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The Quality Imperative: Implementation

Learning Objectives

- Explain the role of process improvement in improving quality
- Apply the concepts of statistical process control
- Identify and explain the tools commonly used in process improvement
- Comprehend the importance of clinician involvement in process improvement
- Identify safety issues that affect patients and staff in HSOs
- Understand the regulatory requirements affecting patient and staff safety
- Explain how HSOs organize to prevent and resolve safety problems

Discussion Questions

1. *What is the purpose of QITs? Distinguish between those that are intradepartmental and those that are cross functional.*

Quality improvement teams (QITs) analyze processes and recommend ways in which they can be improved.

Intradepartmental QITs are those sited in a department or service line and are established by the manager of that unit. They analyze processes that are internal to the unit. Recommendations from the QIT can be considered by the manager and implemented—usually without the need for review by more senior management or the quality improvement council (QIC). Exceptions result from process improvements that are costly or involve a change in policy. Departments or service lines should have several QITs at work at any one time.

Cross-functional QITs are established to analyze and recommend improvement of processes that affect more than one department or service line—they cross functional lines of authority. These QITs usually require approval and sanction (establishment) by the QIC, or other review authority at a level above that activity. Cross-functional QITs are usually involved in improvement of more complex processes, whose effects are more significant in terms of budget, staff, and patient satisfaction.

2. *Define common cause variation. Distinguish it from special cause variation. Why must managers be able to distinguish the two types of variation?*

Common cause variation is variation in a process that is within the control limits. Control limits in HSOs are typically set at 3 standard deviations (SDs). Some processes are stable enough that 2 standard deviations can be used. A process that has only common cause variation is predictable (stable), and quality improvement can be undertaken. Unstable processes (those with special cause variation) are unpredictable (unstable) as to where the next data point will fall. Unstable processes must have the instability (special cause variation) eliminated before process improvement can occur.

Special cause variation is variation in a process that is beyond 3 SDs. Shewhart used the term *assignable*, by which he meant that it could be attributed to something that affected the process but that almost always came from outside the process. Deming used special cause to describe the same kind of data point. Sometimes the occurrence of special cause variation cannot be prevented. In that case, the process must be designed to accommodate it or minimize its effects. Examples are a weather event (hurricane) or an act of nature (earthquake).

Managers must be able to distinguish the two because effective decision making depends on the ability to do so. Mistaking one for the other means managers will respond incorrectly. Managers often think that common cause variation is special cause variation. This error means that they do the wrong thing—the actions for each are very different. Deming described treating a result as special cause variation when it is actually common cause variation as tampering. Tampering increases variation and further diminishes the quality of process outputs.

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.*

International Organization for Standardization (ISO) standards assist organizations (including HSOs) in meeting customers' needs and expectations. Registration by the ISO sets the organization apart from competitors and shows the public that the organization has a commitment to quality improvement.

HSOs should consider conforming to ISO standards and becoming registered because it will focus their attention on improving systems and processes to meet customers' needs and

expectations. Chapter 1 noted that Det Norske Veritas Healthcare, Inc. (DNVHC) has been recognized by the Centers for Medicare and Medicaid Services (CMS) as having “deeming status.” DNVHC uses a combination of the CMS conditions of participation (COPs) and ISO 9000-2000 quality standards to register HSOs.

ISO registration may be sought by individual HSO departments. For example, supply chain, food service, and biomedical engineering are hospital support activities that are well suited to ISO registration. The benefit to them and the HSO is that their focus on meeting customers’ needs and expectations will benefit all customers of the registered department.

4. Define benchmarking. What are its benefits? Identify some risks of benchmarking.

Benchmarking is the process of comparing one’s business processes and performance metrics with industry bests or best practices of other organizations. Commonly compared are quality, costs, and various time measures. The text identifies 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.”

Benefits of benchmarking include 1) identifying aspirational goals, 2) becoming aware of what is achievable in terms of a process and its output, and 3) gaining knowledge about the process(es) that produced the benchmark data.

Benchmarking has several risks: 1) staff members may become dispirited because the benchmark greatly exceeds the performance of their process, 2) staff members may think that achieving benchmark performance is easily accomplished and have false expectations about results, 3) efforts to achieve benchmark performance in one measure may consume resources and energy to the detriment of other quality improvement (QI) or benchmarking efforts.

5. What is the relationship between quality improvement and productivity improvement?

QI will result in productivity improvement. This is shown by the Deming Chain Reaction. Productivity improves because there is less rework and less waste, and there are fewer defective services. Health services delivery provides ready examples of how better quality will result in productivity improvement. A bloodstream infection acquired in the intensive care unit (ICU) results in longer stay (rework), higher costs (waste), and a dissatisfied patient (defective service). Students who have had service experiences—whether or not in healthcare—that were deficient can contribute their own stories. It is estimated that about 30% of the costs of healthcare results from poor quality. Anecdotal experience suggests that it is higher than that.

6. Identify and discuss briefly three quality improvement tools.

There are several examples of tools in the text: run chart; control chart; Plan, Do, Study, Act (PDSA) cycle; Pareto diagram; scatter plot/diagram; fishbone (cause-and-effect [Ishikawa]) diagram; bar chart; and pie diagram. The control chart is the most powerful tool and is the basis for statistical process control (SPC). SPC is the precursor to the PDSA cycle. Students may choose from them. It is useful to have the text available and refer to the QI tools to focus discussion and make specific comments.

7. How does the PDSA cycle relate to the problem-solving model in Figure 6.4?

The PDSA model can be applied to the problem-solving model presented in Figure 6.4 under the condition of improvement. The bracketed numbers refer to the numbers in the figure.

- *Problem Analysis [1]* PDSA involves recognition of a process to improve.
- *Developing Assumptions [2]* The three types of assumptions—structural, personal, and problem centered—apply to PDSA. Restrictive assumptions will produce lower-quality solutions. It is important to stress that inferences (assumptions) must be based on facts.
- *Identifying Tentative Alternative Solutions [3]* This loop is implicit in the PDSA model, especially with initial assessment.
- *Developing and Applying Decision Criteria [4]* This is implicit in PDSA; criteria include customer and output specifications.
- *Selecting [5]* This problem-solving step of selecting an alternative that best meets the decision criteria is part of PDSA.
- *Implementing [6]*. Implementing a solution is the same as “act” in the PDSA cycle.
- *Problem Analysis [1]*. Evaluating results of improvement is explicit in PDSA and includes learning from the improvement.

8. *Define reengineering. What are its attributes? What is common to both CQI and reengineering?*

Hammer and Champy define 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.”¹ Sometimes termed *process innovation* or *core process redesign*, reengineering as applied to health services makes fundamental and radical changes in processes and how healthcare is arranged and delivered. Reengineering

- is outward-in, focusing on customer needs to attain and maintain competitive advantage.
- involves fundamental change by identifying what HSOs/HSs must do (vision) and how to do it.
- requires radical redesign that disregards existing structures and procedures and invents new ones to accomplish work; starts with a clean slate and reinvents how work is done; is analogous to “breaking the china,” challenging the purpose and assumptions of a process and putting it back together (redesign) in a new way.
- is dramatic with breakthrough leaps in performance versus marginal or incremental improvement.
- involves processes with the focus on end-to-end, interlinked processes.

Hammer and coauthors² contend that reengineering involves radical breakthrough leaps in performance and is very different from QI or CQI, which produces incremental and continuous improvement in quality and performance. Although recognizing that QI and CQI are similar to reengineering because they are driven by customer needs, have a process focus, and have a commitment to improvement, those touting reengineering believe that it is more, is macro in scope, and is the iteration beyond CQI.

CQI stresses incremental improvement through structured problem solving, whereas reengineering is about radical improvement through total process redesign. CQI assumes that the basics of the underlying process are sound and seeks to improve it. Reengineering’s proponents see it as the step after CQI. Success with CQI can position an organization to take that next step.³

9. *What are the four steps in strategic quality planning? How is it related to strategic planning as described in Chapter 9?*

When responding to this question, students should refer to the Strategic Quality Planning: Hoshin Planning section (text, Chapter 7) and Figure 7.9. Hoshin planning is customer

oriented, primarily focused on external customers and the marketplace, and seeks to achieve breakthroughs in performance, quality, and competitive position. *Hoshin* is Japanese for “shining metal compass” or “pointing direction.” It is also known as focused planning, policy deployment, policy management, and strategic quality planning. It is a way of linking quality planning such as that in CQI and reengineering to overall HSO/HS strategic planning. The method is to identify and focus improvement programs in a few key, critical areas that are strategic priorities in order to meet customer needs and enhance competitive position.

Hoshin planning is vertical in nature, as opposed to the horizontal planning done in CQI; it is based on the HSO’s/HS’s mission and the vision of where it wants to be. It is a systematic way of prioritizing and integrating key success factor (KSF) process improvement initiatives so as to use those that are most important for enhanced quality and organizational success. It also assists in allocating resources and aligning or restructuring the organization so that all units work toward the common purpose. Hoshin planning is a step beyond CQI and reengineering—that is, it is strategic in nature because it is linked to the HSO’s/HS’s broad strategic plan.

There are four steps in strategic quality planning (also shown in Figure 7.9): 1) choose the focus, 2) align the organization, 3) implement the plan, and 4) review and improve.

- *Choose the Focus (1).* This step includes the tasks inherent in strategic planning: understanding the mission and developing a vision (what is to be achieved and when); analyzing opportunities and threats in the external environment, including customers, markets, and competitive position; and assessing the HSO’s/HS’s internal environment to identify strengths and weaknesses. From this strengths/weaknesses/opportunities/threats (SWOT) analysis, strategies are identified and chosen in strategic planning. Quality planning is an implementation step that can lead to differentiation, low-cost leadership, and enhanced competitive position.
- *Align the Organization (2).* The alignment component of Figure 7.9 identifies the specific performance targets for the KSFs that are part of the strategies necessary to meet customers’ needs. Participation by all employees is critical so that they understand the vision and focus and accept ownership of the performance targets. As plans and targets are developed, they are communicated to employees involved in implementation, modified by employees’ input, and thrown back to employees for further development. Important outcomes are an understanding of how the targets and plans relate to other organization processes and how they are interconnected.
- *Implement the Plan, and Review and Improve (3 and 4).* As shown in Figure 7.9, implementing the plan and reviewing and improving use the same steps as the PDCA cycle. Implementation is based on identified targets at all organizational levels for the KSF process and resulting plan(s). Performance relative to each target is tracked using data. Reviewing and improving the plan are concurrent and interactive with implementation. It is essentially a control activity and similar to problem solving.

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?

Involvement of physicians and other licensed independent practitioners (LIPs) is essential to effective organizationwide CQI in HSOs/HSs. LIPs, especially physicians, are the engine that drives clinical activities. Without their cooperation, the organization may be able to improve the administrative side of the organization, but it cannot improve the clinical side. It would be like trying to have a winning baseball team without pitchers. Given that almost every administrative decision affects clinical practice directly or indirectly, it is virtually impossible to separate the two.

It is common that physicians (and most LIPs) are not employed by the HSO. Even those that are hospital based such as emergency department (ED) physicians, anesthesiologists, and hospitalists are part of a group that has an exclusive contract with the hospital. This means administration has no direct authority and control over them as it would employees. Consequently, management must convince them (encourage, support, demonstrate) of the merits of CQI and how CQI can help them do their work more easily and achieve better outcomes for their patients.

Concerns That Make Cooperation More Difficult

- Regional physician surpluses/deficits
- Changes and reductions in reimbursement
- Increasing numbers, power, and roles of nonphysician providers
- The trend toward more salary arrangements and the decline in fee-for-service medicine
- Controls by government and other third-party payers, such as preferred provider organizations (PPOs) and HMOs

Benefits of Working with LIPs

- Working with clinical staff maximizes efforts to improve quality.
- Involving clinical staff integrates them more fully into the HSO/HS—which in itself is desirable. The total effort of the HSO/HS should be a seamless web in which everything that is done focuses on maximizing clinical quality. This makes clinician involvement vital.
- Clinical activities are the most labor- and cost-intensive work in the HSO/HS.
- Improving quality in clinical processes will reduce costs and improve performance; such a focus is cost-effective and necessitates LIP involvement.

Difficulties of Working with LIPs

- LIP training stresses independence, self-reliance, and personal accountability to and for patients. This makes them less oriented to processes and teamwork.
- LIPs think of themselves as customers—recipients; rarely do they see themselves as suppliers, which they commonly are.
- LIPs rarely think about the processes that support their work and the effects processes have on them.
- LIPs think little about the other staff who affect their clinical practice.
- LIPs, especially physicians, may be reluctant to assist one another, or to be assisted—another effect of their training.
- LIPs are reluctant to accept judgments about performance made by others, especially someone without their clinical background.

- LIPs, especially physicians, are increasingly concerned (perhaps paranoid) about changes in the health services system that are negatively affecting them.

Considerations for Managers

- Get LIP buy-in to any quality/productivity improvement (Q/PI) initiative; physician involvement is vital.
- Remember that HSO/HS decisions and activities affect LIPs.
- Be sure that other staff members, especially managers, are fully trained before bringing clinicians into QI activities; credibility is tenuous and easily lost.
- Assume that LIPs want to improve quality, despite expressions of skepticism and even criticism.
- Proceed at a reasonable pace—becoming a provider with top-tier quality takes years.

Steps to Increase Physician Involvement

- Appeal to their scientific, data-driven training and decision making.
- Train physicians in use of QI theory and tools.
- Involve physicians early in any CQI initiative.
- Eliminate distrust and perceptions that clinical measures are only the interest of management.
- Work through, and gain the commitment of, professional staff organization leadership.
- Eliminate fears that CQI is a way for management to decrease physician autonomy.
- Involve physicians with other nonclinical CQI initiatives; involve physicians in administrative QI teams.
- Identify and encourage physician champions; give them administrative (time, resources, staff) support.
- Ensure that physicians are always the “owners” of clinical process improvement.
- Start with strategically important clinical issues and processes.
- Show physicians how CQI can enhance patient care and satisfaction.
- Show physicians how CQI relates to and can improve their office practices.

11. Patient and worker safety have different histories. What do they have in common?

Although many of the specific issues overlap (i.e., falls, infections, exposure to hazardous material), the QI tools needed to improve safety are the same. In addition, the economic impact on the organization is similar. Employers pay workers' compensation insurance premiums into state insurance plans. Actuaries determine the premiums based on the risk experience of that type of employment. Thus, if the HSO has many injuries because of inadequate worker safety programs, it pays higher premiums. In addition to the workers' compensation insurance premium costs, there are costs to the HSO from sick leave (paid time off), staffing and training problems for replacement staff, and morale issues that can arise from working in an unsafe environment. The influence of federal law through the Occupational Safety and Health Administration (OSHA) has been noted.

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.*

The hierarchy of controls is as follows (Figure 8.10):

1. *Elimination*: Remove trip hazards from the parking garage.
 2. *Substitution*: Replace flooring with nonskid flooring.
 3. *Engineering*: Add hand rails to steep sidewalks where falls have occurred.
 4. *Administrative*: Require placement of “wet floor” signs when floors are mopped.
 5. *Personal protective equipment*: Require staff to wear nonskid shoes.
13. *What is the most important category of management strategies that supports the culture of safety in an HSO?*

Communication is among the most important elements in establishing and maintaining a culture of safety.⁴ This fact is noted in the discussion of retained foreign objects in Chapter 7. Communication cannot occur unless there is a culture of openness and a certainty that speaking truth to power will not cause retribution from those in positions of authority. Supporting communication between patients and staff is an important aspect of establishing and maintaining a culture of safety.

14. *If an HSO continues to struggle with a safety issue, what is the best course for senior leadership?*

Establish a QIT that includes those who work in the process(es) in question (i.e., Comprehensive Unit Safety Program [CUSP]; and Team Strategies to Enhance Performance and Patient Safety [Team STEPPS]).

Case Study 1

The Carbondale Clinic⁵

This case allows students to apply Q/PI principles to a large multispecialty group practice that provides some ancillary services in-house. In addition, the practice operates an outpatient surgical center. Meeting appointment times is a long-standing source of patient dissatisfaction, which appears to be connected to the process by which the practice schedules routine cases and the need to see emergency cases. Presently, scheduling is centralized, but the schedulers have inadequate levels of knowledge as to how long appointments for various complaints should be.

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?*

Neither management (large clinics have an administrator) nor physicians have evidenced concern about patients’ waiting, but they must be aware of the situation. Apparently, physicians want to maximize revenue (they do not want empty [idle] times in their schedules). It is implicit that costs are being transferred to patients by increasing their waiting times, as opposed to the opportunity costs being borne by physicians having empty time slots. The attitude is that delays are unavoidable, but this is not so. Some delays are unavoidable (e.g., because of emergencies); however, proper scheduling will eliminate most delays. Excess demand and little competition cause organizations to think that there is no reason to be customer oriented.

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.*

Assumptions that can be questioned are 1) delays are unavoidable; 2) central scheduling is uncertain of time involved (data analysis would yield rules of thumb or standards for time needed for particular conditions); 3) physicians assume that ordering a physical does not create problems; and 4) scheduling four patients per hour is appropriate (maybe changing to three per hour would solve the problem).

Important factors in the Pareto diagram that contribute to the problem include emergencies; physicians who order unscheduled physicals; the “attitude” on the part of central appointments that, when in doubt, squeeze in patients; the schedulers in central appointments not knowing how long it should take to examine a patient with a certain complaint; and overbooking.

3. *Draw a cause-and-effect (Ishikawa) diagram of causes for patient complaints.*

A cause-and-effect diagram appears in Figure 8.4. Students should be able to use the categories shown in the diagram to identify and place several factors described in the case that contribute to patient dissatisfaction.

4. *What recommendations would you make to decrease patient waiting time?*

Service operations with variation in demand must build in slack time to accommodate spikes in demand. More open slots would be one approach. There is no reason to have so much uncertainty as to the time needed to treat patients. Analysis of historical data and use of control charts will indicate patterns of demand and service times by illness type. Time standards (averages) can be calculated for various treatments, and emergencies can be tracked. Even crude calculations of average times and frequencies provide more information than central schedulers have now. This information will allow more appropriate scheduling.

Scheduling four patients per hour may be unrealistic, and analysis may indicate that three patients per hour is optimal to balance physician utilization and patient wait time. The point is to understand the process. There may be a lack of coordination among medical specialties and ancillary departments (laboratory, radiology). They may be interrupting one another's schedules.

Central appointments needs help. Schedulers should have data and be trained as to average times for appointments of various types. Deming, Juran, and Crosby emphasize training, training, and more training for staff. Perhaps a parallel system is appropriate. Some nonroutine scheduling should be done by the physicians/nurses, especially for those call-in patients who need to be seen soon. Nurses would be able to screen/assess and estimate the time needed to see the patient. If open blocks of time (such as 1 hour) were allocated each day for such patients, nurses could schedule those patients. If nurses are too busy, maybe there are insufficient input resources—more registered nurses (RNs) or licensed practical (vocational [LPN or LVN]) nurses may be needed. Part-time RNs could be employed during the peak morning call-in hours to help in scheduling.

When physicians order an unscheduled physical, patients should be given options—let them decide to proceed (and wait) or return later. Patients allowed to choose, even though they must wait, are seldom as dissatisfied as those with no choice.

An effort should be made to change the clinic managers' and physicians' attitudes about patient service. They must already know about the problem, but they have done nothing to solve it. Quality of care includes both the medical outcome *and* patients' satisfaction/expectations about the encounter. Nothing will happen until attitudes change. Leadership must be committed to improvement.

Case Study 2

Noninvasive Cardiovascular Laboratory

This case study encourages students to think about process (and quality—decreasing customer waiting time, interruptions, and complaints) and productivity improvement. It is rich with activities that can be improved: work methods, flows, facility layout, scheduling, and employee utilization.

1. *Is Findley overworked? Why or why not? Should another technician be hired?*

Findley is not overworked; he works inefficiently. There is also a quality problem. It is not necessary to hire another technician, because the problem is not workload. Consider the following:

- Findley's typical test sequence is ECHO, ECHO, OPG, ECHO, ECHO, PVR, ECHO, ECHO, OPG, and so forth. This sequence breaks Findley's workday into the following pattern: 2 hours (ECHO, ECHO), 10 minutes (setup time), 30 minutes (OPG), 10 minutes (setup time), 2 hours (ECHO, ECHO), 10 minutes (setup time), 30 minutes (PVR), 10 minutes (setup time), 2 hours (ECHO, ECHO).
- Because of cramped space, Findley spends 10 minutes moving equipment in and out of the room to set up for different tests.

In performing this sequence of tests and ignoring the telephone interruptions and test restarts, each day Findley spends 7 hours performing tests, spends 40 minutes in setup time moving equipment, and has 20 minutes of idle time (equipment for the first test is in place from the end of the previous day). Better layout and increased space would eliminate the need to move equipment and would reduce nonproductive time. A 40-minute-per-day increase in productive time over a 5-day work week would provide 200 minutes, or $3\frac{1}{3}$ hours, of extra time each week. Findley could perform three more ECHOs per week (156 per year) or six more OPGs or PVRs per week (312 per year), or some combination of these. There is underutilized space (50%) in the next room—the stress laboratory. Switching locations might be appropriate, or a door could be cut in the wall and part of the stress laboratory could be used.

Findley wastes a lot of time scheduling tests. On average, three of four tests Findley administers are interrupted by telephone calls. Each time, he loses 10 minutes: 2 minutes to talk and 8 minutes to restart a test. At the preceding year's annual rate of 800 ECHOs, 200 OPGs, and 200 PVRs, Findley performs 1,200 tests per year. If he loses 8 minutes restarting the test 75% of the time, that is 120 hours of lost time per year ($1,200 \times 0.75 \times 8 \text{ minutes} = 7,200 \text{ minutes}/60 = 120 \text{ hours}$). If that time were used for testing, Findley could perform 120 more ECHOs or 240 more OPGs or PVRs per year.

Standard times and projected annualized volume are as follows:

$$\begin{aligned} 1,200 \text{ ECHOs} \times 1 \text{ hour each} &= 1,200 \text{ hours/year} \\ 300 \text{ OPGs} \times \frac{1}{2} \text{ hour each} &= 150 \text{ hours/year} \\ 300 \text{ PVRs} \times \frac{1}{2} \text{ hour each} &= 150 \text{ hours/year} \\ \text{Total} &= 1,500 \text{ hours/year} \end{aligned}$$

Excluding breaks and 2 weeks of vacation, Findley has 2,000 work hours per year (40 hours/week \times 50 weeks). The projected hours of work are 1,500. Thus Findley does not need a full-time assistant. In fact, he could work at 75% utilization ($1,500/2,000$) and still perform the expected workload. Stated another way, Findley could increase his present workload by $33\frac{1}{3}\%$ [$(2,000 - 1,500)/1,500$].

Findley could improve scheduling by decreasing the number of different setups. For example, he could group ECHOs from 8:00 a.m. to noon, PVRs from 1:00 p.m. to 3:00 p.m., and OPGs from 3:00 p.m. to 5:00 p.m. However, he should not lose perspective—meeting customers' needs/expectations (convenience) should be a prime concern with any scheduling system. Because Findley works by appointment, he has a degree of control and can make improvements.

Another technician might be hired for reasons other than present workload. It is desirable to have someone else trained so that service to customers (patients and physicians) will continue uninterrupted should Findley resign or become ill. A better solution is to cross-train another employee to perform tests when Findley is sick or on vacation and to serve as a backup. Why not use the underused (40%) employee in the stress laboratory?

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?

Reducing the number of times that Findley is interrupted will improve quality by serving customers with less patient waiting time (resulting from Findley's interruptions) and less chance that he will make a mistake when he is interrupted. Also, more timely tests may affect patient length of stay, and physicians (another type of customer) will be pleased. Productivity improvement—increasing the ratio of outputs (tests) to inputs (Findley's time)—could include those items mentioned in Question 1:

- Change the testing pattern.
- Have someone else (e.g., the stress laboratory technician) answer the telephone and do the scheduling.
- Change the physical facilities; for example, switch the locations of the stress laboratory and noninvasive cardiovascular laboratory (NCVL) (the former has twice the space but uses only half) or combine the two laboratories by removing a wall.
- Have the technicians in both laboratories cross-trained for backup (vacations or illness).
- Ask Findley how the NCVL could be improved—after all, he is the most knowledgeable about the process.

Findley is frustrated. Management should give him the tools, advice, and help to improve his performance. Teaching him and involving him in the improvement process will give surprising results. He will be a more committed and more highly motivated employee.

3. Draw a cause-and-effect (fishbone) diagram of the reasons Findley's work is inefficient.

Students should pattern their cause-and-effect (fishbone [Ishikawa]) diagram on Figure 8.4. The diagrams developed should use the same or similar categories: equipment, policies, procedures, and people. Diagrams should include all important facts stated in the case.

4. Draw a flow diagram showing the steps in the process(es) for Findley's work.

Flow diagrams are also known as process maps. The drawing of the flow diagram will vary by the individual who has drawn it. Important is that standard symbols are used to show the steps. Various symbols are used in constructing a flow diagram, such as a rectangle to show a process step, a diamond to show a decision point, and an oval to show a process end point. Sets of symbols for use in constructing flow diagrams are available on the Internet. For ease of comparison, students should use the same symbols in developing their flow diagrams. Flow diagrams must not have dead ends—points at which the flow (of work) is in an endless loop. The only appropriate process end points are the beginning and end of the process.

Case Study 3

Infections—*C. difficile* (CDI)⁶

This case addresses the problem of minimizing the effects of an outbreak of CDI on a nursing unit that treats medical patients. Patients on a medical unit tend to have longer lengths of stay, are elderly and immunocompromised because of illness and/or medications, and are often in a weakened physical state because of multiple disease problems. The Mayo Clinic describes *Clostridium difficile*, *C. difficile*, or *C. diff.* as a bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon. *C. difficile* most commonly affects older adults in hospitals or long-term care facilities and typically occurs after antibiotic use.

1. What are the next steps?

It is important to understand what has changed on the unit. Given that there is a cluster of cases, something or several things are different. They must be identified and investigated: 1) learn what is happening on the medical unit—possible causes of the outbreak must be understood, 2) ask staff from the medical unit to discuss the operational issues with you, and 3) learn by walking through a day in the life of the CDI patients. Key is that something has changed on the medical unit, and this change is the cause of the outbreak.

2. What other staff should be involved?

Environmental services (housekeeping staff), medical staff (especially experts in infectious disease), infection preventionists, pharmacists, and microbiologists.

3. When do you tell patients and families about the cluster of cases?

The local health department's regulations should guide decision making regarding disclosure. It will have reporting requirements for clusters of cases. Once prevention measures are in effect, the information about the cluster of CDI can no longer be kept confidential. It is important that any information provided focuses on the facts.

4. How do you educate staff, patients, and visitors regarding prevention measures?

Prevention typically focuses on education because the *C. difficile* is spread by contact. Hand hygiene after interacting with *C. difficile*-infected patients is key to reducing spread. Posters on hand hygiene are a common means of reminding staff members about being scrupulous in sanitizing their hands. Flyers describing the basics of isolation techniques are useful reminders. Easy access to hand sanitizers, alcohol wipes, and sinks stocked with soap and towels is essential. Personal discussions between staff members and experts on infection control are helpful. These discussions should allow time for questions, as well as demonstrating proper technique for hand washing and interacting with patients, who should be treated with contact isolation if they are symptomatic (with diarrhea).⁷

Case Study 4

Infections—CLABSI

This case considers an important infection that is often acquired in an HSO. CLABSI is the acronym for central line-associated bloodstream infection. Quality improvement organizations (QIOs) are federally qualified entities charged with measuring and improving the quality of medical services in their regions. The QIO's initiative is important.

The Institute for Healthcare Improvement (IHI) has stated that CLABSI continues to be one of the most deadly and costly hospital-associated infections in the United States. Many lives have been saved in the past decade because of improvements in technique that resulted in a

58% reduction in CLABSI in ICU patients from 2001 to 2009. Nevertheless, CLABSI infections continue to occur, and many of them are in areas of the hospital outside the ICU. Strategies to prevent CLABSI include the IHI Central Line Bundle, implemented by many hospitals in the United States and United Kingdom. Some hospitals report more than 1 year of no CLABSI in their ICU patients. Additional prevention strategies have been identified.

1. Which staff members should be on your unit-specific team?

Staff members to be included on the unit-specific team include clinicians who work at the bedside, physicians specializing in infection control, infection preventionists, and a senior administrator.

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?

Senior management must understand and agree that improving patient safety is likely to require expending resources. Clinicians and administration must decide which safety measures they are willing to spend money on. Typically, it is an easy calculus to show the costs of treating CLABSI patients in terms of medications, longer hospitalizations, and potential denial of reimbursement. The role of supply chain should be supportive and focused on finding needed resources in the most efficient way. Supply chain should not determine if additional expenditures are needed.

3. How do you educate all staff on the necessary components of the quality improvement process?

The CLABSI team must determine what methods of education are most appropriate for their group. Some HSOs may use computer-supported education; others may be more effective with one-on-one training, or in-person group sessions.

4. How do you keep this project “top of mind” for all staff on a daily basis?

A number of techniques may be used to keep the CLABSI education and prevention efforts prominent in minds of staff. Huddles, banners on the units showing the number of days since the last CLABSI, and “defect forms” that are completed by a staff member each time a hospital-acquired infection occurs. In addition, undertake process improvement efforts so that fewer infections occur. Slogans and exhortations are unlikely to be effective—a view consistent with one of Deming’s 14 points.

Case Study 5

Infections—Flu Vaccination

Vaccinating staff against the seasonal influenza is standard operating procedure in HSOs. Many staff members do not get vaccinated, however. Reasons vary, but even free vaccination, raffles, and cash incentives may not be enough to obtain 100% compliance. This case addresses the problem of prevention through vaccination. Here, management has gone further and made vaccination a condition of continued employment.

1. How do you present senior management’s decision to the staff?

Frame it as a “patient safety” issue based on the facts that show the rates of morbidity and mortality from the flu, especially among the elderly and those who are immunocompromised.

2. How do you handle the expected requests for an exemption (medical and religious)?

Check local ordinances and state laws for religious exceptions to vaccination requirements. A call to risk management and/or legal counsel might be appropriate. Have a physician familiar

with occupational health and other staff on the committee review blinded (unattributed) medical exemption requests to determine if they fit the medical requirements for exemptions that are acceptable.

3. What should be done about staff members who receive an exemption but remain in the hospital during a virulent flu season?

There is no body of literature that shows continuous masking prevents the spread of influenza. Nevertheless, many institutions require unvaccinated staff members to wear surgical masks while on duty. Some HSOs monitor the level of disease in the local community and within their walls and ask unvaccinated staff to mask if levels reach a high intensity. This requirement continues until the flu season passes or the intensity level decreases.

Case Study 6

Sharps Injuries

This case addresses the problem of employee injuries because of handling or encountering sharp objects such as suture needles, syringes, scalpels, and razors. Sharps injuries are especially likely in operating rooms (ORs). These injuries are potentially very serious, but at the same time they are largely preventable. In addition, the HSO must be concerned as to the proper response to such injuries and have a policy that is used when sharps injuries occur.

1. Which persons should be included in the group that investigates the increase in sharps injuries in the operating room?

OR leadership, OR staff members, education liaisons, infection prevention, employee health, and a surgeon.

2. What safety measures can be taken in the OR to protect staff and patients from sharps injuries?

Safety measures can include “No-touch” passing techniques (when instruments, etc., are moved from one place or person in the OR to another), and blunted sutures.

3. How likely is it that the sharps injury data from employee health are accurate?

Data collected from staff members who are receiving workers’ compensation are probably as accurate as can be obtained. Data from staff members not employed by the HSO and who do not depend on the organization to pay for their treatment are not necessarily complete.

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?

The OSHA surveyor will ask to see the OSHA 300 log. The OSHA 300 log must be maintained and posted at the organization from February 1 through April 30, annually. This document should also be signed by the CEO.

Case Study 7

Slips, Trips, and Falls

Employee slips, trips, and falls are endemic in HSOs. Such events might seem insignificant, but they are very costly in terms of lost time, sick leave, and workers’ compensation claims and

health insurance costs. In addition to the quantifiable measures, others not so easily measured include staff disruption, reduced staff morale, and employee pain and discomfort.

1. What is the next step needed to get this prevention project moving?

In this situation it is important that the senior executive who is responsible for the budgetary allocation that provides more funding for preventive measures such as nonskid shoes is also the executive responsible for the unit(s) in which most of the injuries are occurring. Employee falls are expensive by every measure, and highlighting the relationship between nonskid shoes and employee falls is a simple but effective way to get the attention it needs.

2. What information will help get the attention of manager and staff?

Calculating the costs of employee slips, trips, and falls will get the attention of the unit managers and senior executives. Known and calculable costs include medical costs and the costs of time away from work after an employee injury. Costs that cannot be quantified but are known to be present include lower employee morale, increased turnover, and the disruption caused by a work force made less stable when a staff member is injured and cannot work or must work a reduced schedule or set of duties. Nonquantifiable costs are important and should not be ignored in an effort to gain budget for nonskid shoes.

3. Identify some internal and external solutions to the risk of slips, trips, and falls.

External. 1) measure the adequacy of lighting in garages and other parking areas, 2) place handrails at points where the elevation of walkways changes.

Internal. 1) place plastic umbrella bags near building entry points, 2) place “walk-off” mats at doorways.

Case Study 8

Safe Patient Handling and Patient Movement Injuries

Moving and handling patients are physically demanding and are a major source of injury to staff members. Despite HSOs’ best efforts such as installing patient lift equipment and training staff in safe techniques for moving and handling patients, staff injuries continue to be a significant problem.

1. How can senior management be convinced that this is an important problem?

It is necessary to show the business case for how much each injury costs in terms of medical treatment, time away from work, and the fact that a patient could be harmed if the lift equipment and correct procedures are not used. Find the relationship between the organization’s strategic initiatives that are affected by the increase in size and bodyweight of Americans and show how lifting and moving heavier patients will affect the staff.

2. How can middle management be convinced that this is an important problem?

Develop reports that show each unit’s specific injury rate, as well as the costs associated with those injuries. Institute a “return to work—light duty” program that forces the payment for staff to come from the budget of the home unit. In other words, put the financial focus on the manager responsible for the injured worker. Promote the concept that if managers make their units safer, there will be less money taken from their budgets to pay for injuries.

3. How can staff members be convinced that this is an important problem?

Educate them on the concept of “safe lifting” and connect that with a “no falls for patients” program. Show staff the effects of, and personal costs involved in, a back, shoulder, or neck injury in terms of money, pain, and career limitations.

Case Study 9

Hazardous Materials

HSOs, especially hospitals, have many types of environmental hazards. The organization has both an ethical and a legal duty to take reasonable precautions to ensure that staff has a safe work environment. This case addresses a complaint by an employee about a potential health hazard in the laboratory.

1. When speaking to the manager, you ask to see the employee's file. What do you want to assess?

It is important to assess the employee's education and competency to handle the chemicals in question. These are stated in the employment file and the job responsibilities of the employee. Recent evaluations should be reviewed. The purpose is to get a complete picture of the job, the employee, and the employee's suitability for the job.

2. What else do you need to know to determine if there is a problem?

It is important to review the measurements of formaldehyde fume levels in the area. Concerns about formaldehyde fumes from other employees will provide additional context. In addition, determine if other employees in the work area have made formal complaints about formaldehyde.

3. What resources are there to assist in determining if there is a problem?

The laboratory manager is an important source of information for solving this problem. In addition, a certified industrial hygienist could be asked to review the facts and the workplace. OSHA should be queried and its voluntary protection program could be consulted. OSHA has developed performance-based criteria for many industries and provides consultative advice to participants.

Case Study 10

Violence in the Workplace

A number of violent incidents have been reported in hospitals, especially hospital EDs. Other types of HSOs, including long-term care facilities and clinics, have not been immune to violent or disruptive behavior by patients, families, and visitors. This case considers violence in the workplace.

1. How can the problem be quantified?

Check available data to determine the sources of problems and the times they are occurring. This information is key to developing solutions. Determine if employee health has data on employees, staff, and patients who were injured by patients or visitors. Follow up where these data lead.

2. What can be done to address the problem of angry, emotional patients and visitors?

Develop cycles of training for staff members on handling aggressive behavior, form a "Code Green" team to respond to situations when security has too few resources, place panic buttons in select areas, educate staff on relationship building, and engage in preplanning with local law enforcement to assure police availability on short notice.

3. *Should a guard be stationed in the ED? Should the guard be armed?*

The presence of a uniformed security staff member in the ED during peak hours of use or when there have been the most incidents of disruptive patients and visitors will have a calming effect. Stationing a uniformed security officer in the ED 24/7 may be justified depending on the local situation. Having security staff in adjacent areas from which rapid response is possible should be considered as an option.

Arming security should be a last resort. If the ED is that dangerous, consideration should be given to hiring an off-duty police officer who is legally authorized to carry firearms and use deadly force. Screening persons seeking to enter the ED is a preventive action that should be considered, as well.

Additional Case Study 1: Effective Consent

This case highlights the issues that arise when consent is obtained in medical education settings. Clinicians and managers often forget that patients do not understand the role(s) of physicians and other clinical staff who are being trained. Organizations such as the American College of Surgeons have made it clear that patients have a right to refrain from participating in teaching activities and that valid consent includes telling patients which caregivers are in training. This case provides an example of how CQI applied in the clinical setting could reduce the risk of the type of problem described. The Joint Commission requires that a “properly executed informed consent is placed in the patient’s medical record prior to surgery, except in emergencies. A properly executed informed consent contains documentation of a patient’s mutual understanding of and agreement for care, treatment, and services through written signature; electronic signature; or, when a patient is unable to provide a signature, documentation of the verbal agreement by the patient or surrogate decision-maker.”

Further, The Joint Commission requires: “The operative or other high-risk procedure *report* includes the following information: The names of the licensed independent practitioner(s) who performed the procedure and his or her assistants.”⁸ This information is included in the operative report done after the procedure; it is not part of the informed consent process. In 2007, the CMS stopped requiring that the consent form list everyone involved in performing the surgery.⁹

Alex Burkowski finished reading the incident report written by the supervisor of the cardiac catheterization laboratory and rescanned the letter from the former patient, Mr. Walter. As Burkowski read, he could not help thinking that this was the silly kind of thing that consumed too much of his time. He wondered whether he or Smokey the Bear fought more fires.

As the director of risk management, Burkowski cochaired the ad hoc interdisciplinary committee that had been established to review the consent policies at the large multispecialty group practice at which he was employed. Now he would have to try to get that committee restarted. At best, it would move at glacial speed; at worst, it would be an exercise in futility.

Burkowski summarized the situation:

Patient Walter admitted for catheterization. Patient alert during procedure; his cardiologist came to head of table to speak to him. Patient became alarmed and wanted to know who was performing procedure (catheter visible to patient on television monitor). Cardiologist told him a qualified cardiology resident was doing procedure. Procedure completed uneventfully. Patient very angry; told cath lab supervisor no one told him someone other than “his doctor” would do procedure, especially a “learner.” Cardiologist can’t remember if he informed patient about resident. No consent form in file.

Patient Walter had threatened to sue, but Burkowski knew the law and understood that, absent an injury, it would be very difficult for him to win damages. Burkowski started to write the memorandum to the committee, but he was not sure what to say.

1. What are the legal issues here? Whose concern are they? Do HSOs with medical education programs have a special legal obligation to patients in cases like this? If so, how is it met?

The legal issue is failure to obtain written consent from the patient. Physicians have the primary obligation to obtain consent. They should provide the information the patient (or surrogate) needs to give informed consent, which should be confirmed in writing. (Oral consent is valid, but usually not a prudent alternative because memories fade, staff members change, and there is no continuity of the record without written consent). Consent is also an issue for the HSO/HS; procedures must not be undertaken if consent forms are not in patients' files. The staff erred in proceeding without them.

HSOs/HSs with medical education programs have special ethical and legal duties to patients in cases such as this. Patients must be informed that trainees are present and involved in care processes. This information may be important to them in deciding whether to receive treatment at that HSO or go elsewhere. The staff of HSOs/HSs with education programs is so accustomed to the presence of students that they forget how they may be perceived by patients. Routine admission and consent processes should make it clear to patients that trainees will be present and will participate in their care. Patients should be able to refuse treatment from trainees, and this should not diminish their relationship with other caregivers and the HSO.

2. Outline the memorandum that Burkowski should write to the committee.

The memorandum should include a statement of the problem highlighted by the Walter case, a brief description of the ethical and legal aspects of informed consent, and comments regarding the importance of continuing the medical education program and the need to review and improve the current consent process. Copies of current policies and procedures on consent should be attached. An important recommendation should be the establishment of a QIT to study and improve the consent process.

3. Is Burkowski a part of the problem? If you were Burkowski's boss, what would you do? Why?

Burkowski seems to think that the issues that are raised in the Walter case are unimportant. This view suggests a problem. Considering only the legal aspects ignores the HSO's/HS's ethical obligations, which demand a higher standard. Also, quality is defined as meeting customer needs and expectations; Mr. Walter's expectations were not met. The CEO should evaluate Burkowski's performance, which the case suggests is marginal. Burkowski may need additional training in risk management; he also needs to be sensitized to the ethical and quality aspects of cases such as this one. Dismissal is a last resort.

4. Assume that there is a QIC and that a QIT has been established. Outline the steps that would be taken once a QIT is established.

The textbook outlines the steps that occur after a QIT has been sanctioned (established) by the QIC. The QIT must be cross-functional because the consent process involves several departments. The QIT prepares an opportunity statement about how the consent process can be improved and the expected benefits of process improvement. The opportunity statement is reviewed and approved by the QIC.

QIT members must have process knowledge. It should be stressed that a QIT composed only of managers will be marginally successful, at best. Managers lack the detailed process knowledge that those who work in the process have. After preparing a flow diagram that shows the process as it currently functions and after selecting the key quality characteristics (KQCs) to be studied, the team identifies the key process variables (KPVs) at which data collection will be focused. Data collection can use previously collected or newly collected data and will determine the performance of the process in terms of KQCs and the contribution various KPVs make to achieving (or failing to achieve) the KQCs. These data will drive process changes designed to improve results, which in turn must be monitored and evaluated to determine their effect.

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