

Quality Initiatives

Developing a Radiology Quality and Safety Program: A Primer¹

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ONLINE-ONLY CME

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LEARNING OBJECTIVES

After reading this article and taking the test, the reader will be able to:

- Discuss the quality and safety national healthcare dilemma.
- Describe how to construct a quality and safety program within a radiology department.
- List the different approaches needed for safety assessment, process improvement, outcome assessment, and satisfaction measurement.

TEACHING POINTS

See last page

Four main areas of quality need to be addressed for a complete quality and safety program in radiology: safety, process improvement, professional outcome assessment, and satisfaction. These areas need to be coordinated by individuals who belong to a quality oversight committee. Management of the data can be facilitated by using a quality scorecard that posts relevant data for each operational group within a department. The ultimate goal is a cultural shift in which all departmental workers assume responsibility for quality and safety improvements and behave consistently with the core values of the organization. A road map for thinking about quality and safety issues in radiology allows all of these areas to be tied together. Four main areas of development are required, each demanding a different skill set and approach.

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Abbreviation: ACR = American College of Radiology

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Introduction

Quality and safety in medicine have become topics of high interest in the past few years, prompted by the Institute of Medicine's report "To Err Is Human" (1). This report provided evidence of the suboptimal state of healthcare in the United States and the prevalence of medical errors that result in patient death or injury. In this report, it was estimated that nearly 100,000 lives yearly are lost to medical errors—accounting for a mortality that exceeds the number of deaths from breast cancer and motor vehicle accidents combined. The staggering economic costs associated with these injuries were estimated to exceed \$38 billion–\$50 billion yearly (2). Subsequently, many other groups and agencies have verified these estimates of medical errors and patient harm—raising the issue to epidemic proportions (3–5). In a second Institute of Medicine report, "Crossing the Quality Chasm," six aims that should be pursued to close our performance gap were proposed, including patient safety, effectiveness, efficiency, timeliness, equity, and patient centeredness.

Radiology, a core service to most clinical areas of medicine and surgery, was not immediately recognized as a potential direct cause of patient harm. Review of the medical literature presents many reports identifying suboptimal radiology processes of care that can lead to patient harm. For example, the issue of interobserver variability in the recommendation of breast biopsies varies by 45% among radiologists practicing at accredited centers (6). Reported variability in the diagnostic sensitivity for the interpretation of computed tomographic (CT) colonographic results has ranged from 25% to 92% (7,8). The number of mislabeled images in a busy radiology practice could potentially lead to misdiagnoses or attribution to the wrong patient (9). Many organizations are still using adult protocols for pediatric imaging, generating undue exposure to ionizing radiation. Communication errors, the root cause of many sentinel events, can be traced to radiology reports where clinicians were not aware of a serious reported finding. In other words,

there are many opportunities for improvement in radiology—and we contribute our fair share to the national health and safety dilemma.

Even when procedures are performed and interpreted correctly, patients can be harmed. The editorial by Casarella (10) details the subsequent care and costs following a successful CT colonographic examination. In the course of the examination, a lung nodule was discovered that led to a thoracotomy, prolonged recovery, pain, and medical costs exceeding \$50,000 for a benign granuloma. This highlights the fact that ultimate patient outcomes can be adversely affected even without medical errors.

The lack of useful outcome data in the scientific literature and in the evaluation of specific local practices reveals a staggering lack of actionable information—which enables us to continue to repeat our traditional processes of care over and over without insight into the positive or negative impact on our patient care. We assume the examination requests are correct, that we perform the examinations and interpret results correctly, and that they meaningfully affect patient care—however, each of these steps is typically unchallenged and performed without adequate evidence of their effect on patient care. These gaping holes indicate a profound system problem in the way we provide and measure the care we routinely deliver. The opportunities for improvement are enormous.

The good news is that new technologies and know-how are not required to provide the corrective action that is needed. The tools required for improvement are based on scientific methodology and industrial engineering techniques that are well established and accepted. To achieve the transformational change that will be required to embed quality and safety in the fabric of everyday care will require a cultural shift that embraces key outcome measures related to quality, safety, teamwork, and the processes that lead to highly reliable care. Leadership, dedication to core values, and the translational impact on behaviors are the threads of that fabric that have the most sustainability.

There is a business case for quality—highlighted by the successful efforts of companies like General Electric, Motorola, and 3M that

Table 1
Quality Buckets

Safety
Process improvement
Professional outcomes
Satisfaction

have shown large returns on investments using Six Sigma Black Belt improvement specialists (11,12). Tasks that are repetitive can be defined into process steps. Each step in the process can be measured, refined, and improved. The same is true in medicine—thereby debunking the theory that business methods can't translate into the healthcare sector. Techniques that reduce waste in a care process translate directly into improved operational efficiency. Lean management techniques describe each process in a care delivery area and assess for ways to reduce effort that does not directly contribute to value in patient care (13).

Teleradiology services have directly turned radiologic interpretations into a commodity. The threat is that the lowest bidder will win the radiology contract. This is especially worrisome to U.S. radiologists, who may someday compete with interpretations from international or other lower-cost teleradiology providers. Institutions contracting for these services often do not consider the value of facility, safety, interpretation accuracy, communication of findings in context, equipment quality control, patient flow issues and efficiency, effective examination protocols, and follow-up care. Quality is the real differentiator in a commodity world—but it must be real and relevant to referring physicians by translating all radiology services into improved patient value.

Regulatory compliance with state and national accreditation bodies is a requisite to doing business. The vast majority of these regulations are focused on safety and mandated by the Joint Commission, Centers for Medicare and Medicaid, and National Quality Forum. They expect high levels of compliance with a few key safety issues such as universal protocol (procedural pause), medication reconciliation, sentinel

event management, hand hygiene, infection precautions, and others. National quality, certifying, and purchasing organizations have recognized the need for harmonization of measures, standards, and practices. They have responded by coordinating and synchronizing their requirements. Imaging and report generation have been targeted as areas for improvement (14,15). It is clear that future metrics will be defined for us unless we lead and develop them for ourselves.

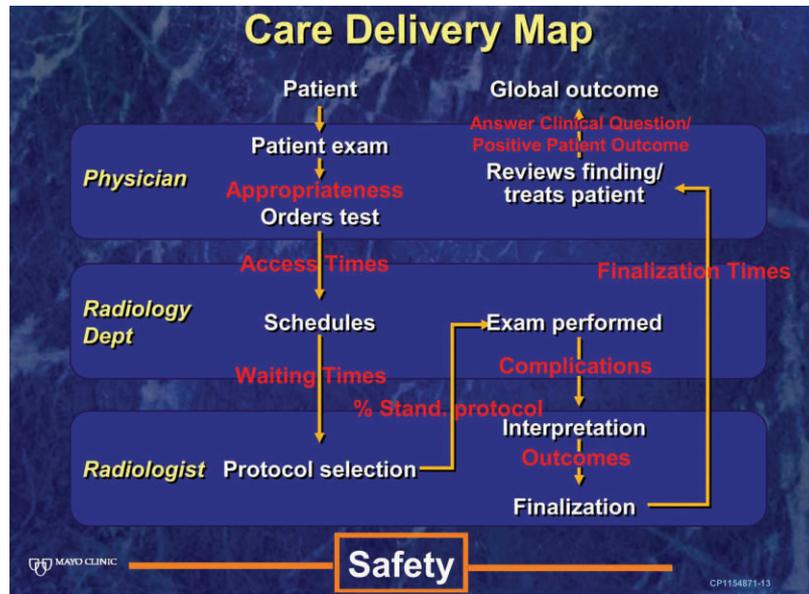
The emphasis on quality and safety is a significant challenge and opportunity for radiologists and radiology practices. Training in system engineering and improvement techniques has not been part of the established medical curriculum. Further, the path has not been well described, bureaucratic requirements often are perceived as missing the mark in truly improving patient care, and radiologists are very busy in clinical practice. Therefore, the purpose of this article is (*a*) to provide a framework for understanding quality, safety, and service science; (*b*) to describe the requisite safety requirements that are specific for radiology; (*c*) to provide a model for developing individual metrics for process improvement; (*d*) to describe methods for assessing professional outcomes; (*e*) to describe the principles of assessing satisfaction; and (*f*) to provide an operational guide for implementation of a quality office within a radiology department.

The Framework

There are probably many ways that can be used to consider the quality and safety field. Four measure categories are evolving on the national scene: outcomes, process, structure, and patient-centered measures. We choose to consider four main buckets of information: safety, process improvement (efficiency), professional outcome assessment, and satisfaction (service) (Table 1). The approach for each of these is different and requires a different knowledge base.

Swensen and Johnson (16) described a quality (value) map for radiology that lends itself to tying all of these areas together (Fig 1). This map follows the path of the patient from the referring

Figure 1. Defining quality in radiology. Diagram shows the path patients take when they see their physician and interface with the radiology department. Each step in the care process is associated with a metric. Combined, these metrics define a comprehensive radiology quality program. *Stand* = standardized.



physician's office into the radiology department and the major steps required for ordering, performing, and reporting an examination. Safety is shown as the foundation for the care processes, outcome assessment as a measure of radiologist accuracy, and service as only patient satisfaction. This simple approach provides a basis for thinking about care processes and the metrics that describe them. The framework can be expanded with more detailed steps and metrics—depending on the requirements of the practice.

Safety

Safe care is assumed by patients and is the foundation of any quality program. Yet one out of five laboratory and imaging studies are undertaken because providers cannot find prior studies or information, one of four families have had a harmful event through their healthcare, and one of three physicians' families have sustained adverse events (17). Many safe practices are required by regulatory bodies (like the Joint Commission) for institutional accreditation and government insurance program payment (18). **Safety metrics that are considered most relevant to a radiology department include radiology-generated infections, medication error rates, patient falls, contrast material-induced nephropathy, critical test reporting, critical test results reporting, specimen labeling errors, universal protocol (procedural pause), hand hygiene, medication reconciliation, and correct image labeling (Table 2) (15,19).**

Teaching Point

Radiology-induced infections can be traced by assessing those patients with positive blood cultures and assessment of the medical record for the likely cause. Patient falls that are of greatest concern are those falls resulting in patient harm. The prevalence, severity, and locale of falls should be monitored for facility improvement or process improvement opportunities. Contrast material-induced nephropathy is very difficult to track accurately. We have chosen to monitor a process metric that aims to minimize this complication. Standardized protocols for contrast material administration and postprocedural hydration have been implemented. These protocols specify contrast material dose depending on creatinine clearance, diabetes mellitus, and other relevant medical history. The frequency of following these protocols is measured. Image labeling errors are reported as the number of labeling errors (patient identification number, date, right-left indicator) that occur at the time of image acquisition (20). Specimen labeling errors relate to labels on specimen containers (usually biopsy specimens) that are typed and contain required information, including patient identification, organ or site, and side (21).

Select radiology practices have also developed safety alert systems that empower and encourage all radiology employees to report adverse events and near misses. Some of these systems are Web based for easy access and rapid delivery to responsible process owners. Rules are established that determine the response time to the report.

Table 2
Key Safety Metrics for Radiology

Infection rates
Medication error rates
Patient falls with harm
Contrast material–induced nephropathy
Critical test reporting
Critical results reporting
Specimen labeling errors
Universal protocol (procedural pause)
Hand hygiene
Medication reconciliation
Correct image labeling

Table 3
Key Process Metrics for Radiology

Appropriateness
Access times
Waiting times
Standardized protocol use rate
Finalization time of reports

For example, adverse events that are deemed severe and could occur again are rated high and demand a response and solution from leadership within 48 hours. Lesser-severity events are associated with longer intervals before an appropriate response is required.

Process Improvement

The value (quality) map of Figure 1 lists several key process metrics that can be readily measured: access times (time for next available appointment), waiting times (appointment time to examination start), standardized protocols (percentage of time standardized protocols were used), and finalization times (examination completion to report finalization time) (Table 3).

Appropriateness measures the frequency with which the referring physician ordered the most appropriate examination to answer the clinical question. This could be measured by using American College of Radiology (ACR) Appropriateness Criteria, measuring compliance with clinical prediction rules, using insurance precertification denial rates, or using other local rule-based methods. Clinical prediction rules are scientifically based rules assessing clinical indicators (history, symptoms, etc) and linking them to the likelihood of a significant finding in a specific

Table 4
Methods to Assess Professional Outcomes

Peer review
Chart review of reports compared with reference standard
Procedural outcomes
Complication rate
Success rate
Radiation dose
Procedural time

imaging examination (22). Because of their scientific basis, they are powerful predictors of appropriateness, but these rules are not available for all imaging indications.

Efficiency can also be gained by analysis of the process steps that are incurred for a particular examination in a specific area. Lean management techniques seek to analyze the process steps and visually record them, usually in the form of a process flow diagram or a value stream map. A search ensues for waste that can be eliminated, keeping only those steps that lead to patient value. Six Sigma, another process improvement technique, can be used in a similar manner—detailing a step-by-step approach to improvement that mimics the scientific method. Design, measure, analysis, improve, and control are the major data-driven steps of the Six Sigma discipline. Statistics are utilized to reduce process variability. The term *Six Sigma* refers to a high state of engineering reliability where only 3.4 defects per million are encountered—a noble goal in the healthcare field (23).

Both Lean and Six Sigma methods have been extensively tested in a variety of fields including healthcare. Many improvement projects don't demand the sophistication of these techniques and are most appropriately managed by using rapid cycles of feedback called PDSA (plan, do, study, act) (24). Depending on the project and its goal, the correct improvement methodology can be selected and implemented.

Professional Outcomes

There are a number of ways to measure professional outcomes (Table 4). Many of these already exist, including medical licensure, educational prerequisites, continuing requirements for medical

education, board certification (and recertification), standards of care, and credentialing. These requirements establish minimum standards but may not encourage dedication to professional excellence and lifelong learning. Societies, boards, and regulatory agencies are beginning to encourage or require a higher level of outcomes assessment to improve patient care.

Peer review is the latest method for assessing colleague competence by asking a peer radiologist to reread cases and determine if he or she agrees with the initial report. Radiologists who are outliers among their peers for the number of reports in disagreement can be identified and improvement plans implemented. Missed findings or other material disagreements from these reviews can be a source of learning for other members in the group—often conducted as part of a quality case review conference, which is typically protected under state quality review statutes. Some accreditation programs sponsored by the ACR require peer review; RADPEER (an ACR product offering) provides centralized peer review data collection for rereading of comparison examinations and measuring the number of disagreements per individual and practice against national benchmarks (25). Unfortunately, there is no way to know if the second review opinion is correct. Our experiences with peer review have failed to translate into widespread learning, and it may be viewed as a punitive exercise without substantive improvements in radiologist skill.

Another method for measuring professional outcomes is to score radiologic examinations that have reference standard proof. These metrics are preferred because they measure true outcomes for radiologist reports. For example, knee magnetic resonance (MR) imaging is compared with knee arthroscopy, coronary CT angiography is compared with conventional coronary angiography, CT colonography is compared with colonoscopy, and liver MR imaging is compared with liver explant pathologic examination. Only a few radiologic examinations have reference standards available to them, and the data collection requires the assistance of trained personnel who can access and understand the medical record for accurate data collection. When performed properly, this type of review can translate into very meaningful data that drive physician learning

Teaching Point

and improvement. Individual physician data can be measured and compared against those of the peer group and national standards. Metrics required by law (Mammography Quality Standards Act) in breast imaging are in many ways a best practice for professional outcomes assessment in radiology. These metrics and their appropriate benchmarks assess the percentage of minimal breast cancers detected, the percentage of breast biopsies that are positive, and other performance outcomes.

Other relevant metrics can also be obtained—particularly among the procedural areas of radiology, including complication rates, success rates, radiation dose, and procedural times. These are particularly helpful in those procedures that are considered the reference standard.

Satisfaction

Radiology departments have multiple potential customer groups including referring physicians, patients, allied health personnel, staff radiologists, industry partners, and students. All of these relationships are important for optimal performance of an organization. Engaged employees are much happier and more productive and have fewer sick days and lower job turnover rates than employees who are not engaged or satisfied (26). Loyal customers advocate for a business and are effective in marketing to others by word of mouth.

The first step in understanding a customer group is to survey the group for their overall satisfaction. Many satisfaction surveys are based on what department leaders believe to be important to their customers. In many cases, these assumptions are erroneous and lead to survey data that miss the crux of satisfaction. In other cases, the questions or surveys are often purchased and are so general or generic that they cannot be used for specific improvements. Careful listening to each customer group (by using surveys, focus groups, or individual meeting notes) needs to be the starting point for any serious actionable satisfaction improvement initiative. Open-ended questions need to be asked to assess customer needs or wants that drive satisfaction. We use a methodology described by Lawton (27) that assists in effectively understanding the key drivers of satisfaction. On the basis of this methodology, a group-specific survey is devised that can be administered regularly for assessment of satisfaction improvement (Table 5).

Table 5
Customer Satisfaction Survey Components

Identify a specific customer group
Develop a way to listen to their needs
Develop a survey based on those needs

Customer groups need to be segmented by their needs and assessed individually. The needs of patients undergoing chemotherapy are quite different from those of women coming for screening mammography, and these individuals have different needs than pediatric families coming for care. Each group requires customized surveys if patient needs and wants are going to be optimally determined.

As an example, we were confident that referring physicians who used MR imaging for evaluation of lumbar pain would want a structured radiology report for lumbar MR examinations detailing the findings at each lumbar interspace. After piloting this structured report and surveying these referring physicians and suggesting that format as an option, we found that they really didn't like this way of communicating; instead, they preferred a report that (a) answered the clinical question and (b) noted any unexpected findings in the first few sentences. Once these two criteria were satisfied, there was less concern, or passion, about the format of the remainder of the report. Had we not asked and not listened, we would likely have crafted a report format of similar or less value than our typical prose report. It is a common error to assume that "we know what they want."

Among allied health personnel, we have found that most workplace dissatisfaction requires relatively few additional resources for improvement. Few respondents requested additional pay or time off. The majority were interested in more information and communication that was relevant to their department and work group. They wanted flexibility in their scheduling, time to ask questions at staff meetings, and knowledge that their work was making a difference for the entire department. Interestingly, employees seek true leadership from administrative and clinical leaders who tap their core values and help them reach their true potential (28). Improvements in satisfaction cannot occur until the problems are identified by listening to the voice of the customer.

Implementation

Improving value in patient care within radiology is a large and complex field that requires effective management of key quality, safety, satisfaction, and cost metrics. **The quality component interfaces with every division or section and individual within a department. In order to carry out such broad improvements, it is mandatory that departmental leaders not only approve of these efforts but be actively engaged to ensure success.**

We believe that dedicated infrastructure to support quality efforts is needed. These efforts may not require full-time engagement by these individuals, depending on departmental size. Sharing highly trained and effective specialists may be an effective strategy for many hospitals or medical facilities. Three main roles are necessary from the start: safety, process improvement, and data collection and posting. Safety initiatives are often supported by an interested nurse within the department. We have found that a partnership between a physician and a registered nurse can be very effective.

Process improvement projects are most effectively guided by personnel with specialized training in process improvement and an understanding of project management. Although certified Six Sigma or Lean trained individuals are optimal for this position, short training programs are available for interested individuals—and can jump-start a career in quality improvement. Organizations like the Institute for Healthcare Improvement (29) and Intermountain Health (30) have proven programs. Many other universities and organizations also have training programs that are worthwhile. Some state and city business organizations have quality councils offering excellent periodic education (31).

Finally, there is a need to effectively collect, consolidate, manage, and distribute or display the quality and safety data in a manner that is simple and meaningful. We have elected to post our key data on a scorecard that reflects the performance for each operational and physician group (Fig 2). Although we strive to automate the data collection as much as possible, some manual effort is still required. Our data are posted monthly for most metrics. If data elements are few or we are monitoring a stable process, quarterly reporting can be a good balance of effort and value.

Teaching
Point

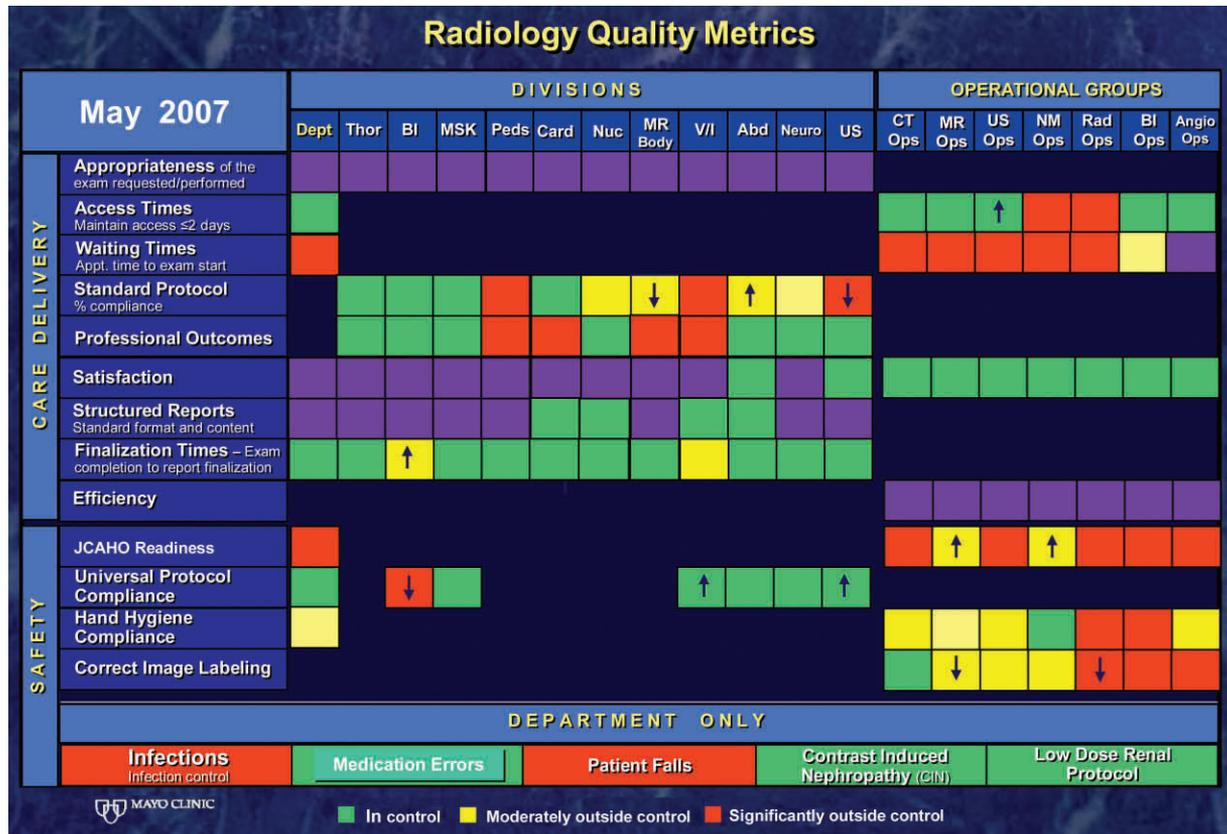


Figure 2. The scorecard. Care delivery metrics and safety metrics are defined in the left-hand column, and the various radiology divisions and operational modalities are listed across the top (horizontally). The metric performance can be mapped as green, yellow, or red depending on whether the process is considered in control, slightly out of control, or out of control (purple boxes represent metrics for which no data are available yet). This scorecard provides an easy way to identify departmental problems.

A quality oversight committee minimally composed of a physician leader, administrative partner, safety leader, and process improvement leader meets regularly to review and implement the strategic direction of the group and to review the progress of ongoing projects and their metrics (Table 6). Barriers and opportunities for improvement are identified and improvement programs are resourced. It is important to recognize that this group is charged only with the oversight of quality initiatives within a department and that the actual work of improvement needs to be accomplished at the grassroots level, where the work is being done (coordinated by the quality office personnel).

The goal is to instill a culture of safety and quality throughout the department and have it become part of daily work for each practice member in each area. When frontline workers understand and are responsible for projects in their area, this goal can be achieved. Leaders must

Table 6
Infrastructure for a Radiology Quality Initiative

- Oversight committee: goals, scope, accountability
- Quality office personnel
 - Safety and compliance expert
 - Process improvement expert
 - Data expert
 - Satisfaction expert (optional)
 - Quality education (optional)
 - Nurse medical record abstractor (optional)

provide the time and resources needed to implement the desired changes. Some centers promote transparency of quality and safety within each work unit by posting their data monthly—so that everyone understands the projects, how they are doing, and how they can contribute to the success of their work unit. Peer pressure can help mold late adopters and difficult autonomous physician behavior into supportive roles.

Teaching Point

Conclusions

In order to achieve the transformational change that will be required to embed quality and safety in the fabric of everyday care, a cultural shift will be required that embraces continuous improvement around key outcome measures related to quality, safety, process improvement, outcome assessment, and satisfaction, which lead to highly reliable and efficient care. High-quality patient care is our most important product and it requires a deliberate and organized approach. The science of quality improvement already exists, and key safety metrics have already been identified. Our successful future in radiology depends on the majority of us assuming this new role and responsibility. Through exemplary quality work, we can save radiologic services from commoditization and continue to experience the satisfaction of radiology's central role in patient care. It is not too soon to become engaged. The train is leaving the station, we need everyone aboard—don't be left behind.

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