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Quality Improvement in Anesthesia Practice and Patient Safety

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KEY POINTS

- Quality needs to be an integral characteristic of the system in which care is delivered. Improving the quality of care often requires reorganization of the way we work. A challenge to the anesthesia team is to combine efficiency in perioperative care (especially the operating room) with safety and the best quality possible.
- The growing demand from patients, clinicians, insurers, regulators, accreditors, and purchasers for improved quality and safety in health care requires that anesthesiologists and members of the anesthesia team persistently evaluate the quality of care they provide.
- Improving quality of care requires measuring performance. Clinicians have an enhanced ability to obtain feedback regarding performance in their daily work, in part because of the increasing use of information systems. Unfortunately, consensus has not been reached on how to measure quality of care.
- The goal of measurement is to learn and improve. The measurement system must fit into an improvement system; clinicians must have the will to work cooperatively to improve, and they must have ideas or hypotheses about changes to the current system of care. Also, the clinical team must have a model for testing changes and implementing those that result in improvements.
- Outcome measures, including in-hospital mortality rates, have been the basis for evaluating performance and quality. However, hospital mortality alone provides an incomplete picture of quality, does not include all domains of quality, and does not measure the overall success of the full cycle of care for a specific medical condition. A balanced set of structures (how care is organized), processes (what we do), and outcome measures (results of care in terms of patient's health over time) is needed to evaluate the quality of care overall.
- Efforts to improve quality of care require development of valid, reliable, and practical measures of quality. Identification of clinical care that truly achieves excellence would be helpful not only to the administration of anesthesia, but also to health care overall.
- Developing a quality measure requires several steps: prioritizing the clinical area to evaluate; selecting the type of measure; writing definitions and designing specifications; developing data collection tools; pilot-testing data collection tools and evaluating the validity, reliability, and feasibility of measures; developing scoring and analytic specifications; and collecting baseline data.
- The best opportunities to improve quality of care and patient outcomes will most likely come not only from discovering new therapies, but also from discovering how to better deliver therapies that are already known to be effective.
- Safety is an integral part of quality that is focused on the prevention of error and patient harm. The airline industry is often lauded as an exemplar of safety because it has embraced important safety principles, including the standardization of routine tasks, the reduction of unnecessary complexity, and the creation of redundancies. Anesthesia care teams have also adopted these principles, although many opportunities remain to further bolster patient safety.
- Healthcare providers can organize their quality improvement and patient safety efforts around three key areas: (1) translating evidence into practice, (2) identifying and mitigating hazards, and (3) improving culture and communication. Although each of these areas requires different tools, they all help health care organizations evaluate progress in patient safety and quality.

The need for improving quality and reducing the cost of health care has been highlighted repeatedly in the scientific literature and lay press. Improving care, minimizing variation, and reducing costs have increasingly become national priorities in many countries. Quality improvement (QI) programs that address these issues not only improve delivery of care but also have a positive effect on practitioner job satisfaction and organizational commitment.¹

The goal of this chapter is to present a practical framework for developing and implementing QI programs in anesthesiology and critical care medicine that are both scientifically sound and feasible. To accomplish this goal, we review the science and approaches to QI, present measures that help evaluate whether QI programs have resulted in improvements, and describe examples of successful QI efforts.

What Is Quality?

DEFINITION OF QUALITY

W. Edwards Deming, scholar, professor, author, lecturer, and consultant to business leaders, corporations, and governments defined quality as “a predictable degree of uniformity and dependability with a quality standard suited to the customer.”¹ This early definition of quality, in the context of QI, stems from its application to industrial production. However, when the term *quality* is applied to health care, the subtleties and implications of treating a human being are of prime importance, as opposed to the concerns involved in producing consumer goods. Use of the term *quality* in the context of health care can sometimes lead to defensive attitudes, economic concerns, and even ethical debates.

In the healthcare sector, quality can have various meanings to different people. For example, a daughter may evaluate quality by the level of dignity and respect with which her elderly mother is treated by a nurse. A cardiac surgeon may see quality as a percentage of improvement in the function of a heart on which he or she has just operated. A business may judge quality by the timeliness and cost effectiveness of the care delivered to its employees and its effect on the bottom line. Finally, society may evaluate quality by the ability to deliver care to those who need it, regardless of their cultural or socioeconomic backgrounds.

Despite the numerous definitions of quality in both business and medicine, a unified definition of quality in the context of QI should exist in health care. This definition of quality may have implications for both its measurement and its improvement. In order to help standardize the definition of quality in health care, the Institute of Medicine (IOM) published its own definition in a 1990 report titled *Medicare: A Strategy for Quality Assurance*. The IOM, which has since been renamed the National Academy of Medicine (NAM), defined *quality* as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”² Inherent in this definition are the elements of measurement, goal orientation, process and outcomes, individual and society preferences, and a dynamic state of professional knowledge. This definition of quality in health care has gained widespread acceptance. A similar definition is offered by the U.S. Government Department of Health and Human Services, which defines quality in public health as “the degree to which policies, programs, services, and research for the population increase desired health outcomes and conditions in which the population can be healthy.”

AIMS OF QUALITY IN HEALTH CARE

In the 2001 report, *Crossing the Quality Chasm*, six aims for quality in health care were outlined.³ These aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity included and extended the issues of patient safety described in their earlier report *To Err Is Human*.⁴ The aims have been adopted by many organizations, including the Institute for Healthcare Improvement (IHI), a United States nongovernmental agency devoted to advancing QI and patient safety in health care. These aims serve as a

basis on which quality is evaluated and improved and are described as follows.

1. **Safety.** No patient or healthcare worker should be harmed by the healthcare system at any time, including during transitions of care and “off hours,” such as nights or weekends. Errors may be categorized as either failure of an action to occur as planned, such as the administration of a wrong medication to a patient, or having the wrong plan altogether, such as misdiagnosing and subsequently mistreating a patient.⁴ As much as possible, patients should be informed about the risks and benefits of medical care in advance. If a complication does occur, medical staff should make full disclosure, provide assistance to the patient and family, and exercise due diligence in preventing any recurrences of the error.
2. **Effectiveness.** Effective medicine requires evidence-based decisions about treatment for individual patients, when such evidence exists. The best available evidence should be combined with clinical expertise and patient values in forming a treatment plan. With effective care, medical practitioners avoid underuse by providing a treatment to all who will benefit and avoid overuse by refraining from giving treatment to those unlikely to benefit.
3. **Patient-centeredness.** Patient-centered care is respectful of individual patient preferences, needs, and values and uses these factors to guide clinical decisions.⁴ More specifically, according to Gerteis and colleagues,⁶ patient-centered care encompasses respect for patients’ values; coordination and integration of care; information, communication, and education; physical comfort; emotional support that relieves fear and anxiety; and involvement of family and friends. The dramatic increase in access to health information on the Internet has resulted in more patients who are well informed and proactive in their care. Patient-centered care embraces this trend and shifts more of the power and control to patients and their families. Examples of patient-centered care include shared decision making, patient and family participation in rounds, patient ownership of medical records, schedules that minimize patient inconvenience, and unrestricted visitation hours.⁷
4. **Timeliness.** Reduced wait time is important to both patients and healthcare practitioners. Long waits signal a lack of respect for a patient’s time. Furthermore, delays may not only affect patient satisfaction, but may impair timely diagnosis and treatment. For healthcare workers, delays in availability of equipment or information may decrease job satisfaction and the ability to perform their jobs adequately.
5. **Efficiency.** Rising costs have increased scrutiny of waste in health care; this includes waste in labor, capital, equipment, supplies, ideas, and energy.⁸ Improved efficiency reduces waste and results in an increased output for a given cost. Examples of efficiency measures include mean length of hospital stay, readmission rate, and mean cost of treatment for a diagnosis. The elimination of waste can result in better quality of care for patients at the same or lower cost.
6. **Equity.** Equitable care does not vary in quality based on personnel. The NAM defines equitable care at two levels. At the population level, equitable care means

reducing or eliminating disparities between subgroups. At the individual level, it means absence of discrimination based on factors such as age, gender, race, ethnicity, nationality, religion, educational attainment, sexual orientation, disability, or geographic location.³

Another framing of quality is the “quadruple aim” proposed by Bodenheimer and Sinsky⁵ and adopted by the IHI. These four aims include better care, better outcomes, lower cost, and better work life for the healthcare workforce. This last aim was added to the IHI’s previous “Triple Aim” in recognition that increasing clinician burnout represents a threat to high-quality care.⁵

DEMING’S SYSTEM OF PROFOUND KNOWLEDGE

Before learning about frameworks and tools for improvement, it helps to have an understanding of the theory behind improvement work. W. Edwards Deming wrote about two different types of knowledge: subject matter knowledge and profound knowledge. Subject matter knowledge is professional expertise, such as expertise in anesthesiology. Profound knowledge is the knowledge of improvement. The most significant improvement occurs where these two types of knowledge overlap. Deming divides profound knowledge into four different categories: appreciation of a system, the theory of knowledge, understanding variation, and psychology.

The first area of profound knowledge is appreciation of a system. A system is a network of interdependent components working together for a common aim.⁶ It is often said that “Every system is perfectly designed to get the results it gets.” If a system is underperforming, it is because it has unintentionally been designed to underperform. If this is the case, it is our responsibility to manage the system to get the results we want.

The second part of Deming’s profound knowledge is the idea that knowledge requires a theory. Information by itself is not knowledge. For example, a dictionary contains information, but it is not knowledge. We must have a theory behind our improvement work, not just data, if we are going to learn.⁶

In order to learn, we must additionally understand variation and how to react to it. Deming says that “life is variation.”⁶ Common cause variation is variation that is inherent to the process. Special cause variation is variation from causes that are not inherent to the process but arise from specific circumstances. A process which only has common cause variation is in statistical “control.” On the other hand, a process that has both common cause and special cause variation is an unstable process.⁷ Two common errors in improvement work are acting upon common cause variation as if it were special cause, and acting upon special cause variation as if it were common cause.

The last area of profound knowledge is psychology. This is often the most challenging part of improvement work. Deming believed in intrinsic motivation, and the need to nurture people’s joy in work and intrinsic motivation to learn.⁶ More recently John P. Kotter describes eight steps to change in his book *The Heart of Change*. These are increase urgency, build the guiding team, get the vision right, communicate for buy-in, empower action, create short-term wins, don’t let up, and make change stick.⁸

Approaches to Quality Assessment

QUALITY ASSURANCE VERSUS CONTINUOUS QUALITY IMPROVEMENT

Although the terms *continuous quality improvement (CQI)* and *quality assurance (QA)* were used interchangeably in the past, substantial differences existed between the two. Most medical CQI systems were built on the foundation of a traditional QA system that used *standards* to define quality.⁹ Standards can be defined as an “acceptable” level of performance. For example, a standard for overall mortality after cardiac surgery is less than 3%; however, is 3% (vs. 4% or 2%) mortality after cardiac surgery acceptable? Similarly, a standard for head injury evaluation is a computerized tomography (CT) brain scan within 4 hours of admission, but in certain circumstances, patients with head injury may warrant a CT scan sooner than that.

Most standards are inherently arbitrary and often lack consensus among medical professionals.⁹ Additionally, QA systems typically react only when a standard is not met. Examples of traditional standard-based QA systems were peer review systems and morbidity and mortality reviews. These systems often exist to flag certain cases or practitioners for intense review. Practitioners may regard this intense review as a punishment because only “failures” or “bad apples” are identified, and process failures are not connected with the outcome on every case. Thus, QA systems are inherently judgmental and, if not carefully administered, can hold practitioners responsible for random causes over which they have no control. CQI systems, on the other hand, recognize that errors occur and require different responses. Often excellence in health care is not identified by analysis of QA systems. Excellence is sometimes defined by the lack of failure. Is there a difference between good (acceptable) and excellent health care?

Systems within health care are a series of interlinked processes, each of which results in one or more outputs. CQI systems, as opposed to QA systems, include an explicit approach to process and the use of specifications to improve a process or outcome. A specification is an explicit, measurable statement regarding an important attribute of a process or the outcome it produces.⁹ Specifications identify variables that need to be measured, but typically do not set acceptable limits or standards. Once specifications have been defined in a CQI system, all outputs or cases, not just failures, are evaluated against these specifications. The system then attempts to correct errors by fixing the process rather than the people. Thus, CQI aims to change the process and prevent quality failures before they happen by building improvements into the process. To quote Philip Crosby, “The system for causing quality is prevention, not appraisal.”¹⁰

FRAMEWORKS FOR IMPROVEMENT

Model for Improvement

The journey toward improvement can be made more efficient and more effective with a systematic approach. The Model for Improvement, developed by the training and management consulting company Associates in Process Improvement (<http://www.apweb.org>), is one such

TABLE 5.1 Steps of a Plan, Do, Study, Act (PDSA) Cycle

Step	Description
Plan	Make a plan for the test of change. Include predictions of results and how data will be collected.
Do	Test change on a small scale. Document data, observations, and problems that occur.
Study	Use data gathered from previous stages to build new knowledge and make predictions. Knowledge is gained from both successful and unsuccessful changes.
Act	Adopt the change, or use knowledge gained to plan or modify the next test of action.

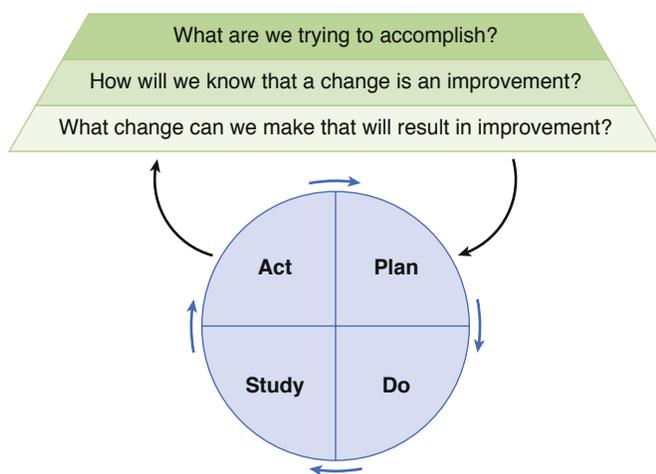


Fig. 5.1 Diagram of model for improvement. (From Langley GJ, Moen RD, Nolan KM, et al. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. San Francisco: Jossey-Bass; 2009. With permission from John Wiley & Sons.)

approach adopted by organizations across varied disciplines and is currently the approach used by IHI. It is a structured, dynamic model that applies the scientific method to testing and implementing a change.⁷ In 1939, Walter A. Shewhart, a physicist, engineer, and statistician, introduced the science of modern QI.¹¹ He introduced a three-step scientific process of specification, production, and inspection, stating that “these three steps must go in a circle instead of in a straight line.”¹² In the 1940s, his protégé, W. Edwards Deming, applied these concepts to government and industry and developed the Plan, Do, Study, Act (PDSA) cycle (Table 5.1).¹³ A modification of the PDSA by the addition of three fundamental questions (as explained in the next paragraph) resulted in the Model for Improvement (Fig. 5.1).¹²

Beginning an improvement project with the three fundamental questions for improvement helps set a clear direction for the project, define what success will look like, and hypothesize successful interventions. The three fundamental questions for improvement are:

1. Aim: “What are we trying to accomplish?” The aim (or objective) for improvement should be specific, measurable, actionable, relevant, and time-specific (also referred to as a SMART aim). Ideas for improvements may come from interviewing those involved or affected by the process, such as staff or patients. Ideas may also

come from examining previous data on operational, clinical, or financial processes.

2. Measure: “How will we know if change is an improvement?” Ideally, measures should be linked directly to the aim or goal of the project and should ensure that the interests of the stakeholders of the process are represented.⁷ Quantitative measures should be used when possible to measure change over time. These measures provide the feedback that enables one to know whether or not the change is an improvement. However, not all projects have an easily quantifiable outcome and the outcome may be more qualitative. It is worth the time and effort to identify opportunities to translate goals into quantifiable outcomes if possible. These can be easier to use to communicate success.
3. Changes: “What changes can we make that will result in improvement?” Ideas for changes that result in improvement often start with observations, modeling the success of others, and brainstorming. The more intimate the understanding of a process and its key drivers, the higher the likelihood of generating successful changes.

The three fundamental questions are followed by a PDSA cycle, which is the framework for testing and implementing previously generated ideas for change. Improvement may require multiple cycles of preferably small tests of change over time. By testing changes on a small scale before implementation, risk is mitigated. Small tests of change may also help overcome individuals’ resistance to change. Through repeated cycles, increased knowledge is acquired, and actions are continuously modified or changed. Measures defined in the first part of the model help determine whether or not a change is a success. These measures are often plotted over time on run charts or control charts (Figs. 5.2 and 5.3). Knowledge can be gained from both successful and unsuccessful tests! Finally, PDSA cycles both test a change and implement a successful change on a larger scale or in diverse clinical areas.

Lean Methodology and Six Sigma

In addition to the Model for Improvement, CQI initiatives have many other frameworks. Two of these frameworks, Lean Production and Six Sigma, are briefly discussed here. These frameworks are sometimes combined, as in “Lean Six Sigma.” Regardless of which framework is employed, benefits are gained by retaining a structured and consistent approach to CQI.

Lean methodology has its roots in Japanese manufacturing, particularly in the Toyota Production System.¹⁴ More recently, Lean has found success in the healthcare industry. Two notable examples of its use are Virginia Mason Medical Center and ThedaCare, Inc., both of which have transformed their organizations through the application of Lean principles. In fact, ThedaCare reported \$3.3 million in savings in 2004 with reduced accounts receivable, redeployed staff, reduced phone triage times, reduced time spent on paperwork, and decreased medication distribution time.¹⁴

Lean methodology is focused on creating more value for the customer (i.e., the patient) with fewer resources. Every step in a process is evaluated to differentiate those steps that add value from those that do not. The ultimate goal is to eliminate all waste so that every step adds value

TABLE 5.2 Steps in the Lean or Six Sigma Process

Step	Description
Define	Define the goals of the improvement project. Obtain necessary support and resources and put together a project team.
Measure	Establish appropriate metrics. Measure baseline performance of the current system.
Analyze	Examine the system for possible areas of improvement.
Improve	Improve the system through implementation of ideas. Statistically validate improvements.
Control	Institutionalize the new system and monitor its stability over time.

to a process. Other key components of Lean include reducing unevenness of workflow—for instance, what we might find in intensive care unit (ICU) admissions or emergency cases—and eliminating the overburdening of people and equipment. Five principles govern Lean improvement:⁷

1. *Define the value* that the customer is seeking. Virginia Mason Medical Center has a “patient-first” focus for all its processes.¹⁴
2. *Identify and map* the value stream. If evaluating preoperative assessment, map the physical flow of a patient from the scheduling of a procedure through the day of surgery (history and physical, preoperative counseling, laboratory tests, imaging, consultations). In this process, all of the steps are accounted for, including the back-and-forth flow of the patient to the front desk, to the laboratory, and so on. Time spent during each step of the process should be documented.
3. *Smooth the flow* between value-added steps. Eliminate steps that do not add value to the overall process and are likely a poor use of time or effort on the part of the caregivers or the patient. An example of this process might be eliminating unnecessary tests or consultations in a patient’s preoperative evaluation and reducing excess wait times that are the result of correctable inefficiencies.
4. *Create pull* between steps. Customer demand should trigger the start of a downstream process. Examples include opening operating rooms (ORs) or increasing staffing based on surgical demand, as opposed to having a fixed amount of time for each surgeon or surgical division.
5. *Pursue perfection* by continuing the process until you have achieved ultimate value with no waste.

The transformation of Motorola in the 1980s from a struggling company to a high-quality, high-profit organization helped give rise to the Six Sigma methodology. Two key fundamental objectives of Six Sigma are a virtually error-free process and a large focus on reducing variation.¹⁵ In fact, a Six Sigma process, or a process whose frequency falls six deviations from the mean, corresponds to just 3.4 errors per million.

Health care often falls far short of this standard. In a 1998 report, Chassin¹⁶ reported that hospitalized patients harmed by negligence were at a four sigma level (10,000/million), patients inadequately treated for depression were

at a two sigma level (580,000/million), and eligible heart attack survivors who failed to receive β -adrenergic blockers were at a one sigma level (790,000/million). In contrast, Chassin found that anesthesiology was the one healthcare specialty that approached the six sigma level, with deaths caused by anesthesia as low as 5.4/million.¹⁶ In comparison with health care, airline fatalities were a two sigma process (230/million) and a traditional company operated around four sigma, the equivalent of 6200 errors/million.¹⁶ Considering that errors are often tied directly to cost, this error rate has significant financial implications.

Six Sigma is similar to the Model for Improvement in that it makes use of a simple framework to guide improvement, in this case using Define, Measure, Analyze, Improve, Control (DMAIC).¹⁵ The DMAIC steps are described in Table 5.2. As mentioned earlier, many organizations have found the greatest benefit by combining elements of different methodologies in their CQI work. One popular example of this is Lean Six Sigma, which combines improvements in flow and value with reduction in error and variation. Furthermore, individual tools from these strategies, such as PDSA cycles or DMAIC processes, can be applied where appropriate.

The Value Framework in Health Care

Since quality in health care is focused on patient outcomes, another approach to quality is the value framework. Quality relative to cost determines value. Hence, in health care, value is defined as the patient health outcomes achieved per dollar spent.¹⁷ Value should define the framework for performance improvement in health care. Value includes goals already embraced by health care such as quality, safety, patient centeredness, and cost containment; the value framework allows for a way to integrate these goals.

Because value is always defined around the customer, in the healthcare industry it is what matters most to patients, and unites the interests of all the stakeholders in the healthcare system. Thus, when value improves, not only do patients, payers, providers, and suppliers all benefit, but the economic sustainability of the healthcare system also improves. As such, value should be the overarching goal of healthcare delivery. According to Porter, the failure to adopt value as the central goal in health care and the failure to measure it, are the most serious failures of the medical community.¹⁸

Value measurement today is limited and highly imperfect. Value should be measured by outputs not inputs. Thus, value is dependent on patient health outcomes and not the volume of services delivered. The only way to accurately measure value is to track individual patient outcomes and costs longitudinally over the full cycle of care, which can vary from 30 to 90 days for hospital care and 1 year for chronic care.

Value is not measured by processes of care utilized by a patient. While process measurement is an important component of improvement, it should not be substituted for measurement of patient outcomes. Outcomes and cost should be measured separately. Outcomes, the numerator of the value equation, refer to the actual results of care in terms of patient health and should consist of a set of multidimensional outcomes that, when considered together, constitute patient benefit. Cost, the denominator of the value equation, should include total costs involved in the full cycle

of care for the patient's medical condition. Most physicians do not know the full costs of caring for a patient, thus they lack the information to make real efficiency improvements.

Outcomes measurement is critical to driving rapid improvements in health care. Without a feedback loop that includes the outcomes achieved, providers lack the information they require to learn and improve. Effective outcome measurement is hampered by several problems. First, there is a lack of consensus as to what constitutes an outcome. Second, electronic medical record (EMR) systems often do not facilitate the capture of longitudinal outcomes measures with appropriate scope; these systems may focus too narrowly or too broadly, giving only a partial view of patient outcomes. Third, outcomes such as infection rates may vary substantially by medical condition. Finally, true outcome measurement has been limited because the cost of gathering longitudinal patient results is high, due in part to fragmented organizational structures and poor EMR interoperability.

Cost is the most pressing issue in health care. Current cost measurement approaches have not only hampered our understanding of costs but also contributed to approaches involving cost-containment. A focus on cost-containment rather than value improvement can be dangerous and is often self-defeating. Two major problems associated with cost measurement include: (a) cost aggregation, wherein we often measure and accumulate costs based on how care is organized and billed for, that is, costs for departments, discrete service areas, and line items such as supplies or drugs and (b) cost allocation where the costs of healthcare delivery are shared costs, involving shared resources and as such are normally calculated as the average cost over all patients for a department. A good example of this is the hourly charge for the OR. However, to truly understand costs, they must be aggregated around the patient, rather than discrete services, and shared costs must be allocated to individual patients on the basis of each patient's actual use of the resources involved. Finally, the perspective used to calculate costs matters and patient costs including lost work may not be included in the analysis.

Proper measurement of outcomes and costs is the single most powerful lever for improving healthcare delivery and although current measurements are highly imperfect, the process of measurement has begun. As Michael Porter outlines in the framework papers underpinning his value commentary in the *New England Journal of Medicine*,¹⁸ if all the stakeholders in health care were to embrace value as the central goal and measure it, the resulting improvements would be enormous.

Quality Improvement Measures and Tools

The concept of using measurement to drive improvement has its origins in both medicine and industry. The use of data to improve patient health originated in the mid-1800s with two pioneers, Florence Nightingale and John Snow. Nightingale used data on mortality among British soldiers to drive improvements in sanitation in field hospitals. Similarly, Snow used data on the incidence and geographic location of cholera to make the connection between the

incidence of the disease and water obtained from the Broad Street water pump. In the early 20th century, Ernest Codman, a surgeon at Massachusetts General Hospital, was the first to advocate tracking of patient outcomes so that adverse events could be identified and improvements in care made for future patients.¹⁹ In the 1960s, Avedis Donabedian emphasized the importance of measurement and described a model for evaluating quality of health care based on structure, process, and outcomes—*structure* being the environment in which health care is provided, *process* being the method by which it is provided, and *outcomes* being the result of the care provided.²⁰ More recently, in 1991, Paul Baltaden and Don Berwick developed the IHI, which has become one of the leading organizations in the application of improvement science to health care.²¹

In QI, measurement can serve many purposes. It can be used to identify problems and establish baseline performance, inform and guide QI projects, select and test changes for improvement, and assess and align progress with organizational goals. Selecting and developing measures that are useful can be challenging. Optimal measures must be comprehensive, carefully defined, tailored to the target audience, and involve minimal measurement burden. Target audiences usually include clinical staff, so measures should address and align with clinical targets for specific patient populations with whom the staff work. Measures should pass the face validity test with clinical practitioners delivering care. National or organizational measures, if applicable, can also be used, but they may not always be relevant or credible to the local target audience. Within an organization, target audiences should include system leaders, so measures should also align with organizational priorities and strategic goals.

PROCESS AND OUTCOME MEASURES

Measures should include the following:

1. Process measures that address the processes of healthcare delivery (e.g., perioperative β -adrenergic blocker administration for patients, antibiotic administration for prevention of surgical site infection)
2. Outcome measures that address patient outcomes from delivery of these services, such as clinical and functional outcomes or satisfaction with health (e.g., morbidity, mortality, length of stay, quality of life)
3. Balancing measures that address the possible consequences of changes in the process (e.g., when process improvements are made to improve efficiency, other outcomes, such as patient satisfaction, should not be adversely affected)

Each of these measures has advantages and limitations.²² A comprehensive set of measures should include at least one process, outcome, and balancing measure. In addition, structural measures, such as ICU nurse-to-physician staffing ratios, can be important to include when appropriate.^{23,24}

Healthcare providers readily accept process measures because they demonstrate the degree to which caregivers can influence a process with the intention to improve patient outcomes. Practitioners generally feel more accountable for the process of care than its outcomes, because outcomes

may be affected by many other variables.²² An obstacle to using process as a measure of quality is sustainability; frequent updating is required as the science of medicine advances.

Process measures, which evaluate how care is delivered, may be easier to measure and implement than outcome measures and can provide important insight into care.²⁵ Process measures can provide immediate feedback regarding performance, allowing for rapid improvements in care. If an outcome occurs infrequently, providers will be unable to obtain meaningful feedback on outcomes on a timely basis. For example, evidence of improved rates of catheter-related bloodstream infections (CRBSI; an outcome measure) may require 12 to 24 months of data (because few patients develop infections), whereas improved adherence to evidence-based practices to reduce infections (process measures) may be observed within a week (because all patients can be evaluated to determine whether they received the intervention).

Process measures have two other important advantages. First, they generally have face validity for providers, meaning that providers believe they can use the data to improve care; and second, because risk adjustment is less important, broad implementation is feasible. Moreover, joint efforts among providers, professional societies, and external government or payer agencies have made process measures more feasible.²⁵

To be valid, process measures should have causal links to important outcomes; a change in the process should produce a desired change in outcome. One of the best opportunities to improve patient outcomes may well come from discovering how to deliver therapies (processes) that are known to be effective in producing a desired outcome.²⁶ For example, hand hygiene and application of chlorhexidine to sterilize the skin site before insertion of a central venous catheter (CVC) are two of five processes known to reduce CRBSI.²⁷ Process measures such as these are indicators of whether patients reliably receive evidence-based interventions known to prevent complications.

Although process measurement is useful and should continue, there is no substitute for measuring outcomes, whose principal purpose is not comparing providers but enabling innovations in care. Process measurement should largely be an internal effort, but should not be the means of external measurement and reporting of quality and value. As mentioned above, measuring value requires measuring actual outcomes over time.

Outcome measurement refers to the actual results of care in terms of patient health over time; for each medical condition there is a set of multidimensional outcomes that together constitute patient benefit. These include survival, functional status, and sustainability of recovery. Outcome measures relate directly to the health status of the patient. Patient satisfaction with care is a process measure, not an outcome. Patient satisfaction with health is an outcome measure. However, current measures for outcome often focus on the immediate results of particular procedures or interventions rather than on the overall success of the full cycle of care of a medical condition.

The relative focus on outcome and process measures will depend on balancing the collection of data between that which is scientifically sound and that which is feasible. In

general, a balanced set of process and outcome measures helps inform improvement efforts and provides evidence that efforts have made a difference in the lives of patients.

For measurement to be effective, the following principles are important. First, measures should focus on something that the improvement team has the power to change and should initially be simple, small-scale measures that focus on the process itself and not on people. Second, measures should be practical, seek usefulness—not perfection—and fit the work environment and cost constraints. Third, data for measurement should be easy to obtain; finding ways to capture data while the work is getting done allows measures to be built into daily work. Fourth, qualitative data (e.g., reasons for patient dissatisfaction in the patients' own words, observations to contextualize quantitative data) are highly informative and should complement quantitative data (e.g., percentage of patients satisfied with care). Finally, when using measures, balance is key; a balanced set of measures can help answer the question, "Are we improving parts of our system at the expense of others?"

Measurement should not overwhelm the change process. Improvement teams should minimize the burden of measurement whenever possible. Measurement can have both direct and indirect consequences on resource use, provider behaviors, and patients.²⁸ Measurement of performance and outcomes of care can be costly, especially if the data collection process is manual and involves chart reviews. The burden of measurement is reduced with an EMR system and computerized order entry, although these information technology systems are costly to implement and maintain. Additionally, these resources may not be equally available throughout a system or organization, leading to disparities in the care provided.

Measurement fixation is an unintended consequence on healthcare staff behavior that may occur with the use of process measures. For example, when a process measure such as "the percentage of diabetic patients who received an action plan" is used rather than an outcome measure such as "improved patient understanding about diabetic management," the measure is perceived by the clinician as defining what is important. Thus, measurement of the process becomes the priority, rather than the intended outcome.²⁸ Alternatively, the clinician may become so focused on what is being measured that different aspects of care are not equally prioritized. In addition, a predominance of process rather than outcome measures can stifle innovation by scripting a process, thus inhibiting process-level innovation. Practice variation does have some utility because medical practice is dynamic, and it is through the trial of new methods of care that innovation occurs. Finally, QI performance measures may not match patient preferences for clinical care. Performance measures that do not take patient preference into account can lead to decreased patient satisfaction, trust, and confidence in their healthcare practitioners and system.²⁸ Thus, selection of a set of appropriate measures with the attributes described previously can be a balancing act that includes weighing the tradeoffs involved.

Consumers, payers, and employers are increasingly requesting outcome measures to both improve care and decrease cost. Even national governmental bodies are influencing the measurement and reporting of quality in health care. In the United States, the Centers for Medicare

and Medicaid Services (CMS), the single largest healthcare purchaser, requires hospitals and physicians to participate in the Quality Payment Program (QPP). This program requires providers to demonstrate quality by either participating in an Advanced Alternative Payment Model (akin to a quality collaborative or participants in a bundled payment model) or by accumulating points through the Merit-based Incentive Payment System.²⁹ The United Kingdom Quality and Outcomes framework³⁰ is an analogous system. These quality mandates have fundamentally changed the ways that clinicians, hospitals, and health systems engage in and report QI activities.

ANALYSIS AND DISPLAY OF QUALITY IMPROVEMENT DATA

Interpretation of data and understanding of process variation are fundamental to QI work. Data elements central to improvement are first and foremost—those data are collected as a basis for action. Second, interpretation of data is made within the context of the process. Last, the analysis technique should filter out noise in the process. Aggregate data or summary statistics typically do not filter out noise in the system and do not present a broad enough context to point practitioners in the direction of proper action or process improvement.

Shewhart postulated that data contain both signal and noise; to be able to learn, one must separate the signal from the noise.³¹ CQI science defines two types of variation within a process: random variation and specific variation. Random variation, also known as common-cause variation, results from differences in the inputs that a process receives or inherent factors in the process itself. Random variation is the random background noise within a system and occurs in the process all the time. Specific variation, also known as special-cause or attributable variation, is not present all of the time as background noise, but rather arises from one or more specific causes that are not part of the system. A process is considered to be unstable when specific variation exists, and efforts should be made to learn about the special causes for this variation. A stable process exists when specific variation no longer occurs, leaving only random or common variation.⁹ CQI aims to eliminate specific variation for every process so that only random variation remains. A standards-based QA system fails to distinguish random cause from special cause and attempts to correct all variation. Attempts to correct random variation will necessarily fail—a process CQI defines as “tampering.” When a process exhibits only random variation, the process should be evaluated to determine whether it is functioning at an acceptable level. If it is not, the process will need to be changed so that the average is moving in the desired direction. Standardization of a process is often the key to reducing random variation and improving a process.

Run Charts and Control Charts

Run charts and control charts are graphic displays of data that enable observation of trends and patterns over time. They are the best tools for determining whether improvement strategies have had an effect. A run chart (see Fig. 5.2), also called a time series chart, plots the variable or measure being studied on the vertical axis and plots the time on the

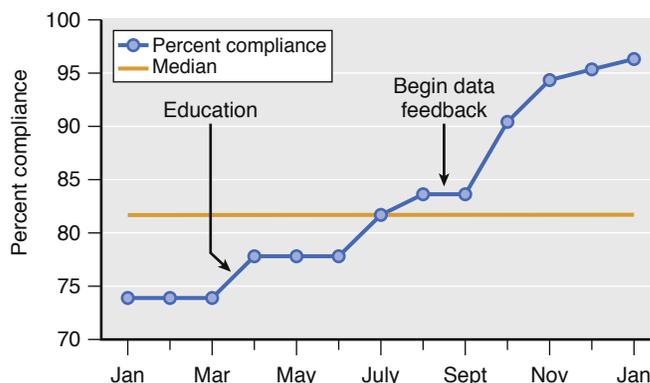


Fig. 5.2 Example of a run chart. This chart shows the plot of a performance measure over time. The horizontal (x) axis represents time in months, and the vertical (y) axis represents the performance measure—the percentage of compliance with the timing of preoperative antibiotics.

horizontal axis. The average, or centerline, is the median. At least 12 data points are required to establish a baseline, and at least 20 to 25 data points are required to detect trends and patterns. Run charts should be annotated with tests of change to provide the context within which data can be interpreted. Four rules can be used with run charts to determine whether nonrandom patterns exist or to detect whether the change has led to an improvement:

1. A shift is indicated by six or more consecutive points above or below the median.
2. A trend is indicated by five or more points all increasing or all decreasing.
3. A run is defined as a series of consecutive points on the same side of the median line.
4. An astronomical data point is an unusual point that is obviously different in value (an outlier).⁷

Because change is by nature temporal, run charts in which data are presented over time are powerful tools for interpreting data within the context of the process.

A control chart (see Fig. 5.3),³² also known as a Shewhart chart,^{7,11} is an extension of a run chart and is used to distinguish between specific and random variation. As on a run chart, the variable is plotted on the vertical axis and time on the horizontal axis. However, with a control chart the centerline or average is the mean, rather than the median, and the upper control limit (UCL) and lower control limit (LCL) are calculated. The UCL and LCL correspond to ± 3 sigma from the mean. A process is considered to be “in control,” or stable, when data points are within these control limits.¹¹ Random variation, or variation that is the result of the regular rhythm of the process, produces a stable process. However, in an unstable process that contains variation from special causes, data points exceed the UCL or LCL.³³

Failure Modes and Effects Analysis

A failure modes and effects analysis (FMEA) is a tool to help identify problems in a process before they occur and cause harm.⁷ An FMEA can help you decide where to target your improvement efforts. In addition, the proactive approach makes it especially useful before implementing a new process.

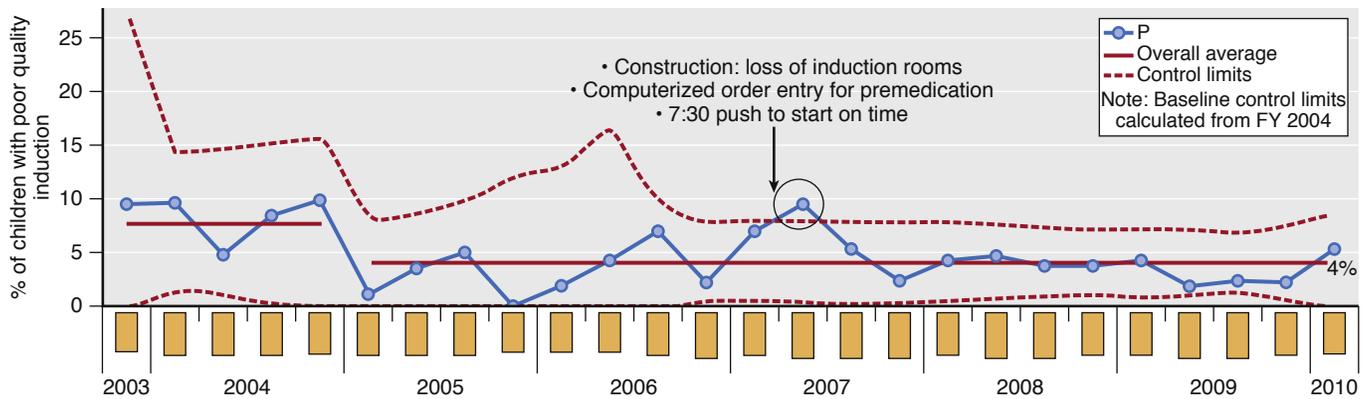


Fig. 5.3 Example of a control chart that monitors the quality of the anesthesia induction process, as measured by an induction compliance checklist. The solid red line marks the mean, and the dashed lines indicate the upper control limit and lower control limit, which are ± 3 standard deviations from the mean. The circled point represents a single special cause variation in quality of induction. (From Varughese AM. Quality in pediatric anesthesia. *Paediatr Anaesth.* 2010;20:684–696.)

An FMEA reviews the steps in a process, the potential failure modes (what could go wrong), failure causes (why would the failure happen?), and failure effects (what would be the consequences?). (IHI, QI Essentials Toolkit) After listing the steps in a process, a risk profile number is calculated based on the likelihood of occurrence, likelihood of detection, and severity. Improvement efforts are then targeted at the steps with the highest risk profile number.

A simplified FMEA is a quicker version of the FMEA that can help guide improvement work. A simplified FMEA consists of listing the steps in a process, listing potential failures that could go wrong for each step, and brainstorming interventions for each of those possible failures. Below is an example simplified FMEA for programming infusion pumps that was used in an improvement project to reduce medication errors.

Putting It All Together: An Example Quality Improvement Project

The following is an example of how the QI methodology previously discussed could be used to address a practical problem. A hypothetical example of reducing medication errors in an anesthesiology department is described.

An anesthesia group was concerned over the large number of medication errors that were occurring in their department. They formed a multidisciplinary group including an anesthesiologist, nurse anesthetist, anesthesia resident, and pharmacist. They addressed the first question in the Model for Improvement—“What are we trying to achieve?”—by writing a SMART aim. Their SMART aim was to reduce medication errors in the Department of Anesthesiology from three errors per month to one error per month within 12 months.

The next question in the Model for Improvement is “How will we know that a change will result in an improvement?” In order to monitor their progress, they constructed a run chart of medication errors per month in their department. They captured data through a previously existing self-reporting system.

The last question of the Model for Improvement is “What changes can we make that will result in an improvement?” To better understand the errors that were occurring, the group categorized the medication errors into categories and

constructed a Pareto Chart. A Pareto Chart is a bar chart in which categories are listed in descending order. The group learned that three categories of errors accounted for about 80% of the total number of errors. These categories were infusion pump errors, acetaminophen errors, and antibiotic errors. They decided to focus their initial efforts on these three categories. They created process maps for these three categories to better understand the current process and develop possible interventions. Finally, to help organize their theory of improvement, they created a key driver diagram listing the drivers they thought would affect their aim, as well as possible interventions targeting the drivers.

Now that they had a theory of improvement, they started testing their interventions. They tested their ideas using PDSA cycles. They adopted the successful tests, adapted tests with mixed results, and abandoned the failed tests. Some of their tests included requiring a sticker from pharmacy and requiring a two-person double check of infusion pumps. As their testing and implementation continued, they saw the centerline, or median, of the run chart decrease from three to two. The run chart rules indicated this was a significant change. The group was excited that they had decreased the number of medication errors in their department, but they had not yet reached their aim of no more than one medication error per month. They decided to continue testing new ideas until the median decreased to less than one error per month.

Dashboards and Scorecards

A dashboard of measures functions like an instrument panel for an aircraft or automobile and provides real-time feedback on what is happening. Balanced *scorecards*, or “whole system measures,” are similar to dashboards and are used to provide a complete picture of quality. Developed by Kaplan and Norton, the balanced scorecard is defined as a “multi-dimensional framework for describing, implementing, and managing strategy at all levels of an enterprise by linking objectives, initiatives, and measures to an organization’s strategy.”³⁴ A set of measures should reflect the culture and mission of an organization. Viewed collectively, this set of measures provides a gauge of current performance and can also guide the direction for future organizational improvement efforts. A balanced set of measures is critical to ensure

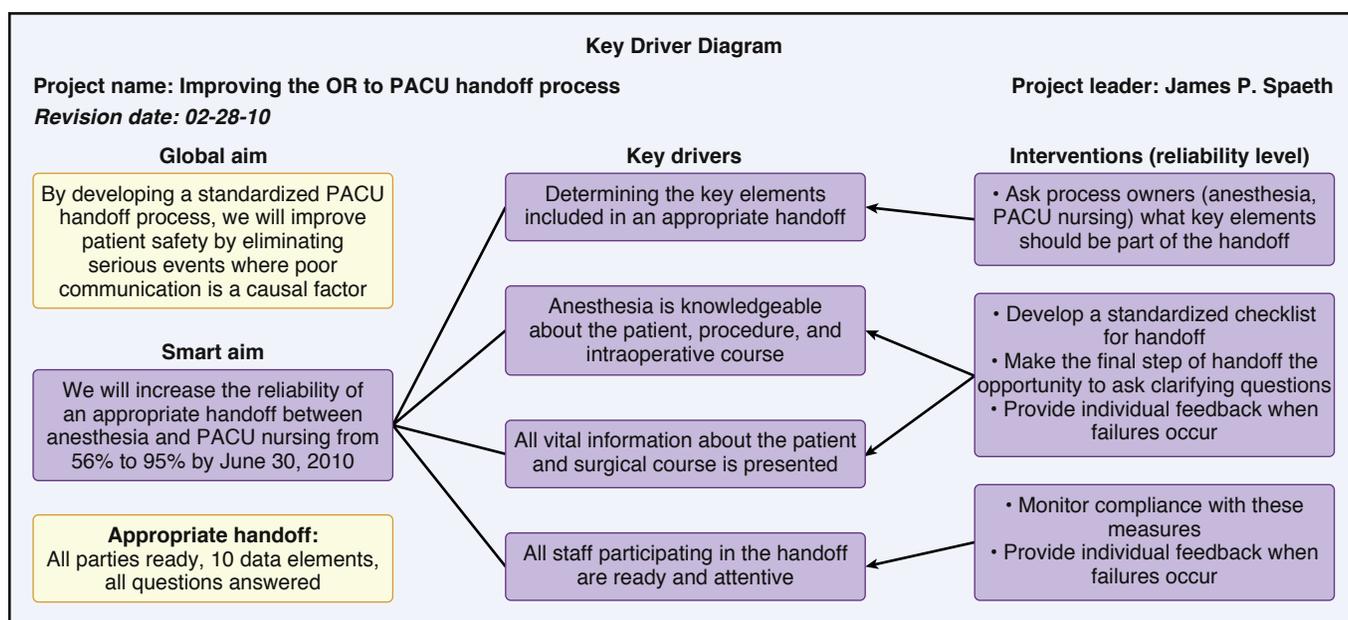


Fig. 5.4 Example of a key driver diagram developed to improve the operating room (OR) to postanesthesia care unit (PACU) handoff process. This diagram incorporates the global and smart aim of the project, the key drivers inherent to the process, and specific interventions targeting each of the key drivers. (From Boat AC, Spaeth JP. Handoff checklists improve the reliability of patient handoffs in the operating room and postanesthesia care unit. *Paediatr Anaesth.* 2013;23(7):647-654.)⁹³

that improvement efforts in one area do not adversely affect outcomes in other areas.

Additional Quality Improvement Evaluation and Communication Tools

In most situations, QI frameworks such as the Model for Improvement or Lean Sigma are sufficient to help guide the development, testing, implementation, and spread of improvement. However, to better understand problems within a system or process, QI professionals have developed or adapted a number of methods and tools. Some of these methods and tools help with viewing systems and processes and organizing and communicating information. These are described in the following section.

Understanding how a process or system works is fundamental to improving it. Process mapping is a method to gain this understanding. A flow diagram, or flow chart, is an improvement tool used during process mapping; it provides a visual picture of the process being studied, wherein the series of activities that define a process is graphically represented. Flow charts identify and clarify all steps in the process. They also help the team understand the complexity of the process and identify opportunities for improvement.

Failure mode and effects analysis is a systematic, proactive method of identifying and addressing problems associated with a process. It uses a standardized approach to analysis that includes identifying the various steps in a process and addressing their failure modes, effects, and possible interventions.

A key driver diagram (KDD) (Fig. 5.4)³⁵ is another approach to organizing the theories and ideas for improvement that a team has developed. The KDD presents the aim or outcome of the project with both the theories (key drivers) behind the improvement and ideas for test of change.⁷ Initially, the driver diagram helps lay out the descriptive theory behind the improved outcomes. As these theories

are tested, the driver diagram is updated and enhanced to develop a predictive theory. KDDs are extremely useful because they provide a shared mental model for the team during its improvement efforts.

IMPROVEMENT INTERVENTION TOOLS

Efforts in QI and patient safety have produced tools with which to reorganize the way care is delivered. QI intervention tools are used to improve communication and teamwork. Examples of these tools include daily goals sheets, briefings/debriefings, and checklists.

Daily Goals Sheet

For nearly 20 years, documentation of daily goals as either a hand-written sheet or a whiteboard have been used to improve communication during multidisciplinary rounds in adult and pediatric ICUs.^{36,37} As a one-page paper checklist, this tool would be completed every morning to establish the care plan, set goals, and review potential safety risks for each patient (Fig. 5.5).

Before implementation of the daily goals sheet in an adult ICU, an initial survey showed that ICU team members were unable to answer two simple questions after rounding at each patient's bedside: "Do you understand the patient's goals for the day?" and "Do you understand what work needs to be accomplished on this patient today?" Fewer than 10% of the residents and nurses knew the care plan for the day—a finding that was not surprising because traditional bedside rounds tended to focus on teaching the staff about disease processes rather than focusing on the work that was necessary to treat the patient. Approximately 4 weeks after the daily goals sheet was implemented, 95% of residents and nurses understood the goals for each patient. Moreover, after the daily goals sheet was implemented, length of stay in the

	Room Number _____	Shift: <input type="checkbox"/> AM / <input type="checkbox"/> PM
Safety	What needs to be done to d/c patient from the ICU?	
	Patient's greatest safety risk? How can we ↓ risk?	
	What events or deviations need to be reported? ICUSRS issues?	
Patient Care	Pain & Sedation Management	Pain goal ____ /10
	Cardiac Review ECGs	HR goal ____ <input type="checkbox"/> at goal <input type="checkbox"/> ↑ <input type="checkbox"/> ↓ β-blockade
	Volume status Net goal for midnight	Even <input type="checkbox"/> Pos <input type="checkbox"/> Neg ____ Net ____ (cc) <input type="checkbox"/> Patient determined
	Pulmonary: Ventilator, ventilator bundle, HOB ↑, wean	<input type="checkbox"/> OOB/pulmonary toilet/ambulation
	SIRS/Infection/Sepsis evaluation Temp >38°C or <36°C; HR >90 RR >20 or PaCO ₂ <32 WBC >12000 < 4000 or >10% bands	<input type="checkbox"/> No current SIRS/sepsis issues <input type="checkbox"/> Known/suspected infection <input type="checkbox"/> Culture blood ×2/urine/sputum <input type="checkbox"/> Antibiotic changes <input type="checkbox"/> Discontinue sepsis bundle
	Can catheters/tubes be removed?	Y/N
	GI/Nutrition/Bowel regimen: TPN catheter, ND tube PEG needed?	<input type="checkbox"/> TPN <input type="checkbox"/> NPO/Advance diet
	Is patient receiving DVT/PUD prophylaxis?	Y/N
	Can meds be discontinued, changed to PO, adjusted?	
	To Do	Tests/Procedures today
Scheduled labs		
AM labs needed/CXR?		
Consultations		
Description	Has primary service been updated?	
	Has family been updated?	
	Social issues addressed?	
	Long-term/Palliative care	

Fig. 5.5 Example of an intensive care unit (ICU) daily goals sheet. *CXR*, Chest radiograph; *d/c*, discharge; *DVT*, deep vein thrombosis; *ECG*, electrocardiogram; *GI*, gastrointestinal; *HOB*, head of bed; *HR*, heart rate; *ICUSRS*, ICU self-reporting system; *ND*, naso-duodenal; *NPO*, nothing by mouth; *OOB*, out of bed; *PEG*, percutaneous endoscopic gastrostomy; *PUD*, peptic ulcer disease; *RR*, respiratory rate; *SIRS*, severe infectious respiratory syndrome; *temp*, temperature; *TPN*, total parenteral nutrition; *vent*, ventilator; *WBC*, white blood cell count.

surgical ICU decreased from a mean of 2.2 days to only 1.1 days.³⁸ These results have been reproduced in ICUs with nurses, physicians, and pharmacists. Interviews supported that communication, patient care, and education were enhanced by providing a structured, thorough, and individualized approach to the patient's care. The daily goals checklist helped to identify new patient care issues and sparked management discussions, especially for sedation, weaning, and medications.³⁶ Additionally, a QI intervention using daily goals checklists in 118 ICUs in Brazil improved the use of low tidal volumes, avoidance of heavy sedation, use of CVCs, use of urinary catheters, perception of teamwork, and perception of patient safety climate, but did not reduce in-hospital mortality.³⁷

A further improvement was implemented in a pediatric cardiac ICU using a whiteboard for visual display of the daily goals.³⁹ Use of the whiteboard increased the percent agreement among the patient care team for patient goals from 62% to over 87%.³⁷ The goals were updated as needed and used as an information source for all staff involved in the patient's care as well as for the patient's family. A daily goals display

such as this can be modified for use on other nursing units or during OR sign-out or emergency department rounds.

Checklists

Checklists have been used in health care and other industries to ensure that important steps in a process are not forgotten. The Food and Drug Administration recommends that a checklist be used when checking out and inspecting an anesthesia machine before use to ensure that the equipment and monitors are functioning properly.^{40,41} Checklists have been shown to be effective in reducing central line associated blood stream infections (CLABSI) by standardizing practice, reducing complexity, and providing a redundant safety check. The idea behind having a person, such as a nurse or another physician, be responsible for actually reading the checklist also empowers that person or anyone involved to stop the procedure if the checklist is not followed or if sterile technique is compromised. An early study showed that use of a central line insertion checklist and bundle resulted in a 66% reduction in the overall CLABSI rate; the median rate was reduced from 2.7 per 1000

Surgical Safety Checklist		
Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist, and surgeon)	Before patient leaves operating room (with nurse, anaesthetist, and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? <input type="checkbox"/> Yes	<input type="checkbox"/> Confirm all team members have introduced themselves by name and role.	Nurse verbally confirms:
Is the site marked? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.	<input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labeling (read specimen labels aloud, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed
Is the anaesthesia machine and medication check complete? <input type="checkbox"/> Yes	Has antibiotic prophylaxis been given within the last 60 minutes? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	To surgeon, anaesthetist and nurse:
Is the pulse oximeter on the patient and functioning? <input type="checkbox"/> Yes	Anticipated critical events To surgeon:	<input type="checkbox"/> What are the key concerns for recovery and management of this patient?
Does the patient have a: Known allergy? <input type="checkbox"/> No <input type="checkbox"/> Yes Difficult airway or aspiration risk? <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available Risk of >500 mL blood loss (7 mL/kg in children)? <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available	<input type="checkbox"/> What are the critical or nonroutine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss? To anaesthetist: <input type="checkbox"/> Are there any patient-specific concerns? To nursing team: <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?	
	Is essential imaging displayed? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	
		This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Fig. 5.6 World Health Organization Safe Surgery Checklist. (Reproduced with permission from World Health Organization. WHO Surgical Safety Checklist)

catheter days before the intervention to 0 by month 3 and through month 18 of the postintervention.⁴² A central line insertion checklist has since been adopted by institutions, safety groups, and regulatory agencies as a tool to ensure compliance with the best practices for CVC placement and prevent CLABSI. Checklists and central line insertion bundles are widely available online; one such resource is the IHI (<http://www.ihl.org>).

In addition to standardizing technical tasks, checklists are also used to standardize communication. Haynes and colleagues⁴³ described the use of a checklist to guide the perioperative time-out, briefing, and debriefing process. They showed that implementing the World Health Organization Surgical Safety Checklist (Fig. 5.6) reduced mortality and inpatient complications.⁴³ The use of surgical checklists is now widespread and is standard of care in most OR settings around the world. Numerous studies related to surgical checklists either as a tool or a process have shown their effectiveness, while some studies have reported limited impact. A review of 25 highly cited research papers on surgical safety checklists from 2009 to 2016 showed the complexity of standardizing, implementing, and sustaining

the use of surgical safety checklists.⁴⁴ Complexities include variations in the environment, distribution of staff, timing of when the checklist is actually used, relationship between those using the checklist, and the culture of the institution.⁴⁴ These complexities may undermine the effectiveness of checklists and should be considered prior to checklist implementation.

Briefings and Debriefings

The surgical checklist is part of the Universal Protocol, which was created to prevent wrong person, wrong procedure, and wrong site surgery. In order to address many of the other important safety issues, such as antibiotic needs, deep vein thrombosis prevention, fire prevention, special equipment needs, and blood product availability, many institutions have implemented OR briefings or huddles, as well as debriefings at the end of surgery. Preoperative briefings have been shown to improve team communication, improve compliance with best practices, and enhance the overall perception of the safety climate in the OR.⁴⁵

Briefing and debriefing tools are designed to promote effective interdisciplinary communication and teamwork.

Briefing: Before Every Procedure	
	Team introductions: First and last names, including roles; write names on board
	Verify: Patient ID band, informed consent (read out loud), site marking, OR posting, patient's verbalization of procedure (if patient awake), H&P or clinic note
	Are there any safety, equipment, instrument, implant, or other concerns?
	Have antibiotics been given, if indicated?
	What are the anticipated times of antibiotic redosing?
	Is glucose control or β -blockade indicated?
	Is the patient positioned to minimize injury?
	Has the prep solution been applied properly, without pooling, and allowed to dry?
	Have the goals and critical steps of the procedure been discussed?
	Is the appropriate amount of blood available?
	Is DVT prophylaxis indicated? If yes, describe.
	Are warmers on the patient?
	Is the time allotted for this procedure an accurate estimate?
	Have the attendings reviewed the latest laboratory and radiology results?
Debriefing: After Every Procedure	
	Could anything have been done to make this case safer or more efficient?
	Has the Surgical Site Infection data collection form been completed?
	Are the patient's name, history number, surgical specimen name, and laterality on the paper work? (must be independently verified by the surgeon)
	Did we have problems with instruments? Were they reported?
	Plan for transition of care to postop unit discussed?
	<input type="checkbox"/> Fluid management?
	<input type="checkbox"/> Blood transfusion paperwork in chart?
	<input type="checkbox"/> Antibiotic dose and interval to be continued postop?
	<input type="checkbox"/> Pain management/PCA plan?
	<input type="checkbox"/> New medications needed immediately postop?
	<input type="checkbox"/> β -blockers needed?
	<input type="checkbox"/> Glucose control?
	<input type="checkbox"/> DVT prophylaxis?

Fig. 5.7 Example of an operating room briefing and debriefing tool. DVT, Deep vein thrombosis; H&P, history and physical; ID, identification; OR, operating rooms.

Both have been used in the OR, during sign-out from the ICU nursing staff to the intensivist, and between OR nursing and anesthesia coordinators.^{40,46,47} A briefing is a structured review of the case at hand that takes place among all team members before the start of an operative procedure. A debriefing occurs after the procedure; the team reviews what worked well, what failed, and what could be accomplished better in the future (Fig. 5.7).

An example of an OR briefing includes introduction by name (first and last) and role of each team member, confirmation of the correct patient, confirmation of the site/side and procedure (time-out), and a verbal assurance that all team members agree that they understand the procedure and what is required to ensure its success. A check of all necessary equipment, medications (e.g., appropriate antibiotic), and blood availability is performed. The question, "If something were to go wrong, what would it be?" is asked, and plans to mitigate or respond to the potential hazard are discussed.

A collaborative effort by the Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense adopted crew resource management strategies for OR briefings and produced an evidence-based resource called Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) www.ahrq.gov. This

team approach in the OR encourages situational awareness and communication among all members of the health-care team.⁴⁸⁻⁵¹

Sources of Quality Improvement Information

Development of a QI project first requires that an issue be identified. Baseline data are then collected and an improvement intervention instituted, often using one of the approaches described earlier. Data are re-collected after the intervention. If the intervention is found to be effective, ongoing monitoring or audits are instituted to ensure that the change is sustained. As part of the audits, feedback must be given to the providers. Healthcare providers traditionally have had limited ability to obtain feedback regarding performance in their daily work, in part because of a lack of information systems and a lack of agreement on how to measure quality of care.⁵²

Ideas for QI projects can be identified from a multitude of sources, but they typically start with surveys and input from local medical staff and reviews of reported incidents. Additional information is gathered from the literature, review of national guidelines and quality metrics, and information obtained from external or internal reviews.

Sources of QI data that span both the clinical and administrative arenas include evidence-based medicine and evidence-based clinical practice guidelines, alerts from accrediting agencies and nonprofit safety organizations, standards and guidelines put forth by medical specialty associations, closed claims databases, and government agency administrative databases. United States governmental agencies, including the AHRQ, CMS, and the National Quality Forum (NQF), promote the development and reporting of healthcare quality measures.⁵³

INCIDENT REPORTING

Voluntary incident reporting capturing hazardous conditions has been successfully used to improve patient care and foster QI programs.⁵⁴ As the potential of voluntary incident reporting is being realized in health care, this reporting has become less punitive and more focused on systems rather than on individuals. Voluntary incident reporting, when appropriately applied, helps identify hazards to patients that can then become the focus of QI efforts that seek to mitigate those hazards.⁵⁵ Unlike other methods that evaluate harmed patients, voluntary incident reporting provides the potential to also learn from near misses—incidents that did not lead to harm but were potentially hazardous. These near misses and potential hazards are a rich source for QI projects highlighting the importance of preventing harm.

All anesthesiology departments should have a process in place for capturing adverse events and near misses. Although most departments have a process for reporting, many incidents go unreported for a variety of reasons. Departments should encourage voluntary reporting without threat of punishment. Electronic capture of adverse events, near misses, and complaints can provide data that can subsequently be analyzed to identify trends and assess the degree of harm that a hazard poses to patients.

Events that occur frequently with low harm can be just as important as an event that occurs rarely with high harm. At the local level, it is more effective to focus on a more frequently occurring adverse event (e.g., perioperative skin abrasions, mislabeling of laboratory specimens) or on a process that can be measured with high frequency (e.g., hand hygiene, administration of antibiotic prophylaxis). For rarely occurring harmful events, a QI initiative may encompass a more expansive analysis of a national adverse-event database with multicenter participation.

With multiinstitutional event reporting systems, events that would rarely be seen in a single institution can be collected in larger numbers. Such systems allow analysis for common causes that increase our knowledge base for prevention initiatives. Larger multiinstitutional data gathering systems include the Vizient collaborative (the former University HealthSystem Consortium), which supports event reporting and databases that can be used to develop QI programs, benchmarking, and evidence-based practice.⁵⁶ Reporting systems that have been developed specifically to investigate rarely occurring anesthesia-related events include the Anesthesia Incident Reporting System (AIRS) created by the Anesthesia Quality Institute (AQI)⁵⁷ and Wake Up Safe, a QI initiative of the Society for Pediatric Anesthesia.⁵⁸ The AIRS program publishes a learning case each month in the *ASA Newsletter*, including a summary of a reported case with learning points.

More expansive international incident-reporting systems that are anonymous and voluntary have also been analyzed in the literature and have provided important information. Examples are the United Kingdom's Serious Incident Reporting and Learning Framework⁵⁹ and the Australian Incident Monitoring Study.⁶⁰ These incident registries do not require that the events be considered human error or preventable to merit reporting and are a source of ideas for QI projects.

Although voluntary systems often prove fruitful, many events and near misses still frequently go unreported. One way to capture these incidents is to survey local medical staff members to obtain their thoughts on how the last patient was harmed or how the next patient might be harmed. This process of performing a staff safety assessment survey is described in two later sections of this chapter (see "Collaborative Programs" and "Comprehensive Unit-Based Safety Program"). Staff safety assessment surveys can be particularly helpful for identifying issues for QI projects. Additionally, if staff members identify the issue, the likelihood is greater that they will have a vested interest in participating in the QI efforts.

PUBLISHED LITERATURE

Literature reviews offer ideas for QI topics in specific areas and information to guide interventions. For example, if the QI project plan is to reduce hazards in cardiac anesthesia, a literature review will provide reports of various cardiac anesthesia risks. Once a topic within a clinical area is selected, a literature search should be performed again to determine whether similar QI projects have been performed and whether they were successful. Such information will help with the design of a future initiative. The literature also provides published reports that identify guidelines and/or evidence-based practices that can be the basis for future programs.^{61,62}

NATIONAL INITIATIVES AND QUALITY METRICS

The AHRQ is the source for both the U.S. National Quality Measures Clearinghouse and the National Guideline Clearinghouse. Professional organizations, such as the American Society of Anesthesiologists (ASA) and the World Federation of Societies of Anesthesiologists, offer field-specific guidelines. The ASA has supported the review and development of many important guidelines that can serve as a rich source of QI initiatives. These guidelines cover a range of practices and include guidelines for the placement of central venous access,⁶³ management of patients with obstructive sleep apnea,⁶⁴ and management of preoperative fasting.⁶⁵ For those who are also involved in critical care medicine, guidelines and protocols do improve performance with specific care processes such as sedation and ventilator weaning protocols in ICUs. Such protocols decrease the duration of mechanical ventilation and ICU length of stay.^{66,67}

Review of national quality metrics is another source of ideas for QI topics. National initiatives from CMS, such as the QPP (described earlier in "Quality Improvement Measures and Tools") and Surgical Care Improvement Project (SCIP), provide quality metrics and are associated with pay for performance. Most of the SCIP measures, which predominantly

TABLE 5.3 Nonprofit and Governmental Quality Improvement Organizations Pertinent to Anesthesia

Quality Improvement Organization	Website	Description
Agency for Healthcare Research and Quality (AHRQ)	www.ahrq.gov	Lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care
American Health Quality Association (AHQA)	www.ahqa.org	Represents quality improvement organizations and professionals working to improve the quality of health care
Anesthesia Patient Safety Foundation (APSF)	www.apsf.org	Promotes investigations and programs that will provide a better understanding of anesthetic injuries
Centers for Disease Control (CDC)	www.cdc.gov	One of the major operating components of the U.S. Department of Health and Human Services
Emergency Care Research Institute (ECRI)	www.ecri.org	Uses applied scientific research to discover which medical procedures, devices, drugs, and processes are best
Institute for Healthcare Improvement (IHI)	www.ihl.org	Health care improvement organization based in Cambridge, Massachusetts
Institute for Safe Medication Practices (ISMP)	www.ismp.org	The nation's only 501(c)(3) organization devoted entirely to medication error prevention and safe medication use
Medicare Quality Improvement Community (MedQIC)	www.medquic.org	A national knowledge forum for health care and quality improvement professionals
National Quality Forum	www.qualityforum.org	Created to develop and implement a national strategy for health care quality and reporting
National Patient Safety Foundation (NPSF)	www.npsf.org	An independent 501(c)(3) organization with a mission to improve the safety of patients

measure processes of care, are topped out (nearly 100% in all hospitals) and have therefore been retired from active surveillance. The Joint Commission (TJC) website (www.jointcommission.org) lists United States National Patient Safety Goals and national quality core measures that are surveyed during site visits for accreditation. In 2004, TJC partnered with CMS to align measures common to both organizations in an initiative called Hospital Quality Measures. These measures are also endorsed by the NQF, a private, nonprofit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting (www.qualityforum.org). One of NQF's functions is to endorse quality and safety measures (consensus standards), which are then incorporated into other national quality initiatives. The goal for NQF-endorsed standards is that they become the primary standards used to measure the quality of health care in the United States. Increasingly, anesthesia programs are focusing on the standards that are relevant to the specialty because facilities are being evaluated on compliance with regulations and are required to report their performance regarding these standards to the governing bodies.

An increasing number of regional and national organizations are developing initiatives that are stimulating the reporting of specific evidence-based practices and outcomes. These initiatives are also determining the local selection of areas for QI (Table 5.3). As described earlier, reporting of these measures to CMS is being incentivized by performance-based payment. National professional organizations such as the ASA are developing metrics specific to the field.

OUTCOMES RESEARCH

The comparison of outcomes associated with different process decisions, or variations in care delivery, is the basis for outcomes research. Outcomes research offers a potential to

identify these variations in care and to determine whether they improve outcomes for patients undergoing anesthesia. One of the key issues in outcomes research is risk adjustment, a challenging goal that requires a robust dataset. Using administrative data to identify patient risk factors has many limitations.⁶⁸ Registries designed specifically for research, benchmarking, and QI are good sources for this purpose.

The Society of Thoracic Surgeons (STS) and the National Surgical Quality Improvement Programs (NSQIP) are examples of outcomes research registries. Established in the early 1990s, the STS database now includes participation by nearly all U.S. cardiac surgery centers and has developed robust risk-stratification models. Findings from this database have led to initiatives associated with significant reductions in mortality; examples include the use of β -adrenergic blockers and aspirin perioperatively and the use of internal mammary arteries for coronary artery bypass grafting. NSQIP is a newer registry that was developed by the U.S. Department of Veterans Affairs (VA). Findings from this risk-adjusted outcomes database were used to identify variations in care. The changes that were instituted based on these findings resulted in improved surgical outcomes throughout the VA network. NSQIP has been adopted by the American College of Surgeons to provide comparisons among hospitals. Currently, more than 350 general surgery centers participate.⁶⁹ Hospitals that participate submit detailed data on a sample of general surgical patients for a number of common surgical procedures. They then receive a graphic display that compares their outcomes with those of the entire cohort. Surgery centers then use these data to identify areas in which they might be able to make improvements and initiate QI projects with that focus. As an example, the Kaiser Permanente group used this information to develop a QI program focused on reducing the percentage of patients with prolonged perioperative intubation.⁶⁹

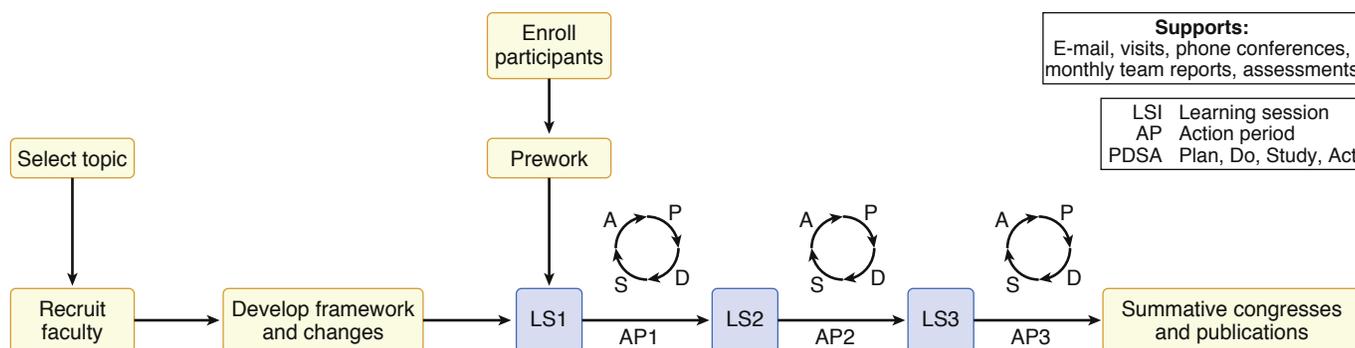


Fig. 5.8 Breakthrough series collaborative model. (Reproduced with permission from Institute for Healthcare Improvement: The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement. IHI Innovation Series white paper, Boston, 2003. *PDSA*, Plan, Do, Study, Act. <http://www.ihl.org/knowledge/Pages/IHIWhitePapers/TheBreakthroughSeriesIHIsCollaborativeModelforAchievingBreakthroughImprovement.aspx>.)

The ASA created the AQI and the National Anesthesia Clinical Outcomes Registry with the goal of improving anesthesia outcomes through capture of case-specific data directly from electronic anesthesia data systems.^{70,71} These resources are still evolving and moving forward to improve outcomes in anesthesia. Another important effort in anesthesia is the Multicenter Perioperative Outcomes Group (MPOG), which is led by researchers at the University of Michigan.⁷² MPOG has established a national network of anesthesia practice groups that contribute data to a unified database. The goals of MPOG are to develop a structure for multiinstitutional collaboration and data sharing, to develop the information technology infrastructure to pool a wide variety of perioperative data for patient-centered research, to develop the statistical infrastructure to analyze the data, and to provide an academic venue in which faculty from multiple institutions will be able to collaborate in outcomes research (<http://mpog.med.umich.edu>).⁷²

INTERNAL OR EXTERNAL INSTITUTIONAL REVIEWS

Internal or external institutional reviews of healthcare processes can provide important insights and ideas for QI initiatives. In addition to the external regulatory reviews, institutions are expected to perform internal reviews of quality and identify areas for improvement. These reviews are often used for QI projects at the institutional level.

Examples of Quality Improvement Programs

Examples of QI frameworks and tools have been discussed. This section addresses broad initiatives for quality and safety improvement that have used some of the methodologies and tools detailed earlier in this chapter.

COLLABORATIVE PROGRAMS

Use of a collaborative is one approach to improving broad areas of care. A QI collaborative involves the participation of two or more healthcare teams working toward a shared goal. In healthcare, a set of multidisciplinary representatives (from all of the clinical and administrative areas that

are linked to the area of focus) should participate in the collaborative. A collaborative can be developed within a single organization and/or across multiple healthcare organizations. Collaborative programs are typically led by a team that is responsible for the following:

1. Determining the evidence-based interventions to be used and presenting these to the participants (if evidence-based interventions are not available, the team will generate interventions based on local and broad expert consensus)
2. Establishing the data collection approach (defining measures, collection methods, and feedback mechanism)

A key element to the success of collaboratives is an established process for educating members and for sharing interventions and obstacles. Through group discussions (meetings and/or conference calls), teams can learn about best practices and innovative methods used by other teams to approach a problem. In addition, collaboratives bring a shared momentum and enthusiasm that can increase sustainability.^{24,73,74}

INSTITUTE FOR HEALTHCARE IMPROVEMENT BREAKTHROUGH SERIES COLLABORATIVES

QI collaboratives provide an opportunity to learn from other teams, work collaboratively, and spread change on a larger scale. The IHI has used a collaborative model for improvement, called the Breakthrough Series Model, for more than a decade. Collaboratives run from 12 to 160 teams across multiple organizations. Successful IHI collaboratives have included reducing waiting times by 50%, reducing ICU costs by 25%, and reducing hospitalizations of heart failure patients by 50%.⁷⁵

In the Breakthrough Series Model, a topic is selected and participating teams are enrolled (Fig. 5.8). Expert faculty from across the country, or even internationally, are recruited for an expert meeting to develop a framework for change called a “change package.” The change package describes interventions for improvement based on available evidence. Next, team members from all groups attend collaborative learning sessions where they learn the model for improvement and share their progress implementing the change package. At the end of the collaborative, a summative meeting and publications are used to share the findings with others.

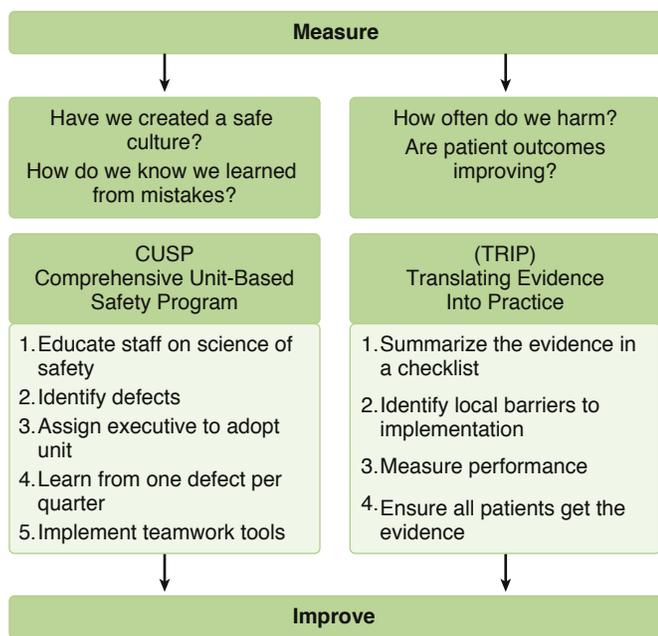


Fig. 5.9 Comprehensive unit-based safety program (CUSP) and translating evidence into practice (TRIP): basic steps to ensure patients receive evidence-based care. (Reproduced with permission from Sawyer M. Using evidence, rigorous measurement, and collaboration to eliminate central catheter-associated bloodstream infections. *Crit Care Med.* 2010;38:S292–S298.)

COMPREHENSIVE UNIT-BASED PROGRAM

Sawyer and associates reported the success of a collaborative that incorporates a “mechanism to move evidence to the bedside and foster a culture where the focus is the patient.”⁷⁶ The collaborative includes an emphasis on translating evidence into practice (TRIP) and the Comprehensive Unit-Based Safety Program (CUSP). This methodology has been reproduced and validated in several large collaborative efforts (Fig. 5.9).⁷⁶⁻⁷⁸

The TRIP model incorporates the following key steps and emphasizes the importance of measurement and feedback of data to teams.

1. Identify evidence-based interventions associated with an improved outcome through review of peer-reviewed publications.
2. Select goal-oriented interventions that have the most impact on outcomes and transform them into behaviors. In selecting behaviors, focus on interventions with the strongest treatment effect (smallest number needed to treat) and the lowest barrier to use.
3. Develop and implement measures that evaluate either the interventions (processes) or the outcomes.
4. Measure baseline performance and establish databases to facilitate accurate data management and timely feedback to teams.
5. Ensure that patients receive evidence-based interventions through four basic steps: engagement, education, execution, and evaluation (Table 5.4).

The format for the collaborative also includes annual face-to-face meetings with the participating teams and periodic conference calls, which focus on education about the actual processes being implemented, the evidence base

TABLE 5.4 Four Steps That Ensure Patients Receive Evidence-Based Interventions Through a Collaborative Using the Example of Catheter-Related Bloodstream Infections

Step	Action	Example
Engage	Make the problem real	Share information of local CRBSI rate vs. national rate
Educate	Develop an educational plan to reach ALL members of the care-giver team	Present evidence-based practices at grand rounds and multidisciplinary team meetings Present plans to improve care and measure outcome
Execute	Develop a safety culture Reduce complexity of the processes Introduce redundancy in processes Hold regular team meetings	Develop a culture of intolerance for CRBSI Ensure that all equipment and supplies for sterile CVC insertion are in one place and easily available Use checklists that identify key steps to reduce CRBSI Focus on one to two tasks per week and identify team member responsible for task
Evaluate	Measure and provide feedback	Develop data collection plan and database to track progress Give staff real-time feedback; post progress in highly visible location Identify causes of defects

CRBSI, Catheter-related bloodstream infections; CVC, central venous catheter.

to support these processes, and the sharing of experiences. First, weekly immersion calls provide an initial overview of the program, describe the roles and responsibilities of each of the individuals, and introduce the tools that are to be used. Once the collaborative is introduced, monthly content calls are held throughout the program and are typified by a slide presentation of the evidence base for the intervention or of other components of the program to be implemented. The monthly coaching calls offer an opportunity for teams to share how well or how poorly they are implementing the interventions and share ideas for overcoming barriers.

Inclusion of the CUSP program in the collaborative provides a structured approach to improve safety culture and identify and mitigate hazards (i.e., learn from mistakes).^{38,47} CUSP is a five-step program that has been tested and used successfully to improve quality and safety in ICUs (Table 5.5).^{79,80} CUSP programs have been used in many different environments including inpatient units, primary care practices,⁸¹ and in the perioperative period⁸² to enhance the safety culture and improve the patient experience.⁸³

Safety culture is assessed before the implementation of CUSP and reassessed after 1 year to evaluate the impact of the program. Multiple culture assessment tools are available.^{64,65} The AHRQ offers a free survey online (www.ahrq.gov). The initial measure provides a baseline assessment of staff perceptions of safety culture in their clinical areas and their perceptions of the organization’s commitment to patient safety.

Education is a crucial aspect of CUSP; it provides staff with a new set of lenses through which to identify hazards and

TABLE 5.5 Five-Step Comprehensive Unit-Based Safety Program

Step	Description
1	Present educational material Educate staff on science of safety through lectures and other educational materials
2	Complete forms that identify patient safety issues Ask the following questions: <ul style="list-style-type: none"> ■ How will the next patient be harmed? ■ How can this harm be prevented? ■ Establish voluntary incident reporting
3	Assign senior executive responsible for specific area Senior executive meets with all staff of the clinical area to: <ul style="list-style-type: none"> ■ Help prioritize safety efforts ■ Remove barriers for system changes ■ Provide resources ■ Demonstrate hospital commitment to patient safety ■ Foster relationship between senior leadership and staff
4	Learn from defects Implement projects focused on two to three safety issues Keep goals simple: <ul style="list-style-type: none"> ■ Reduce complexity in the process ■ Create independent redundancies to ensure critical steps are accomplished
5	Implement teamwork tools Implement programs such as checklists, training, and daily goals targeted at improving teamwork and communication

recommend system changes to improve care. The objectives of these educational efforts are to ensure that staff: (1) understand that safety is a system property, (2) learn concepts for reliable healthcare design, and (3) understand the basics of change management. After an educational lecture on the science of safety, staff members are requested to identify patient safety hazards in their clinical areas and suggest improvement interventions. For this process, staff members review incident reports, liability claims, and sentinel events from their unit. In addition, two questions are asked: “How do you think the next patient will be harmed?” and “How can we prevent it from happening?”

After the completion of the survey and educational component, a senior leader of the institution (e.g., hospital president, vice president, director) is partnered with a unit or clinical area. This leader attends rounds on the unit monthly to help staff members prioritize safety efforts, to ensure that they have the resources to implement improvements, and to hold them accountable for evaluating whether safety has improved. Staff members are asked to learn from one defect per month and to implement one tool per quarter designed to improve care delivery.^{38,47}

CUSP was pilot-tested in ICUs and subsequently implemented throughout Johns Hopkins Hospital and in the Michigan Keystone project.⁷⁷ In the pilot, a patient-safety team that consisted of staff from the clinical area was responsible for oversight of the program. To be most effective, this team included the ICU director as the ICU physician safety champion, the nurse manager, another ICU physician and nurse, a risk manager or patient-safety officer, and a senior executive from the institution. The program worked best if the physician and nurse who led the program dedicated at least 20% of their time to improving quality and patient safety. The first unit was the beta site; subsequent teams

from other clinical areas would learn from its successes and failures. The ultimate goal was to have every area in the hospital organizing and managing safety through CUSP.

CUSP has been associated with significant improvements in safety culture. The percentage of staff reporting a positive safety climate increased from 35% before CUSP to 60% after CUSP.^{80,84} In addition, teams identified and mitigated several specific hazards through CUSP. As a result of asking staff members to speculate on how the next patient might be harmed, the ICU created a dedicated ICU transport team, implemented point-of-care pharmacists, implemented the daily goals sheet, clearly labeled epidural catheters to prevent inadvertent intravenous connection, and standardized the equipment in transvenous pacing kits.⁸⁵ Moreover, the use of CUSP decreased the length of stay and nurse turnover.

In summary, CUSP provides several benefits for improving safety culture and is a primer for staff compliance in implementing any safety or QI intervention or project. It provides enough structure to convert the often-vague goals of improving safety into a focused strategy; yet it is flexible enough to allow units to work on issues most important to them. CUSP provides a venue to introduce rigorous research methods, acts as a learning laboratory to identify and mitigate hazards, and has the potential to improve patient outcomes.

CHALLENGES AND BARRIERS TO QUALITY IMPROVEMENT PROJECTS

Multicentered and/or single-hospital projects can fail because of inadequate resources, lack of leadership support, vague expectations and objectives for team members, poor communication, complex study plans, inadequate management of data collection, and wasted efforts to “reinvent the wheel” rather than adopting practices proven to be effective. Successful collaboratives require a local culture (the set of values, attitudes, and beliefs of the group) that is ready for change and participants who have a shared view of safety and who understand the science of patient quality and safety (i.e., the technical components of how care is organized and delivered).

RELATED CONCEPTS: IMPROVEMENT SCIENCE AND IMPLEMENTATION SCIENCE

The focus of this chapter has been QI operations, or the efforts concerned with the measurement and timely improvement of quality in a given setting. QI operations is related to improvement science and implementation science, both of which aim to create generalizable knowledge that has the potential to improve care quality and patient outcomes across settings. These three fields are often confused because they share tools and are all interested in improving patient outcomes, but may use different terms to refer to similar concepts. To provide clarity about the similarities and differences between these fields, Koczwara and colleagues conceptualized a spectrum with QI operations at one end, implementation science at the other, and improvement science in the middle.⁸⁶ Understanding the roles for these fields may prove useful to those interested in anesthesia QI.

QI operations. As described at length in this chapter, QI is the systematic approach to improving problems in

healthcare delivery that compromise care quality and outcomes. It is a timely, context-dependent team endeavor that has the potential to improve local care in the short, medium, and long term.

Improvement science. A common criticism of QI is that it is “unscientific” and more concerned with action than with understanding the mechanisms through which improvement occurs (or the reasons underlying the failure of improvement efforts). Improvement science draws from QI principles, aiming to “create practical learning that can make a timely difference to patient care.”⁸⁷ But improvement science is also concerned with the creation of generalizable knowledge. Hence, close attention is paid to both internal and external validity in the design of improvement studies. Rigorously designed improvement science projects may sacrifice some of the timeliness of QI projects, but balance this downside with greater potential utility of the findings outside of a local setting.

Implementation science. Implementation science (known as knowledge translation in Canada) aims to narrow the evidence-to-practice gap evident when proven-effective interventions do not translate into improved care and outcomes.⁸⁸ Although the field is characterized as a new one, it draws from psychology, education, management, and related sciences. Two features clearly distinguish implementation science from QI and improvement science: the reliance on evidence-based practices and the use of explicit frameworks, theories, and models. Implementation science is a major focus for research funding agencies in the United States and Canada, as it is seen as one approach to maximize the return on grant dollars allocated to scientific discovery in health care. As with QI and improvement science, the adequate characterization of “real world” contexts is paramount. In contrast, there tends to be greater emphasis on generalizability in implementation science as compared to improvement science.

A key distinction between these three fields is their relationship to evidence. Implementation science relies on evidence-based interventions. However, there is not always evidence to guide our practice in situations with clearly suboptimal quality. In these situations, QI approaches can be useful, as rapid-cycle small-scale tests of change can minimize harm and mitigate risk at the same time as quality is addressed.

The Future: Research, Education, and Ethics

Much remains to be accomplished in QI. The opportunity to improve patient care is substantial, and the pressure to improve the quality of perioperative care continues to increase. Improving quality of care requires the ability to measure and improve performance. Research is needed to develop measures of quality that clinicians believe are valid and to learn how to ensure that all patients reliably receive recommended interventions. Innovation is needed to develop information systems that can be used by multiple disciplines. Anesthesiologists and professional societies may need to partner with experts in quality measurement to develop and implement quality measures. Future efforts should balance the feasibility and validity of quality

TABLE 5.6 Accreditation Council of Graduate Medical Education (ACGME) Six Core Competencies and Institute of Medicine (IOM) Six Aims for Improvement

	ACGME Core Competencies	IOM Aims for Improvement
1	Patient care	Safe
2	Medical knowledge	Timely
3	Interpersonal and communication skills	Effective
4	Professionalism	Efficient
5	System-based practice	Equitable
6	Practice-based learning and improvement	Patient-centered

measures and develop integrated approaches to improving quality, including strategies to develop care bundles, decrease complexity, and create independent redundancies.

Clinicians now need the skills necessary to improve quality. Health care will cross the quality chasm only when all view quality and safety as their primary job, rather than as an added activity, and healthcare organizations provide the infrastructure to monitor and improve performance. Front-line healthcare providers must understand the science of quality and safety and evaluate safety risks as hazardous systems, not incompetent people. Integral to this is the education of our trainees. CQI in anesthesia residency training programs has been touted for more than 25 years.⁸⁹ In the United States, residents in training are expected to master six core competencies, as mandated by the Accreditation Council of Graduate Medical Education,⁹⁰ competencies that are linked to the NAM’s six Aims for Improvement (Table 5.6).³ In an effort to link these two sets of goals and apply them to the clinical setting for training purposes, Bingham and colleagues⁹¹ developed a framework called the Healthcare Matrix that can be used as both an educational tool and a research tool for improvement.

With the increasing amount of intellectual focus and healthcare resources being directed toward QI programs, the ethics of QI have come to light. QI projects have generally been exempt from the rigorous review of human-subjects research. However, a Hastings Center Report on the ethics of using QI methods to improve health quality and safety suggests that some QI projects may involve risk to patients and should undergo a formal review.⁹² This report lists QI initiatives that may trigger the need for a review as those that have a randomized design, use novel treatments, involve researchers, have delayed feedback of monitoring, or are funded by external sources. The reporting of QI activities should be encouraged, as should requiring approval by an internal review board and following a standardized format for reporting the results. All of these practices support the premise that delivery of quality care is a science as well as an art.

Summary

Healthcare organizations need a systematic approach to three areas of patient safety: (1) TRIP, (2) identifying and mitigating hazards, and (3) improving culture and

communication. The underlying principle for all of the approaches discussed in this chapter is that improvement of the quality of care dictates that practitioners must be able to measure their performance. Healthcare practitioners traditionally have had limited ability to obtain feedback regarding performance in their daily work, in part because of the absence of information systems and a lack of agreement on how to measure quality of care.⁴⁴ As a result, many in health care do not have access to performance data and consequently do not know what results they achieve (or fail to achieve). As consumers, payors, regulators, and accreditors increasingly require evidence regarding quality of care, the demand for quality measures will grow. To meet these demands, anesthesiologists must be prepared to use valid measures to evaluate the quality of care that they provide and to implement evidence-based best practices in the perioperative care of patients.

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