or their practices, orient them to CQI methods, and arrange for them to interact with physician champions who are committed to CQI.¹⁰³

Results of Involving Physicians

The rise of managed care has given impetus to improving the consistency of clinical practice and the development of evidence-based “best practice” guidelines. Data from implementing clinical guidelines and improving clinical performance in 25 integrated delivery systems and managed healthcare plans that provided healthcare to 40 million people are instructive. The most frequently cited method for improving clinical practice was feedback on clinical profiles of individual clinicians through audits of medical records and comparing their practice with peers or other benchmarks. The second most frequently cited method was clinician feedback from clinical department or administrative heads at regular department meetings. The third most frequent method was involvement of local physicians in developing practice guidelines; the same number of organizations also reported using or considering the use of financial incentives by “tying a small percentage of income to factors such as

patient satisfaction, rates of preventive services, and efforts to improve quality.”¹⁰⁴ In 2012, the effort to improve quality of care included tying patient satisfaction to the incomes of about three-quarters of employed physicians. Quality of practice is factored into the incomes of 72% of employed physicians. The rates affect only 3%–5% of total compensation, but it is predicted to rise to 7%–10% in the next several years.¹⁰⁵

Failed approaches to achieving improvement in clinical performance included sending information to physicians or increasing their knowledge alone, feedback with group data alone, and development of practice guidelines outside the managed care plan or practice unit without local physician involvement.¹⁰⁶ The success of clinical improvement was based on HSO/HS leadership’s promoting a CQI culture, respect for physicians, involvement of physicians and other workers, a customer perspective, organizational support, and “viewing physicians as important participants but not necessarily the focus of a system whose performance is to be improved.”¹⁰⁷ The latter point paraphrases Deming—blame problems with quality on the process, not the workers.

Regardless of their skills or professional eminence, physicians are a vital part of HSO processes and are a reification of Juran’s triple role of the worker. They are part of processes such as admitting, medication, therapeutic dietetics, laboratory, radiology, and discharge. They are “suppliers” by writing orders and providing information, they are “processors” by reviewing test results and judging the appropriateness and specifics of continued treatment, and they are “customers” by receiving information from various sources and using it in treatment decisions. Physicians are part of processes in a variety of ways, and their work, regardless of their eminence, will be enhanced or diminished by the quality of the processes that support them and of which they are a part. If they ever existed in history, the days of the Lone Ranger are gone.¹⁰⁸ Modern medicine cannot be practiced in isolation.

Patient and Worker Safety in Healthcare¹⁰⁹

Although patients and healthcare workers have a separate history of how safety was incorporated into their realms, the work being done with high-reliability organizations (organizations adept at achieving goals and avoiding errors¹¹⁰) and safety cultures in healthcare has introduced a new paradigm of safety in healthcare. This paradigm focuses on dissolving the distinct silos of patient and worker safety and captures the synergy of the work for both groups on the many issues they have in common.¹¹¹

The essence of the Hippocratic oath is embodied in the phrase “First, do no harm,” and patient safety has been a core value of medicine since its beginning. However, it was not until the 1999 report from the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System*, that the harm being done was described and quantified.¹¹² The view that the human beings delivering care were fallible and sometimes made fatal mistakes had been accepted for generations. This attitude was challenged by comparing service organizations such as airlines and credit card issuers that also function in high-risk environments, but have a process reliability of over 99%. HSOs began to consider utilizing the tools and processes that produced that level of quality. The IOM report stated the six aims of healthcare: effective, safe, patient centered, timely, efficient, and equitable.¹¹³ Most importantly, the IOM stated that errors occurred because of faulty systems or processes, not individuals.

The IOM report spawned a wave of new organizations that focus on patient safety. The federal Agency for Healthcare Research and Quality (AHRQ), established in 2000 by the U.S. Congress, became the largest funding source for patient safety research.¹¹⁴ In addition to the federal government, the private sector became involved. The Leapfrog Group, a conglomerate of *Fortune 500* companies, was launched in November 2000. Its goal is to provide quality healthcare to employees of member

companies by rewarding hospitals that significantly improve quality and safety.

Additionally, once the federal government and the insurance industry announced that there would be no payment (or a decreased reimbursement) for inferior patient outcomes, the health-care industry began to view patient safety differently. The National Quality Forum defined a never event in 2002 as a serious reportable event, such as surgery on the wrong body part. The Center for Medicare and Medicaid Services (CMS) went further and defined the never event as a nonreimbursible, serious hospital-acquired condition (see Table 8.2). Surgery on the wrong body part is now an event for which CMS will not pay. It is considered a “universal protocol” that the surgeon and surgical team will pause and jointly confirm that preprocedure verification, site marking, and the time out have occurred and are correct before surgery begins.

Table 8.2. Centers for Medicare and Medicaid Services “never events” (27 established in 2002; revised through 2011)

Issue	Examples of
Surgical events	Surgery performed on the wrong body part, Surgery performed on the wrong patient, Wrong surgical procedure performed on a patient, Unintended retention of a foreign object in a patient after surgery or other procedure, Intraoperative or immediately postoperative death in an American Society of Anesthesiologists Class I patient, Artificial insemination with the wrong sperm or donor egg
Product/device related events	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility, Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended, Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility
Patient protection	Infant discharged to the wrong person, Patient death or serious disability associated with patient elopement (disappearance), Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility
Care management	Patient death or serious disability associated with a medication error (eg, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration), Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products, Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility, Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates, Stage 3 or 4 pressure ulcers acquired after admission to a health care facility, Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility, Patient death or serious disability due to spinal manipulative therapy
Environmental	Patient death or serious disability associated with an electric shock or electrical cardioversion while being cared for in a health care facility, Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances, Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility, Patient death or serious disability associated with a fall while being cared for in a health care facility, Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
Criminal	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider, Abduction of a patient of any age, Sexual assault on a patient within or on the grounds of the health care facility, Death or significant injury of a patient or staff member resulting from a physical assault (ie, battery) that occurs within or on the grounds of the health care facility

From Agency for Healthcare Research and Quality, "Patient Safety Primers: Never Events." Retrieved August 8, 2013, from <http://psnet.ahrq.gov/primer.aspx?primerID=3>.

Table 8.3. National Patient Safety Goals (2013)

Identify patients correctly	Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment. Make sure that the correct patient gets the correct blood when they get a blood transfusion.
Improve staff communication	Get important test results to the right staff person on time.
Use medicines safely	Before a procedure, label medicines that are not labeled. For example, medicines in syringes, cups and basins. Do this in the area where medicines and supplies are set up. Take extra care with patients who take medicines to thin their blood. Record and pass along correct information about a patient's medicines. Find out what medicines the patient is taking. Compare those medicines to new medicines given to the patient. Make sure the patient knows which medicines to take when they are at home. Tell the patient it is important to bring their up-to-date list of medicines every time they visit a doctor.
Prevent infection	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning. Use the goals to improve hand cleaning. Use proven guidelines to prevent infections that are difficult to treat. Use proven guidelines to prevent infection of the blood from central lines. Use proven guidelines to prevent infection after surgery. Use proven guidelines to prevent infections of the urinary tract that are caused by catheters.
Identify patient safety risks	Find out which patients are most likely to try to commit suicide.
Prevent mistakes in surgery	Make sure that the correct surgery is done on the correct patient and at the correct place on the patient's body. Mark the correct place on the patient's body where the surgery is to be done. Pause before the surgery to make sure that a mistake is not being made.

From The Joint Commission, "2013 Hospital National Patient Safety Goals." Retrieved August 8, 2013, from http://www.jointcommission.org/assets/1/6/2013_HAP_NPSG_final_10-23.pdf.

The Joint Commission, which is discussed in Chapter 2, developed the National Patient Safety Goals (NPSGs) in 2003 (Table 8.3).¹¹⁵ The NPSGs have been supplemented since their release and now cover patient identification, effectiveness of communication, improving the safety of medication use, as well as the prevention of healthcare-associated infections, among others. The Joint Commission uses the term *sentinel event*, which is "an event that is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."¹¹⁶ These events are called sentinel because they signal the need for immediate

investigation and response, and they could be evidence of underlying process problems.

The Joint Commission also develops and releases “sentinel event alerts” (SEAs) based on data reported from organizations that have experienced sentinel events related to patient and worker safety. The SEAs summarize up-to-date knowledge on the topic and make recommendations on reducing the risk of that type of event occurring.

The concern for the safety of healthcare workers is more recent than that of patient safety. Florence Nightingale worked to improve the conditions of hospitals, but it wasn’t until the growth of organized labor in the early 20th century that worker rights, in general, were addressed.¹¹⁷ In 1958, the American Medical Association (AMA) and the American Hospital Association (AHA) issued a joint statement supporting worker health programs in hospitals. In 1971 the Occupational and Safety Health Administration (OSHA) was established to protect the safety and health of all American workers. OSHA includes the “general duty clause” that requires employers to provide a safe working environment. The right to know the hazards in the workplace was covered in the *hazard communications* standard in 1983 by requiring employers to provide chemicals that have labels, material safety data sheets (MSDSs), and worker training.¹¹⁸ This standard has recently been updated to be in accordance with the United Nations’ classification and labeling system of chemicals (Globally Harmonized System of Classification and Labeling of Chemicals). The changes essentially give workers the right “to understand” the information on chemicals that the employer must provide. An internationally understood series of pictograms and symbols will soon be found on all chemicals.¹¹⁹

Since OSHA can survey only a small percentage of the more than 8 million worksites in the United States, it has a hierarchy of priorities that is followed during inspections—imminent danger, fatality/catastrophe, complaints/referrals, programmed inspections. There is a process by which organizations with over 10 employees must document and report injuries (OSHA 300 Log). The log provides information important to the prevention of injuries.

OSHA also instituted the hierarchy of controls required when addressing a safety issue. Logic would dictate that the most effective control is eliminating the hazard from the workplace. Next in effectiveness is substituting a less hazardous material or procedure. Engineering controls require a physical change to the workplace to make it safer. Administrative or work practice changes require the worker to follow a policy or procedure that will limit exposure to the hazard. Finally, and least effective, is the use of personal protective equipment (PPE), which requires the worker to wear gloves, gowns, masks, and other protection to prevent contact with the hazardous substance (Figure 8.10).

In addition to the 1977 National Institute for Occupational Safety and Health (NIOSH), which was established by the OSHA legislation, *Criteria for an Effective Occupational Health Program in Hospitals* and the 1982 Centers for Disease Control (CDC) *Guidelines for Infection Control in Hospital Personnel*, the most significant legislation was the 1991 *blood-borne pathogen standard*. These requirements, and the 2001 *safe sharps* legislation, required all HSOs to assess their practices and initiate the hierarchy of controls to mitigate and possibly eliminate blood-borne pathogen hazards. Sharps injuries have decreased significantly since the legislation.¹²⁰

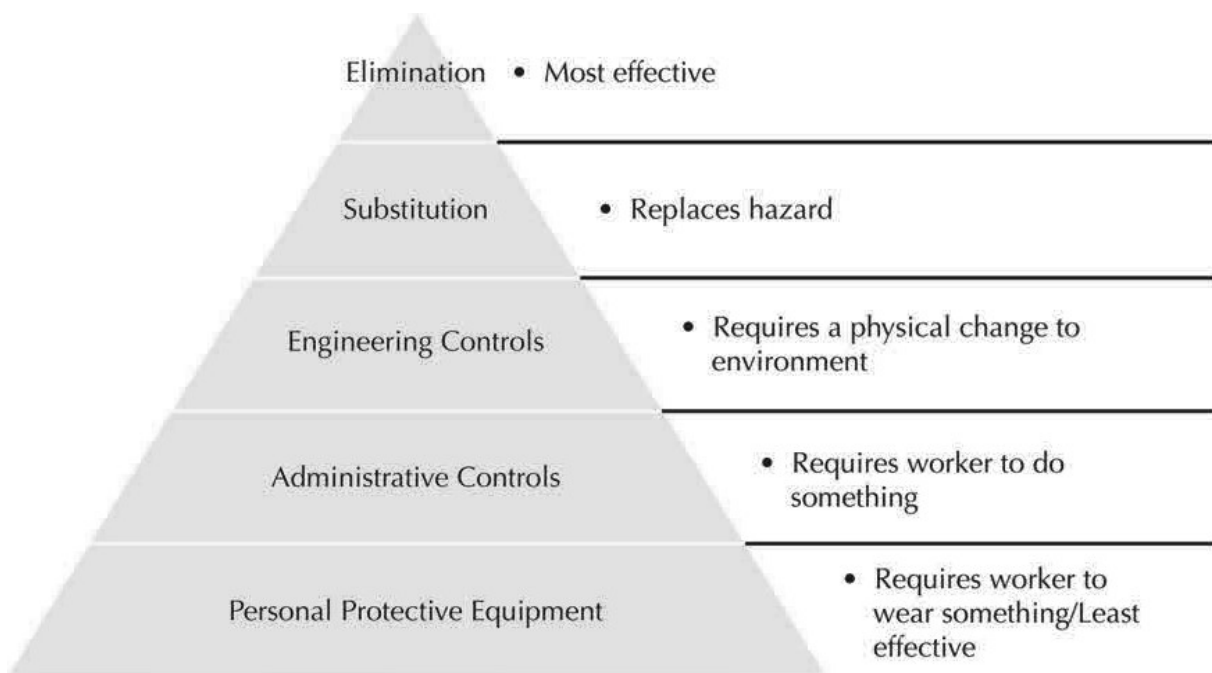


Figure 8.10. Hierarchy of Controls. (Adapted from the Occupational Safety and Health Administration, “Hierarchy of Controls.” Retrieved August 8, 2013, from https://www.osha.gov/dte/grant_materials/fy10/sh-20839-10/hierarchy_of_controls.pdf)

Regardless of these interventions, healthcare continues to be a high-hazard industry. The U.S. Department of Labor (DOL) reported that healthcare support workers have an incidence rate of nonfatal occupational injuries and illnesses requiring days away from work that are almost two and one-half times that of workers in other industries.¹²¹ It is clear that there are many risks in HSOs that must still be ameliorated.

Quality Improvement Structures/Processes Useful in Patient/Worker Safety

It is apparent from the data that both patient and worker safety issues need attention. To date, however, they have been addressed independently. Most HSOs have focused on worker safety in an environment of care (EOC) safety committee that focuses primarily on the physical plant. The patient safety committee is an extension of hospital risk management (discussed in Chapter 11), which involves members of the medical staff and focuses on actual events that harm patients. These two groups often competed for resources even though both had a mission of safety.

The study of high reliability organizations provided a new paradigm to improve safety for patients and workers. It is grounded in the fact that the tools necessary to create safety for both are the same. This raises the question as to how improvement efforts can be coordinated to benefit all those in the HSO.

In addition to the technical details of preventing specific injuries to patients and workers, administrators must determine how to organize internally to address safety issues. This applies to HSOs of all types: hospitals, nursing homes, free-standing surgical centers, dialysis centers, as well as outpatient clinics and home health services. The structure

chosen will include staff members who will address the issues and the culture of safety that must be nurtured.

A culture of safety is present when everyone focuses on possible failure of a system or process. In this culture staff must consider all possible underlying reasons why an event occurred, and there is rigorous attention to operational processes and staff resilience. This model was borrowed from other high-reliability organizations to reduce errors and improve reliability in healthcare. Executives must understand that building and maintaining a culture of safety requires resources. Failing to nurture a culture of safety increases economic and other costs of worker and patient injuries, as well as negative internal and external publicity for the HSO.

Human factors—the relationship between human behavior, system design, and safety,¹²² and systems engineering—has been used by the military and aviation for decades.¹²³ Such efforts allow organizations to assess the relationships of individuals and organizations to technology and the environment.¹²⁴ Work processes are reengineered to make it difficult to do the wrong thing and easier to do the right thing. In 2012, The Joint Commission found that human factors such as staffing levels, staffing skills mix, staff orientation, in-service education, competency assessment, staff supervision, medical resident supervision, medical staff credentialing/privileging, medical staff peer review, and factors such as rushing, fatigue, distraction, complacency, and bias were among the most common root causes of sentinel events.¹²⁵

Successful management strategies that have supported the culture of safety and the science of human factors and systems engineering include mapping work processes, training, recognizing and rewarding performance, using area-based safety coaches and champions, and surveying workers about the status of the safety culture. Among the most important strategies is increasing communication among all parties. In addition to giving staff an opportunity and structure to constantly update each other on what needs to be done and where the risks are (use of situation, background, assessment, recommendation [SBAR] reports, daily huddles, and staff meetings), staff must be empowered to communicate

clearly enough that everyone knows when a safety concern has been raised. Some institutions have been successful using the phrase *CUS words*, which means, “I am Concerned. I am Uncomfortable. This is a Safety issue.” Key to success is that everyone knows the implication of these phrases when they are being used. Another communication tactic uses methodologies that allow staff to close the communication loop and assure that the message was correct as received. Repeating back verbal orders and recording them, as well as asking patients to repeat back any teaching provided by the healthcare worker, are two examples of this strategy. Management must reinforce these communication methodologies as the norm and intervene when staff does not use them.

There are multiple methodologies that HSOs employ to help assess their safety landscape and then resolve the safety and culture issues that were uncovered. The following are some that were not mentioned previously:

Team STEPPS (Team *S*trategies to *E*nhance *P*erformance and *P*atient *S*afety)

Developed by the U.S. Department of Defense, Team STEPPS is an evidence-based teamwork system to improve communication and teamwork skills among healthcare professionals. The three phases of Team STEPPS are as follows:

- Assessing the need
- Planning, training, and implementation
- Sustainment¹²⁶

The methodology is based on lessons learned, existing master trainer or change agent experience, the literature of quality and patient safety, and culture change. A successful Team STEPPS initiative requires a thorough assessment of the organization and its processes and a carefully developed implementation and sustainment plan.

IHI Bundles

The Institute for Healthcare Improvement (IHI) has identified interventions and treatments that are already considered best practice and are generally recognized by clinicians. The parts of the bundle are expected to be monitored as all or none. For example, the “central line bundle” has five elements. When the audit of compliance is done the team must accomplish all five elements to get credit. The first two bundles were the “central line bundle” and the “ventilator bundle.”¹²⁷ Both of these were developed to prevent the hospital-acquired infections associated with these devices.

Johns Hopkins University CUSP (Comprehensive Unit Safety Program) Initiative

CUSP is a five-step process to change the culture of the unit by empowering frontline staff to assume responsibility for safety in their environment. The AHRQ has partnered to use this process throughout the country especially with the central line–associated bloodstream infection (CLABSI) prevention projects.

Step 1. Staff is educated on the science of safety.

Step 2. Staff completes an assessment of how they perceive the patient safety culture in their organization.

Step 3. A senior hospital executive partners with the unit to improve communications and educate leadership.

Step 4. Staff learns from unit defects.

Step 5. Staff uses tools, including checklists, to improve teamwork, communication, and other systems of work.¹²⁸

Overlapping Safety Issues for Patients and Workers

Safe Patient Handling

Staff injuries related to moving a patient are usually categorized as musculoskeletal disorders (MSDs), which include back injuries, as well as neck, shoulder, arm, wrist, and knee injuries. The rate of injuries incurred by nursing and patient care staff is among the highest of any occupation.

Safe patient handling has finally become an issue that is discussed, studied, and addressed by most HSOs. The healthcare workforce is aging and the American patient population is getting heavier. The injuries to workers from unassisted lifting are costly in time, money, and pain. Best practice dictates adopting a safe lifting program that requires all staff to use equipment to move or lift any patient. Some states have enacted laws that require organizations to adopt a safe lifting program. The success of the lifting program depends on how willing the staff is to embrace new processes and utilize new equipment. Patients can be injured from inappropriate or ineffective attempts to lift them. These injuries are often overlooked or mis-categorized as to the cause. A patient fall or a skin ulcer could have begun as a failed attempt to move a patient. Two groups analyze these injuries—the EOC safety committee and the patient safety committee. Most EOC requests for solutions to the patient movement issues are subordinated to projects the patient safety committee has in the queue.

Lift equipment can be freestanding and portable or built into ceilings. Storage of the equipment (near point of use) is key to staff using it for every lift. Hanging roll boards in hallways or in each patient room can keep the equipment “top of mind” for staff. With some training, patients can use many types of lift equipment themselves. This has the further advantage of giving patients a feeling of control over their movement. Of course, this also requires that the staff assess the risk to the patient when the patient takes the helm.

Historically, this topic was managed through the employee or occupational health department and reported to the EOC committee. The economic costs of lifting injuries are usually hidden, but calculating them for a specific employee or annualizing them HSO-wide will show administration that lifting injuries have a major financial impact.

Combining patient and worker lifting-related injuries assists in addressing all aspects of the problem. Initial assessment of the HSO's quantifiable injuries is required. This allows the work plan to identify what actions are most problematic—lateral transfers, wheelchair transfers to automobiles, or patient transfers from stretcher to bed. These data will show which equipment and training are needed. A further advantage is that the care team is forced to discuss its assessment of patients' mobility needs and how that information is communicated among themselves and with the patient and family.

Slips, Trips, and Falls

Injuries from slips, trips, and falls in hospitals are the second most common reason for staff to lose days from work. Data collected by the U.S. DOL show that falls from the same level are more common than falls from a higher elevation. The causes of staff falls are usually wet floors, tripping over cords or objects on the floor, and often for reasons the injured staff member cannot explain.

Solutions to this group of hazards include floor mats at building entrances, umbrella bags to prevent water on floors near entrances, spill clean-up centers in hallways adjacent to high-risk spill areas (cafeterias, etc.), wet floor sign usage by environmental service staff, and cord control equipment in offices and patient care areas. Requiring or providing nonskid shoes for staff with the highest rates of falls can decrease falls substantially.

Slips, trips, and falls that occur outside the HSO necessitate assessing the external conditions that contribute to them. Handrails along changes in elevation, easy access to snow-melting materials, monitoring the condition of sidewalks and curbs, and adequate lighting in walkways and parking

areas are all helpful. HSOs in northern climates have been successful in supplying ice cleats for staff shoes.

Overall, falls are a leading cause of death for people ages 65 or older. In hospitals, 3%–20% of inpatients fall at least once during their stay. Patient falls must be viewed differently than those of staff. Patients are affected by medications and must react to new physical surroundings and emotional states. Falls by patients in HSOs are considered a CMS never event. Injuries from patient falls in the HSO are not reimbursed by CMS. Various interventions have been tried with mixed results. Universal fall precautions may mean an admission assessment of all patients and their risk of falling, signage or bright bracelets that designate patients at risk of falling, low-rise beds, bed or chair alarms, and nonskid socks.¹²⁹

Data for employee injuries are often reported at the environmental safety committee, whereas falls by patients or volunteers are reported at the patient safety committee. Administration is paying closer attention to falls of healthcare workers, the majority of whom are women of advancing age.¹³⁰

The costs of these falls are significant due to an employee's lost work time. Hazard assessments by the HSO are necessary to prioritize the interventions that could be used.

Using quality improvement methodologies to bring questions of patient and staff safety to caregivers can develop creative and realistic solutions to diminish injuries. Incident reports by staff on injuries that occurred or almost occurred (near misses) also help direct priorities. Root cause analysis should be done on each fall to pinpoint the cause. Sharing this information with committees and staff will make the injury tangible and highlight the importance of prevention.

Sharps Injury Prevention

Blood-borne pathogen exposures of healthcare workers through needlesticks and other sharp objects such as scalpels and broken glass (from test tubes, etc.) are a significant problem that results in almost 400,000 sharps injuries per year.¹³¹ Infection with hepatitis B, hepatitis C,

and HIV can result from these injuries. Legislation addressed this problem in 1990 with the blood-borne pathogen standard (universal precautions) and the 2000 “safe sharps” legislation. These enactments have not eliminated sharps injuries to workers, however.

The cost of one blood-borne pathogen exposure may be as high as \$5,000, but will vary with the situation.¹³² The costs do not include the stress on exposed workers who must wait through an incubation period to see if they have contracted a disease from the needlestick or sharps exposure.

There are multiple components to a sharps safety program, not the least of which is that healthcare workers have to consider it important enough to participate. There are many ways to circumvent the safety systems that can end in an exposure. The federal mandate to offer the hepatitis B vaccine to at-risk staff, the long incubation period of hepatitis C, and the low numbers of healthcare workers with occupationally acquired HIV have made some staff think that they have little cause for concern.

According to the CDC, nurses are the group most likely to have a blood-borne pathogen exposure. Other groups of healthcare workers that are frequently exposed include staff in the ORs and laboratory.

The CDC’s database on sharps injuries is called the National Surveillance System for Healthcare Workers (NaSH). It shows that most injuries occur on inpatient units (40%) or in the OR (29%) and generally involve hollow-bore needles (56%).¹³³ More importantly, each HSO must review its specific injuries and identify the operational issues that must be addressed.

The hierarchy of controls for blood-borne pathogen injuries starts with eliminating as many sharps as possible from day-to-day operations. Using intravenous (IV) systems that do not contain needles or replacing glass with plastic, as appropriate, are examples of this first level of control. Engineering controls include a sharps disposal system that helps prevent injuries when workers are disposing of needles and syringes, as well as injection equipment with immediate retraction to prevent workers from sticking themselves after the injection. Work practice controls depend on

cooperation of staff and include OR teams using no-touch passing or blunted sutures to prevent staff from sticking each other accidentally.

Blood-borne pathogen exposures are uncommon among patients, but they do occur. For example, a patient may be exposed to the body fluids of a staff member or someone else. Each institution must have a policy that addresses how this situation will be handled in compliance with state and federal laws. In summary, a culture of safety that reports and analyzes all injuries and near misses and involves the staff who are injured is the way to diminish these potentially serious events.

Healthcare-Associated Infections

Healthcare-associated infections (HAIs) can be categorized in several ways. Categories can include infections that patients bring into the organization and spread to healthcare workers and others, infections associated with devices, procedures, or environments to which patients are exposed during their treatment in the HSO, or infections transmitted to patients from ill or infected healthcare workers.

Transmission of disease in the healthcare setting is not intended by anyone. But the data show that disease continues to be spread in HSOs due to lack of compliance with best practices. For example, for many years the compliance rate of healthcare workers taking the seasonal flu vaccine was only about 40%. Since the flu virus can be spread while a person is asymptomatic, many HSOs began to mandate flu vaccination. Some healthcare workers contend that they have medical and/or religious reasons for not being vaccinated. Mandating vaccination requires an understanding of state laws and labor union contracts, developing a fair process to judge requests for exemptions, and determining what to do with staff members who were exempted from the flu vaccination, but will work during flu season.

The wide range of settings in healthcare means that healthcare workers fill many different jobs, such as registered nurse, physical therapist, physician, and pharmacist. Each type of healthcare provider has a different risk of exposure to healthcare-associated infection. Management in each area and for each work group must assess the risk of potential harms that

could be encountered and institute the appropriate controls (administrative, engineering, work practice, and personal protective equipment) to safeguard workers and patients.

Many interventions have been implemented to address these infectious risks and can be categorized by the hierarchy of controls. Administrative controls include policies and procedures based on national and best practice guidelines. These can include screening patients for multiresistant organisms on admission to the hospital, requiring mandatory vaccination against seasonal flu for the staff, or annual screening of staff for tuberculosis. Engineering controls cover a large number of interventions such as providing negative-pressure rooms for patients with diseases that require airborne isolation (tuberculosis, measles, varicella [chicken pox]), as well as utilizing safe sharps and needle boxes to protect workers from contaminated equipment. Personal protective equipment (PPEs), including gloves, gowns, masks, and eye protection, are basic accoutrements in the healthcare field, but they have very specific, required uses. According to the 1991 OSHA blood-borne pathogen standard and the concept of universal precautions (now known as standard precautions), gloves must be worn whenever healthcare workers may be in contact with body fluids or other potentially infectious materials. Finally, work practices include one of the most basic underpinnings of infection prevention and control—hand hygiene. Cleaning one's hands is expected before and after each interaction with a patient. Patients and visitors can also help prevent spread of organisms by sanitizing hands before touching all surfaces, animate and inanimate.

Diseases that healthcare workers are potentially exposed to during care of patients can be divided into three basic modes of transmission—contact, droplet, and airborne. Contact transmission can be subdivided into direct contact and indirect contact. Direct contact includes situations in which disease can be spread through skin-to-skin contact with the patient. Indirect contact occurs if someone comes into contact with the contaminated environment or equipment used by the infected person. Infectious diseases that require contact isolation are multidrug-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* infection (CDI).

Droplet transmission occurs when the air someone exhales contains organisms that can travel 3–6 feet and potentially reach another person's eyes or respiratory tract causing diseases such as pertussis (whooping cough) or *Neisseria meningitidis* meningitis (as in bacterial meningitis).

Airborne transmission occurs when the air a person exhales contains organisms that can travel long distances for a considerable period of time. Such diseases include tuberculosis (TB), varicella (chicken pox), and rubeola (measles), when the causative organisms can float for hours in the right environment. There are vaccines for some, but few vaccines are 100% effective. Exposure to some of these diseases requires either antibiotic prophylaxis or monitoring over time.

The highest risk for patients is the infections related to devices used in their care or procedures performed on them. Device-related infections include CLABSI, catheter-associated urinary tract infections (CAUTIs), and ventilator-associated pneumonias (VAPs). Much work has been done to identify best practices and develop them into “bundles” of preventive measures that healthcare workers can use. Device-related infection rate data are collected by many organizations. These outcome data are publically reported, and patients can use them to help them choose HSOs as sources for healthcare. Surgical procedures have specific rates of infection that can be obtained from the CDC National Healthcare Safety Network (NHSN) database. Many states require hospitals to participate in NHSN. CMS requires collection of data on specific surgical procedures to receive payment for services provided under Medicare.

Healthcare is provided in a variety of settings, all of which have different risks of infection. Recently, guidelines were developed for outpatient settings as they have been found to have many outbreaks of communicable diseases because of failure to standardize the environment of care and work practices.¹³⁴ Substandard injection practices are especially problematic. This is true despite the fact that some providers are highly regulated to make their services safer. Dialysis centers are in this category. Surgicenters have received more attention to assure that their standards are the same as hospital standards. Long-term care (LTC) facilities have long been known as potentially high risk for residents. Multiple factors converge to cause this problem. Typically, residents are

elderly and thus more susceptible to communicable diseases such as influenza. Many residents are cognitively impaired and unable to follow basic hygiene practices. The residents meet in public places at the LTC, such as dining rooms and day rooms, which increases exposure to any communicable diseases carried by other residents. Caregivers may not have the level of training to prevent healthcare-associated infections. These factors coalesce when dealing with urinary tract infections, skin and soft tissue infections, diarrhea—possibly from *C. difficile*—multidrug-resistant organisms, and influenza.

Exposure to Hazardous Materials

Many of the hazards for both workers and patients in the environment of care or healthcare workplace have been noted. Even day-to-day activities in the healthcare setting are fraught with risks. These risks include something as simple as the chemicals used to clean the environment, drugs used for treatment, and various chemicals needed to diagnose a condition. Of course, the patient and the healthcare worker differ in the risk–benefit ratio that exists when considering diagnosis and treatment. For patients, the benefits usually outweigh the risks. Healthcare workers must deal with potential unintentional exposure without personal benefit, except for the employment relationship.

There are many substances to consider—chemicals, pharmaceuticals, and radioactive materials are the primary categories. Methods of exposure include inhaling a substance, skin contact, ingestion, and injection.

The public expects HSOs will be clean. Combine that expectation with the fact that there are increasing numbers of resistant organisms within all HSOs. This necessitates that hospital-grade disinfectants are necessarily strong and can irritate the body in various ways. For example, studies show an association between the use of various cleaning products and asthma in female hospital workers.¹³⁵ This creates tension between those attempting to clean the environment and HSO staff and patients in the environment. Oftentimes, decisions about the cleaning agents to be used, as well as environmental textiles (carpeting, upholstery fabric, curtains),

are based on negative comments administration has received from those in the environment.

In addition to cleaning the environment, the HSO must clean, disinfect, and sterilize equipment. Chemicals used for these procedures can be very toxic, and specific rules and processes are used to minimize errors in their use. The high temperatures of equipment used for sterilization can injure workers.

Other areas in healthcare settings that use potentially harmful substances include pharmacies, dialysis units, laboratories, and morgues. Pharmacies have many hazardous drugs on their shelves. Laboratories and morgues use a wide variety of chemicals in routine work. Formalin and xylene are used to preserve and fix specimens. Dialysis units use large quantities of chemicals to assure that the water they use for patients is safe.

The NIOSH estimates that approximately 8 million healthcare workers in the United States are exposed to hazardous drugs at their worksites.¹³⁶ A recent study by Lawson et al. found that there was a twofold increase in the rate of spontaneous abortion for staff who handled chemotherapeutic agents for more than 1 hour per day during their first trimester of pregnancy.¹³⁷ The most recent recommendations from NIOSH describe a comprehensive safety program to protect healthcare workers, including medical surveillance. The program involves collecting information on employees' potential exposures as well as periodic communication concerning reproductive and general health. A comprehensive prevention program also includes engineering controls, policies and procedures that delineate high-quality work practices, personal protective equipment, and educating and training staff.¹³⁸

Exposure to radiation is another potential environmental risk in HSOs where many forms of radiation are used for diagnosis and treatment. Again, a patient's exposure to radiation has a different risk–benefit ratio than a healthcare worker's exposure. However, both groups have specific risks and ways to reduce those risks.

Since the mid-1980s, exposure to ionizing radiation in the United States has doubled.¹³⁹ New technology may require that staff is

physically closer to patients than previously. Such changes require a review of the impact that radiation exposure has on healthcare workers as well as patients. HSOs must be able to communicate to staff the cumulative amount of radiation the patient has received when tests are done in different settings over a short period of time. The risks of repetitive radiological testing need to be explained to patients who request this technology. The Joint Commission Sentinel Event Alert on the risks of radiation exposure in diagnostic imaging describes the issues and risks, as well as actions to mitigate the risks.¹⁴⁰

Violence in the Workplace

Media reports about workplace violence are common. NIOSH defines violence in the workplace as “violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty.” This definition can cover the gamut from bullying to terrorism. Although HSOs are thought to be safer in terms of workplace violence than the rest of the work world, the U.S. Merit Systems Protection Board reported in *Employee Perceptions of Federal Workplace Violence* that employees in medical, hospital, and police/security occupations experience higher rates of workplace violence than other occupations.¹⁴¹ Patients are the most common source of violence, but a third of the time coworkers are responsible.¹⁴² Of the fatal occupational injuries reported to the U.S. Bureau of Labor Statistics in 2011, 30% were associated with violence against healthcare and education workers. This compares with 17% for all types of workers.¹⁴³

Healthcare and social service workers have an increased risk of work-related assaults linked to several factors:

- The prevalence of handguns and other weapons among patients, their families, or friends
- The increasing use of hospitals by police and the criminal justice system for criminal holds and the care of acutely disturbed, violent individuals
- The increasing number of acute and chronic mentally ill patients being released from hospitals without follow-up care (these patients have the

right to refuse medicine and can no longer be hospitalized involuntarily unless they pose an immediate threat to themselves or others)

- The availability of drugs or money at hospitals, clinics, and pharmacies, making them likely robbery targets
- Factors such as the unrestricted movement of the public in clinics and hospitals and long waits in emergency or clinic areas that lead to client frustration over an inability to obtain needed services promptly
- The increasing presence of gang members, drug or alcohol abusers, trauma patients, or distraught family members
- Low staffing levels during times of increased activity such as mealtimes, visiting times, and when staff is transporting patients
- Isolated work with clients during examinations or treatment
- Solo work, often in remote locations with no backup or way to get assistance, such as communication devices or alarm systems (this is particularly true in high-crime settings)
- Lack of staff training in recognizing and managing escalating hostile and assaultive behavior
- Poorly lit parking areas¹⁴⁴

As with any risk an organization faces, prevention and mitigation of workplace violence are dependent on how thoroughly an effective safety and health program is employed. Management commitment, employee involvement, engineering and administrative controls, workplace practices, employee training, record keeping, and analysis are all required.

Stress in the Healthcare Setting

It is important to understand that workplace stress in healthcare has an effect well beyond the staff member. Issues of staffing (or too few staff), rotating schedules, no scheduled breaks, excessive assignments, and overtime have an obvious effect on workers. But, the fact that all these elements have been associated with increased worker errors affects patients. Research links more registered nurse staffing with decreased patient mortality.¹⁴⁵ Long before HSOs addressed worker schedules, the aviation industry sought to increase safety by adopting rules that protected the rest periods of pilots. However, this is not a simple issue with one

solution. Often what has been proven to be safer (e.g., shorter shifts) may not be what the work force wants. Longer shifts that permit fewer working days with more days off may appeal to parents. Rotating shifts may appeal to students or those with multiple positions. The prohibition against napping on the job is being reviewed in light of research showing that short, planned rest periods are beneficial to fatigue management.

Another aspect of workplace stress is the organizational response to errors. Does the healthcare worker feel supported and not blamed when a system or process fails? Is there a “just-culture” present that distinguishes between human error, at-risk behavior, and reckless behavior?¹⁴⁶ Are workers able to report errors or near misses without fear of retaliation? If the healthcare worker does become the “second victim” or “second patient” after a poor patient outcome, is there a system that allows the worker to recover, thrive, and move on?¹⁴⁷ Such questions reflect Deming’s concept of the workplace, as discussed in Chapter 7.

How is the patient informed and supported when an error occurs? In the past, many HSOs allowed the physician to determine if the patient needed to know about the event at all—no matter what the cause or outcome. Currently, disclosure to the patient with an apology by administration and involved caregivers is becoming common. Doing both is key in the follow-up to an event. How an HSO supports a patient who may feel anger, sorrow, or fear varies, but must be addressed.

Other Issues

Although it is very easy to separate patients from healthcare workers when addressing safety issues, both groups have much in common when solutions are sought. No one thinks that a healthcare worker or patient starts the day wanting to put anyone in the healthcare setting at risk. It is the process or the system involved that must be evaluated for potential failure points. The system must be strengthened to make it easy to do the right thing for anyone involved. If all of this is done with input from the frontline worker, or even patients themselves, the healthcare setting will become safer for all.

Discussion Questions

1. What is the purpose of QITs? Distinguish between those that are intradepartmental and those that are cross functional.
2. Define common cause variation. Distinguish it from special cause variation. Why must managers be able to distinguish the two types of variation?
3. What is the purpose of ISO standards? Why should HSOs consider their use? Identify other ways to use ISO registration in addition to the entire organization.
4. Define benchmarking. What are its benefits? Identify some risks of benchmarking.
5. What is the relationship between quality improvement and productivity improvement?
6. Identify and discuss briefly three quality improvement tools.
7. How does the PDSA cycle relate to the problem-solving model in Figure 6.4?
8. Define *reengineering*. What are its attributes? What is common to both CQI and reengineering?
9. What are the four steps in strategic quality planning? How is it related to strategic planning as described in Chapter 9?
10. Why must physicians and other LIPs be involved in CQI? What are the benefits and difficulties? What steps should be used to increase their involvement?
11. Patient and worker safety have different histories. What do they have in common?

12. Use the concept of the hierarchy of controls when considering the patient/worker safety issue of slips, trips, and falls. Give an example of each tier of the controls.
13. What is the most important category of management strategies that supports the culture of safety in an HSO?
14. If an HSO continues to struggle with a safety issue, what is the best course for senior leadership?

Case Study 1

The Carbondale Clinic¹⁴⁸

The Carbondale Clinic, located in Carbondale, Illinois, is a large group practice of about 30 physicians. The clinic employs about 100 people and serves a regional population of about 100,000. Specialties ranging from pediatrics to psychiatry are offered by the clinic, which also operates its own laboratory, basic imaging services, and outpatient surgical center.

For some years, the clinic has been receiving complaints from its patients that appointment times are not being met. For instance, a patient with an appointment for 2 p.m. might not get in to see the physician until 4 p.m. However, the clinic has felt that such delays are unavoidable due to the uncertainty involved in the time it takes to adequately examine each patient and the possibility of emergency cases that must be inserted into the schedule.

Several criteria are used for scheduling. For instance, many patients are scheduled for annual physical exams. These are usually scheduled at least several weeks in advance because they require coordination of laboratory services and physicians' time. However, some physicians will begin examining a patient and decide that the patient needs a physical immediately. The physicians feel this does not really cause problems

because they can send the patient down to the laboratory while they continue to see other patients.

Some patients also phone the clinic for an appointment when they have nonemergency, routine problems such as a mild fever or sore throat. Such patients are scheduled into available time slots as soon as possible—usually a day or two from the time they call. The objective here is to fit such patients in as quickly as possible without overloading the schedule with more patients than can reasonably be examined in a time period. Usually the plan is to schedule four patients per hour.

However, each day, various emergencies occur. These can range from a splinter in the eye to a heart attack, and these cases cannot wait. For an emergency that is not life threatening, the approach is to try to squeeze the person into a time slot that is not too heavily scheduled. However, a case of life or death—such as a heart attack—means that the schedule must be disrupted and the patient treated immediately.

Currently, all scheduling of appointments is done centrally. However, this frequently causes problems because the people making appointments often do not know how long it should take to examine a patient with a particular complaint. On the other hand, the nurses in each department are usually too busy to do the scheduling themselves. Generally, if there is a doubt about whether a patient can be fitted into a time slot, the preference is to go ahead and schedule the patient. This is because the physicians prefer not to have any empty times in their schedules. At times, if it looks as if there might be an available opening, the clinic even calls patients who were originally scheduled for a later time and asks them to come in early.

Questions

1. “For some years, the clinic has received complaints from its patients that appointment times are not being met.” Why has no action been taken to correct the situation?
2. You are a member of a QIT that was asked to evaluate the appointment/scheduling process. Are there some

“assumptions” in the narrative that you question? If data were sufficient for a Pareto diagram of problems with the appointment/scheduling process, what do you think the items would be? Please list them.

3. Draw a cause-and-effect (Ishikawa) diagram of causes for patient complaints.
4. What recommendations would you make to decrease patient waiting time?

Case Study 2

Noninvasive Cardiovascular Laboratory

The assistant vice president for operations at Barbarossa Hospital has identified a problem concerning the noninvasive cardiovascular laboratory (NCVL). First, patients have complained to their physicians about long waits and interruptions during tests. Second, the number of tests ordered increased when more LIPs joined the professional staff organization early this year, and the only NCVL technician, Loren Findley, has told his supervisor that he is overworked. Findley has threatened to resign if he does not get a full-time assistant. The hospital has no other employees who can perform the tests. The tests are not difficult; Findley could train someone to perform them in about 2 months.

Findley schedules all inpatient and outpatient tests ordered by house staff (residents) and attending physicians. Phone calls to schedule tests are received frequently during the day. On average, three of four of the tests Findley administers are interrupted by phone calls. It takes 10 minutes to return to the point in the test before the interruption (2 minutes talking on the phone and 8 minutes to restart the test).

Observing the technician and talking with him and his supervisor provided the following information. The NCVL is located on the third

floor of the hospital. It is adjacent to the stress test laboratory, which has twice the space of the noninvasive laboratory but uses only half of it. The stress test technician is productive only 60% of the time. Findley's workspace is cramped and crowded with two patient beds, a very large desk, and supplies in boxes that are stacked floor to ceiling along two walls. The room's configuration does not permit easy movement, and some equipment must be placed in the hall. Consequently, Findley spends an average of 10 minutes moving equipment into or out of the room when setting up for a test that is different from the preceding one.

Findley is qualified to administer three tests:

1. Echocardiography (ECHO): A graphic recording generated by ultrasound that is used to study the structures and motions of the heart
2. Ocular plethysmography (OPG): A test to measure changes in size and volume of the eye
3. Pulse volume recording (PVR) plethysmography: A test to measure changes in volume of a cross-section of a blood vessel over several heartbeats

Extensive observation showed the following standard times for each test (assume there is no difference for inpatients and outpatients):

Test	Standard time
ECHO	1 hour
OPG	½ hour
PVR	½ hour

Hospital records were used to compare the number of tests performed last year with the number performed in the first 3 months of the year:

Test	No. performed		
	Previous year	This year	
		First 3 months	Annualized
ECHO	800	300	1,200
OPG	200	75	300
PVR	200	75	300

The typical pattern for scheduled tests on any given day is ECHO, ECHO, OPG, ECHO, ECHO, PVR, ECHO, ECHO, OPG, and so forth.

Questions

1. Is Findley overworked? Why or why not? Should another technician be hired?
2. Assume that there is no budget to add a new technician. How should the current NCVL process be changed to improve quality and productivity?
3. Draw a cause-and-effect (fishbone) diagram of the reasons Findley's work is inefficient.
4. Draw a flow diagram showing the steps in the process(es) for Findley's work.

Case Study 3

Infections— *C. difficile* (CDI)¹⁴⁹

Your infection prevention department has reported that there is a cluster of cases of hospital-acquired CDI on the medical unit. The infection preventionists have put all the cases on contact isolation and are meeting with the manager of the unit as well as environmental services to develop a plan.

Questions

1. What are the next steps?
2. What other staff should be involved?
3. When do you tell patients and families about the cluster of cases?
4. How do you educate staff, patients, and visitors regarding prevention measures?

Case Study 4

Infections—CLABSI

Your state quality improvement organization (QIO) has asked all hospitals to participate in an initiative to prevent central line–associated bloodstream infections (CLABSI). You have agreed to form a team and work on the CLABSI prevention bundle.

Questions

1. Which staff members should be on your unit-specific team?
2. What is the appropriate response if staff asks for a specific piece of equipment to assist in complying with the prevention bundle, and supply chain says that it is too expensive?
3. How do you educate all staff on the necessary components of the quality improvement process?
4. How do you keep this project “top of mind” for all staff on a daily basis?

Case Study 5

Infections—Flu Vaccination

Your hospital has provided free flu vaccinations to its staff for more than a decade. Despite the best efforts of employee health, staff compliance with flu vaccination cannot be raised above 65%. Besides giving away \$100 gift certificates during weekly raffles last year, employee health attempted to utilize “declination statements” to force staff to state their reasons for not being vaccinated. Senior management has decided to make vaccinations mandatory for all staff members.

Questions

1. How do you present senior management’s decision to the staff?
2. How do you handle the expected requests for an exemption (medical and religious)?
3. What should be done about staff members who receive an exemption but remain in the hospital during a virulent flu season?

Case Study 6

Sharps Injuries

While reviewing the quarterly sharps injury statistics, the employee health manager notices a significant increase in sharps injuries over the past 90 days. After review, it is found that the OR had the majority of injuries. In addition, the OR had 50% more sharps injuries than they had in any quarter for the past 3 years. One of the OR injuries occurred when a medical student stuck himself just before the needle he was holding stuck a patient. The employee health manager reported this incident to the patient safety committee.

Questions

1. Which persons should be included in the group that investigates the increase in sharps injuries in the OR?
2. What safety measures can be taken in the OR to protect staff and patients from sharps injuries?
3. How likely is it that the sharps injury data from employee health are accurate?
4. If an employee complains to the OSHA about the increase in sharps injuries, what document will the surveyor ask to see upon arriving at the hospital?

Case Study 7

Slips, Trips, and Falls

All employee health metrics have improved over the past 5 years except slips, trips, and falls of employees. There is a systemwide collaborative on patient falls, but there is little interest in employee falls. The only time employee health had a decrease in injuries from employee falls was 5 years ago when a small amount of money was budgeted to buy nonskid shoes for the patient support team, which included environmental services,

security, dietary, and transportation. The budget for shoes was exhausted after 6 months. Managers were told to put the nonskid shoe requirement into job descriptions and assure that employees were complying.

Questions

1. What is the next step needed to get this prevention project moving?
2. What information will help get the attention of manager and staff?
3. Identify some internal and external solutions to the risk of slips, trips, and falls.

Case Study 8

Safe Patient Handling and Patient Movement Injuries

For years, hospital employee health (EH) has collected statistics on employee injuries related to moving patients. These data have been reported to the environment of care safety committee, but the committee has shown little interest in the fact that the number of injuries has not decreased. The health system of which the hospital is part has offered safety rebates to EH that include money to be used to purchase lift equipment. Equipment has been procured (with staff input), put on the units, and staff members have been trained repeatedly in its use. Injuries have not decreased. Often, staff members interviewed after they are injured report that they feel there isn't time to use the equipment.

Questions

1. How can senior management be convinced that this is an important problem?
2. How can middle management be convinced that this is an important problem?
3. How can staff members be convinced that this is an important problem?

Case Study 9

Hazardous Materials

An employee in the laboratory has complained to employee health services (EH) that he is being exposed to high levels of formaldehyde, a dangerous chemical used to preserve tissue. He believes that he is showing symptoms of overexposure to the chemical. EH reviews his symptoms and determines that they are also descriptive of his chronic diabetes. The employee complains to his manager, again. His manager comes to you for advice.

Questions

1. When speaking to the manager, you ask to see the employee's file. What do you want to assess?
2. What else do you need to know to determine if there is a problem?
3. What resources are there to assist in determining if there is a problem?

Case Study 10

Violence in the Workplace

At the monthly environment of care safety meeting, the security office reports data on disruptive patients and visitors. The number of incidents has been increasing, especially in the ED. To date, however, senior management has not agreed to station a security guard in the emergency department 24/7.

Questions

1. How can the problem be quantified?
2. What can be done to address the problem of angry, emotional patients and visitors?
3. Should a guard be stationed in the ED? Should the guard be armed?

Notes

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149. Cases 3 through 10 were written by Mary Mohyla, RN, CIC, Director, Infection Control, Employee Health and Accreditation Services, Holy Cross Hospital, Silver Spring, Maryland.