Section VI:

Tools for Quality Improvement and Patient Safety

Chapter 44. Tools and Strategies for Quality Improvement and Patient Safety

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Background

The necessity for quality and safety improvement initiatives permeates health care.[1, 2] Quality health care is defined 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"[3] (p. 1161). According to the Institute of Medicine (IOM) report, *To Err Is Human*,[4] the majority of medical errors result from faulty systems and processes, not individuals. Processes that are inefficient and variable, changing case mix of patients, health insurance, differences in provider education and experience, and numerous other factors contribute to the complexity of health care. With this in mind, the IOM also asserted that today's health care industry functions at a lower level than it can and should, and it put forth the following six aims of health care: effective, safe, patient-centered, timely, efficient, and equitable.[2] The aims of effectiveness and safety are targeted through process-of-care measures, assessing whether providers of health care perform processes that have been demonstrated to achieve the desired aims and avoid those processes that are predisposed toward harm. The goals of measuring health care quality are to determine the effects of health care on desired outcomes and to assess the degree to which health care adheres to processes based on scientific evidence or agreed to by professional consensus and is consistent with patient preferences.

Because errors are caused by system or process failures,[5] it is important to adopt various process-improvement techniques to identify inefficiencies, ineffective care, and preventable errors to then influence changes associated with systems. Each of these techniques involves assessing performance and using findings to inform change. This chapter will discuss strategies and tools for quality improvement—including failure modes and effects analysis, Plan-Do-Study-Act, Six Sigma, Lean, and root-cause analysis—that have been used to improve the quality and safety of health care.

Measures and Benchmarks

Efforts to improve quality need to be measured to demonstrate "whether improvement efforts (1) lead to change in the primary end point in the desired direction, (2) contribute to unintended results in different parts of the system, and (3) require additional efforts to bring a process back into acceptable ranges"[6] (p. 735). The rationale for measuring quality improvement is the belief that good performance reflects good-quality practice, and that comparing performance among providers and organizations will encourage better performance. In the past few years, there has been a surge in measuring and reporting the performance of health care systems and processes.[1, 7–9] While public reporting of quality performance can be used to identify areas needing improvement and ascribe national, State, or other level of benchmarks,[10, 11] some providers have been sensitive to comparative performance data being published.[12] Another audience for public reporting, consumers, has had problems interpreting the data in reports and

has consequently not used the reports to the extent hoped to make informed decisions for higher-quality care.[13–15]

The complexity of health care systems and delivery of services, the unpredictable nature of health care, and the occupational differentiation and interdependence among clinicians and systems[16–19] make measuring quality difficult. One of the challenges in using measures in health care is the attribution variability associated with high-level cognitive reasoning, discretionary decisionmaking, problem-solving, and experiential knowledge.[20–22] Another measurement challenge is whether a near miss could have resulted in harm or whether an adverse event was a rare aberration or likely to recur.[23]

The Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum, the Joint Commission, and many other national organizations endorse the use of valid and reliable measures of quality and patient safety to improve health care. Many of these useful measures that can be applied to the different settings of care and care processes can be found at AHRQ's National Quality Measures Clearinghouse (http://www.qualitymeasures.ahrq.gov) and the National Quality Forum's Web site (http://www.qualityforum.org). These measures are generally developed through a process including an assessment of the scientific strength of the evidence found in peer-reviewed literature, evaluating the validity and reliability of the measures and sources of data, determining how best to use the measure (e.g., determine if and how risk adjustment is needed), and actually testing the measure.[24, 25]

Measures of quality and safety can track the progress of quality improvement initiatives using external benchmarks. Benchmarking in health care is defined as the continual and collaborative discipline of measuring and comparing the results of key work processes with those of the best performers[26] in evaluating organizational performance. There are two types of benchmarking that can be used to evaluate patient safety and quality performance. Internal benchmarking is used to identify best practices within an organization, to compare best practices within the organization, and to compare current practice over time. The information and data can be plotted on a control chart with statistically derived upper and lower control limits. However, using only internal benchmarking does not necessarily represent the best practices elsewhere. Competitive or external benchmarking involves using comparative data between organizations to judge performance and identify improvements that have proven to be successful in other organizations. Comparative data are available from national organizations, such as AHRQ's annual National Health Care Quality Report[1] and National Healthcare Disparities Report,[9] as well as several proprietary benchmarking companies or groups (e.g., the American Nurses Association's National Database of Nursing Quality Indicators).

Quality Improvement Strategies

More than 40 years ago, Donabedian[27] proposed measuring the quality of health care by observing its structure, processes, and outcomes. Structure measures assess the accessibility, availability, and quality of resources, such as health insurance, bed capacity of a hospital, and number of nurses with advanced training. Process measures assess the delivery of health care services by clinicians and providers, such as using guidelines for care of diabetic patients. Outcome measures indicate the final result of health care and can be influenced by environmental and behavioral factors. Examples include mortality, patient satisfaction, and improved health status.

Twenty years later, health care leaders borrowed techniques from the work of Deming[28] in rebuilding the manufacturing businesses of post-World War II Japan. Deming, the father of Total

Quality Management (TQM), promoted "constancy of purpose" and systematic analysis and measurement of process steps in relation to capacity or outcomes. The TQM model is an organizational approach involving organizational management, teamwork, defined processes, systems thinking, and change to create an environment for improvement. This approach incorporated the view that the entire organization must be committed to quality and improvement to achieve the best results.[29]

In health care, continuous quality improvement (CQI) is used interchangeably with TQM. CQI has been used as a means to develop clinical practice[30] and is based on the principle that there is an opportunity for improvement in every process and on every occasion.[31] Many in-hospital quality assurance (QA) programs generally focus on issues identified by regulatory or accreditation organizations, such as checking documentation, reviewing the work of oversight committees, and studying credentialing processes.[32] There are several other strategies that have been proposed for improving clinical practice. For example, Horn and colleagues discussed clinical practice improvement (CPI) as a "multidimensional outcomes methodology that has direct application to the clinical management of individual patients"[33] (p. 160). CPI, an approach lead by clinicians that attempts a comprehensive understanding of the complexity of health care delivery, uses a team, determines a purpose, collects data, assesses findings, and then translates those findings into practice changes. From these models, management and clinician commitment and involvement have been found to be essential for the successful implementation of change.[34–36] From other quality improvement strategies, there has been particular emphasis on the need for management to have faith in the project, communicate the purpose, and empower staff.[37]

In the past 20 years, quality improvement methods have "generally emphasize[d] the importance of identifying a process with less-than-ideal outcomes, measuring the key performance attributes, using careful analysis to devise a new approach, integrating the redesigned approach with the process, and reassessing performance to determine if the change in process is successful"[38] (p. 9). Besides TQM, other quality improvement strategies have come forth, including the International Organization for Standardization ISO 9000, Zero Defects, Six Sigma, Baldridge, and Toyota Production System/Lean Production.[6, 39, 40]

Quality improvement is defined "as systematic, data-guided activities designed to bring about immediate improvement in health care delivery in particular settings"[41] (p. 667). A quality improvement strategy is defined as "any intervention aimed at reducing the quality gap for a group of patients representative of those encountered in routine practice"[38] (p. 13). Shojania and colleagues[38] developed a taxonomy of quality improvement strategies (see Table 1), which infers that the choice of the quality improvement strategy and methodology is dependent upon the nature of the quality improvement project. Many other strategies and tools for quality improvement can be accessed at AHRQ's quality tools Web site (www.qualitytools.ahrq.gov) and patient safety Web site (www.patientsafety.gov).

Table 1. Taxonomy of Quality Improvement Strategies With Examples of Substrategies

QI Strategy	Examples
Provider reminder systems	• Reminders in charts for providers • Computer-based reminders for providers • Computer-based decision support
Facilitated relay of clinical data to providers	• Transmission of clinical data from outpatient specialty clinic to primary care provider by means other than medical record (e.g., phone call or fax)

QI Strategy	Examples
Audit and feedback	• Feedback of performance to individual providers • Quality indicators and reports • National/State quality report cards • Publicly released performance data • Benchmarking – provision of outcomes data from top performers for comparison with provider's own data
Provider education	• Workshops and conferences • Educational outreach visits (e.g., academic detailing) • Distributed educational materials
Patient education	• Classes • Parent and family education • Patient pamphlets • Intensive education strategies promoting self-management of chronic conditions
Patient reminder systems	• Materials and devices promoting self-management
Promotion of self-management	• Postcards or calls to patients
Organizational change	• Case management, disease management • TQM, CQI techniques • Multidisciplinary teams • Change from paper to computer-based records • Increased staffing • Skill-mix changes
Financial incentives, regulation, and policy	Provider directed: • Financial incentives based on achievement of performance goals • Alternative reimbursement systems (e.g., fee-for-service, capitated payments) • Licensure requirements Patient directed: • Copayments for certain visit types • Health insurance premiums, user fees Health system directed: • Initiatives by accreditation bodies (e.g., residency work hour limits) • Changes in reimbursement schemes (e.g., capitation, prospective payment, salaried providers)

Note: Reprinted with permission from AHRQ[38] (pp. 17–18).

Quality improvement projects and strategies differ from research: while research attempts to assess and address problems that will produce generalizable results, quality improvement projects can include small samples, frequent changes in interventions, and adoption of new strategies that appear to be effective.[6] In a review of the literature on the differences between quality improvement and research, Reinhardt and Ray[42] proposed four criteria that distinguish the two: (1) quality improvement applies research into practice, while research develops new interventions; (2) risk to participants is not present in quality improvement, while research could pose risk to participants; (3) the primary audience for quality improvement is the organization, and the information from analyses may be applicable only to that organization, while research is intended to be generalizable to all similar organizations; and (4) data from quality improvement is organization-specific, while research data are derived from multiple organizations.

The lack of scientific health services literature has inhibited the acceptance of quality improvement methods in health care,[43, 44] but new rigorous studies are emerging. It has been asserted that a quality improvement project can be considered more like research when it involves a change in practice, affects patients and assesses their outcomes, employs

randomization or blinding, and exposes patients to additional risks or burdens—all in an effort towards generalizability.[45–47] Regardless of whether the project is considered research, human subjects need to be protected by ensuring respect for participants, securing informed consent, and ensuring scientific value.[41, 46, 48]

Plan-Do-Study-Act (PDSA)

Quality improvement projects and studies aimed at making positive changes in health care processes to effecting favorable outcomes can use the Plan-Do-Study-Act (PDSA) model. This is a method that has been widely used by the Institute for Healthcare Improvement for rapid cycle improvement.[31, 49] One of the unique features of this model is the cyclical nature of impacting and assessing change, most effectively accomplished through small and frequent PDSAs rather than big and slow ones,[50] before changes are made systemwide.[31, 51]

The purpose of PDSA quality improvement efforts is to establish a functional or causal relationship between changes in processes (specifically behaviors and capabilities) and outcomes. Langley and colleagues[51] proposed three questions before using the PDSA cycles: (1) What is the goal of the project? (2) How will it be known whether the goal was reached? and (3) What will be done to reach the goal? The PDSA cycle starts with determining the nature and scope of the problem, what changes can and should be made, a plan for a specific change, who should be involved, what should be measured to understand the impact of change, and where the strategy will be targeted. Change is then implemented and data and information are collected. Results from the implementation study are assessed and interpreted by reviewing several key measurements that indicate success or failure. Lastly, action is taken on the results by implementing the change or beginning the process again.[51]

Six Sigma

Six Sigma, originally designed as a business strategy, involves improving, designing, and monitoring process to minimize or eliminate waste while optimizing satisfaction and increasing financial stability.[52] The performance of a process—or the process capability—is used to measure improvement by comparing the baseline process capability (before improvement) with the process capability after piloting potential solutions for quality improvement.[53] There are two primary methods used with Six Sigma. One method inspects process outcome and counts the defects, calculates a defect rate per million, and uses a statistical table to convert defect rate per million to a σ (sigma) metric. This method is applicable to preanalytic and postanalytic processes (a.k.a. pretest and post-test studies). The second method uses estimates of process variation to predict process performance by calculating a σ metric from the defined tolerance limits and the variation observed for the process. This method is suitable for analytic processes in which the precision and accuracy can be determined by experimental procedures.

One component of Six Sigma uses a five-phased process that is structured, disciplined, and rigorous, known as the define, measure, analyze, improve, and control (DMAIC) approach.[53, 54] To begin, the project is identified, historical data are reviewed, and the scope of expectations is defined. Next, continuous total quality performance standards are selected, performance objectives are defined, and sources of variability are defined. As the new project is implemented, data are collected to assess how well changes improved the process. To support this analysis, validated measures are developed to determine the capability of the new process.

Six Sigma and PDSA are interrelated. The DMAIC methodology builds on Shewhart's plan, do, check, and act cycle.[55] The key elements of Six Sigma is related to PDSA as follows: the plan phase of PDSA is related to define core processes, key customers, and customer requirements of Six Sigma; the do phase of PDSA is related to measure performance of Six Sigma; the study phase of PDSA is related to analyze of Six Sigma; and the act phase of PDSA is related to improve and integrate of Six Sigma.[56]

Toyota Production System/Lean Production System

Application of the Toyota Production System—used in the manufacturing process of Toyota cars[57]—resulted in what has become known as the Lean Production System or Lean methodology. This methodology overlaps with the Six Sigma methodology, but differs in that Lean is driven by the identification of customer needs and aims to improve processes by removing activities that are non-value-added (a.k.a. waste). Steps in the Lean methodology involve maximizing value-added activities in the best possible sequence to enable continuous operations.[58] This methodology depends on root-cause analysis to investigate errors and then to improve quality and prevent similar errors.

Physicians, nurses, technicians, and managers are increasing the effectiveness of patient care and decreasing costs in pathology laboratories, pharmacies,[59–61] and blood banks[61] by applying the same principles used in the Toyota Production System. Two reviews of projects using Toyota Production System methods reported that health care organizations improved patient safety and the quality of health care by systematically defining the problem; using root-cause analysis; then setting goals, removing ambiguity and workarounds, and clarifying responsibilities. When it came to processes, team members in these projects developed action plans that improved, simplified, and redesigned work processes.[59, 60] According to Spear, the Toyota Production System method was used to make the "following crystal clear: which patient gets which procedure (output); who does which aspect of the job (responsibility); exactly which signals are used to indicate that the work should begin (connection); and precisely how each step is carried out"[60] (p. 84).

Factors involved in the successful application of the Toyota Production System in health care are eliminating unnecessary daily activities associated with "overcomplicated processes, workarounds, and rework"[59] (p. 234), involving front-line staff throughout the process, and rigorously tracking problems as they are experimented with throughout the problem-solving process.

Root Cause Analysis

Root cause analysis (RCA), used extensively in engineering[62] and similar to critical incident technique,[63] is a formalized investigation and problem-solving approach focused on identifying and understanding the underlying causes of an event as well as potential events that were intercepted. The Joint Commission requires RCA to be performed in response to all sentinel events and expects, based on the results of the RCA, the organization to develop and implement an action plan consisting of improvements designed to reduce future risk of events and to monitor the effectiveness of those improvements.[64]

RCA is a technique used to identify trends and assess risk that can be used whenever human error is suspected[65] with the understanding that system, rather than individual factors, are likely

the root cause of most problems.[2, 4] A similar procedure is critical incident technique, where after an event occurs, information is collected on the causes and actions that led to the event.[63]

An RCA is a reactive assessment that begins after an event, retrospectively outlining the sequence of events leading to that identified event, charting causal factors, and identifying root causes to completely examine the event.[66] Because it is a labor-intensive process, ideally a multidisciplinary team trained in RCA triangulates or corroborates major findings and increases the validity of findings.[67] Taken one step further, the notion of aggregate RCA (used by the Veterans Affairs (VA) Health System) is purported to use staff time efficiently and involves several simultaneous RCAs that focus on assessing trends, rather than an in-depth case assessment.[68]

Using a qualitative process, the aim of RCA is to uncover the underlying cause(s) of an error by looking at enabling factors (e.g., lack of education), including latent conditions (e.g., not checking the patient's ID band) and situational factors (e.g., two patients in the hospital with the same last name) that contributed to or enabled the adverse event (e.g., an adverse drug event). Those involved in the investigation ask a series of key questions, including what happened, why it happened, what were the most proximate factors causing it to happen, why those factors occurred, and what systems and processes underlie those proximate factors. Answers to these questions help identify ineffective safety barriers and causes of problems so similar problems can be prevented in the future. Often, it is important to also consider events that occurred immediately prior to the event in question because other remote factors may have contributed.[68]

The final step of a traditional RCA is developing recommendations for system and process improvement(s), based on the findings of the investigation.[68] The importance of this step is supported by a review of the literature on root-cause analysis, where the authors conclude that there is little evidence that RCA can improve patient safety by itself.[69] A nontraditional strategy, used by the VA, is aggregate RCA processes, where several simultaneous RCAs are used to examine multiple cases in a single review for certain categories of events.[68, 70]

Due the breadth of types of adverse events and the large number of root causes of errors, consideration should be given to how to differentiate system from process factors, without focusing on individual blame. The notion has been put forth that it is a truly rare event for errors to be associated with irresponsibility, personal neglect, or intention,[71] a notion supported by the IOM.[4, 72] Yet efforts to categorize individual errors—such as the Taxonomy of Error Root Cause Analysis of Practice Responsibility (TERCAP), which focuses on "lack of attentiveness, lack of agency/fiduciary concern, inappropriate judgment, lack of intervention on the patient's behalf, lack of prevention, missed or mistaken MD/healthcare provider's orders, and documentation error"[73] (p. 512)—may distract the team from investigating systems and process factors that can be modified through subsequent interventions. Even the majority of individual factors can be addressed through education, training, and installing forcing functions that make errors difficult to commit.

Failure Modes and Effects Analysis

Errors will inevitably occur, and the times when errors occur cannot be predicted. Failure modes and effects analysis (FMEA) is an evaluation technique used to identify and eliminate known and/or potential failures, problems, and errors from a system, design, process, and/or service before they actually occur.[74–76] FMEA was developed for use by the U.S. military and has been used by the National Aeronautics and Space Administration (NASA) to predict and evaluate potential failures and unrecognized hazards (e.g., probabilistic occurrences) and to

proactively identify steps in a process that could reduce or eliminate future failures.[77] The goal of FMEA is to prevent errors by attempting to identifying all the ways a process could fail, estimate the probability and consequences of each failure, and then take action to prevent the potential failures from occurring. In health care, FMEA focuses on the system of care and uses a multidisciplinary team to evaluate a process from a quality improvement perspective.

This method can be used to evaluate alternative processes or procedures as well as to monitor change over time. To monitor change over time, well-defined measures are needed that can provide objective information of the effectiveness of a process. In 2001, the Joint Commission mandated that accredited health care providers conduct proactive risk management activities that identify and predict system weaknesses and adopt changes to minimize patient harm on one or two high-priority topics a year.[78]

HFMEA. Developed by the VA's National Center for Patient Safety, the health failure modes and effects analysis (HFMEA) tool is used for risk assessment. There are five steps in HFMEA: (1) define the topic; (2) assemble the team; (3) develop a process map for the topic, and consecutively number each step and substep of that process; (4) conduct a hazard analysis (e.g., identify cause of failure modes, score each failure mode using the hazard scoring matrix, and work through the decision tree analysis);[79] and (5) develop actions and desired outcomes. In conducting a hazard analysis, it is important to list all possible and potential failure modes for each of the processes, to determine whether the failure modes warrant further action, and to list all causes for each failure mode when the decision is to proceed further. After the hazard analysis, it is important to consider the actions needed to be taken and outcome measures to assess, including describing what will be eliminated or controlled and who will have responsibility for each new action.[79]

Research Evidence

Fifty studies and quality improvement projects were included in this analysis. The findings were categorized by type of quality method employed, including FMEA, RCA, Six Sigma, Lean, and PDSA. Several common themes emerged: (1) what was needed to implement quality improvement strategies, (2) what was learned from evaluating the impact of change interventions, and (3) what is known about using quality improvement tools in health care.

What Was Needed To Implement Quality Improvement Strategies?

Substantial and strong leadership support,[80–83] involvement,[81, 84] consistent commitment to continuous quality improvement,[85, 86] and visibility,[87] both in writing and physically, [86] were important in making significant changes. Substantial commitment from hospital boards was also found to be necessary.[86, 88] The inevitability of resource demands associated with changing process required senior leadership to (1) ensure adequate financial resources[87–89] by identifying sources of funds for training and purchasing and testing innovative technologies[90] and equipment;[91] (2) facilitate and enable key players to have the needed time to be actively involved in the change processes,[85, 88, 89] providing administrative support; [90] (3) support a time-consuming project by granting enough time for it to work;[86, 92] and (4) emphasize safety as an organizational priority and reinforce expectations, especially when the process was delayed or results were periodically not realized.[87] It was also asserted that senior leaders needed to understand the impact of high-level decisions on work processes and staff time,[88] especially when efforts were

underway to change practice, and that quality improvement needed to be incorporated into systemwide leadership development.[88] Leadership was needed to make patient safety a key aspect of all meetings and strategies,[85, 86] to create a formal process for identifying annual patient safety goals for the organization, and to hold themselves accountable for patient safety outcomes.[85]

Even with strong and committed leadership, some people within the organization may be hesitant to participate in quality improvement efforts because previous attempts to create change were hindered by various system factors,[93] a lack of organization-wide commitment,[94] poor organizational relationships, and ineffective communication.[89] However the impact of these barriers were found to be lessened if the organization embraced the need for change,[95] changed the culture to enable change,[90] and actively pursued institutionalizing a culture of safety and quality improvement. Yet adopting a nonpunitive culture of change took time,[61, 90] even to the extent that the legal department in one hospital was engaged in the process to turn the focus to systems, not individual-specific issues.[96] Also, those staff members involved in the process felt more at ease with improving processes, particularly when cost savings were realized and when no layoff policies were put in place to protect job security even when efficiencies were realized.[84]

The improvement process needed to engage[97] and involve all stakeholders and gain their understanding that the investment of resources in quality improvement could be recouped with efficiency gains and fewer adverse events.[86] Stakeholders were used to (1) prioritize which safe practices to target by developing a consensus process among stakeholders[86, 98] around issues that were clinically important, i.e., hazards encountered in everyday practice that would make a substantial impact on patient safety; (2) develop solutions to the problems that required addressing fundamental issues of interdisciplinary communication and teamwork, which were recognized as crucial aspects of a culture of safety; and (3) build upon the success of other hospitals.[86] In an initiative involving a number of rapid-cycle collaboratives, successful collaboratives were found to have used stakeholders to determine the choice of subject, define objectives, define roles and expectations, motivate teams, and use results from data analyses.[86] Additionally, it was important to take into account the different perspectives of stakeholders.[97] Because variation in opinion among stakeholders and team members was expected[99] and achieving buy-in from all stakeholders could have been difficult to achieve, efforts were made to involve stakeholders early in the process, solicit feedback,[100] and gain support for critical changes in the process.[101]

Communication and sharing information with stakeholders and staff was critical to specifying the purpose and strategy of the quality initiative;[101] developing open channels of communication across all disciplines and at all levels of leadership/staff, permitting the voicing of concerns and observations throughout the process of creating change;[88] ensuring that patients and families were appropriately included in the dialogue; ensuring that everyone involved felt that he or she was an integral part of the health care team and was responsible for patient safety; sharing lessons learned from root-cause analysis; and capturing attention and soliciting buy-in by sharing patient safety stories with staff and celebrating successes, no matter how small.[85] Yet in trying to keep everyone informed of the process and the data behind decisions, some staff had difficulty accepting system changes made in response to the data.[89]

The successful work of these strategies was dependent upon having motivated[80] and empowered teams. There were many advantages to basing the work of the quality improvement strategies on the teamwork of multidisciplinary teams that would review data and lead change.[91]

These teams needed to be comprised of the right staff people,[91, 92] include peers,[102] engage all of the right stakeholders (ranging from senior managers to staff), and be supported by senior-level management/leadership.[85, 86] Specific stakeholders (e.g., nurses and physicians) had to be involved[81] and supported to actually make the change, and to be the champions[103] and problem-solvers within departments[59] for the interventions to succeed. Because implementing the quality initiatives required substantial changes in the clinician's daily work,[86] consideration of the attitude and willingness of front-line staff for making the specific improvements[59, 88, 104] was needed.

Other key factors to improvement success were implementing protocols that could be adapted to the patient's needs[93] and to each unit, based on experience, training, and culture.[88] It was also important to define and test different approaches; different approaches can converge and arrive at the same point.[81] Mechanisms that facilitated staff buy-in was putting the types and causes of errors in the forefront of providers' minds, making errors visible,[102] being involved in the process of assessing work and looking for waste,[59] providing insight as to whether the improvement project would be feasible and its impact measurable,[105] and presenting evidence-based changes.[100] Physicians were singled out as the one group of clinicians that needed to lead[106] or be actively involved in changes,[86] especially when physician behaviors could create inefficiencies.[84] In one project, physicians were recruited as champions to help spread the word to other physicians about the critical role of patient safety, to make patient safety a key aspect of all leadership and medical management meetings and strategies.[85]

Team leaders and the composition of the team were also important. Team leaders that emphasized efforts offline to help build and improve relationships were found to be necessary for team success.[83, 93] These teams needed a dedicated team leader who would have a significant amount of time to put into the project.[84] While the leader was not identified in the majority of reports reviewed for this paper, the team on one project was co-chaired by a physician and an administrator.[83] Not only did the type and ability of team leaders affect outcomes, the visibility of the initiative throughout the organization was dependent upon having visible champions.[100] Multidisciplinary teams needed to understand the numerous steps involved in quality improvement and that there were many opportunities for error, which essentially enabled teams to prioritize the critical items to improve within a complex process and took out some of the subjectivity from the analysis. The multidisciplinary structure of teams allowed members to identify each step from their own professional practice perspective, anticipate and overcome potential barriers, allowed the generation of diverse ideas, and allowed for good discussion and deliberations, which together ultimately promoted team building.[100, 107] In two of the studies, FMEA/HFMEA was found to minimize group biases by benefiting from the diversity within multidisciplinary composition of the team and enabling the team to focus on a structured outline of the goals that needed to be accomplished.[107, 108]

Teams needed to be prepared and enabled to meet the demands of the quality initiatives with ongoing education, weekly debriefings, review of problems solved and principles applied,[84] and ongoing monitoring and feedback opportunities.[92, 95] Education and training of staff[95, 80, 95, 101, 104] and leadership[80] about the current problem, quality improvement tools, the planned change in practice intervention, and updates as the project progressed were key strategies.[92] Training was an ongoing process[91] that needed to focus on skill deficits[82] and needed to be revised as lessons were learned and data was analyzed during the implementation of the project.[109] The assumption could not be made that senior staff or leadership would not need training.[105] Furthermore, if the team had no experience with the quality tools or successfully creating change, an additional

resource could have been a consultant or someone to facilitate the advanced knowledge involved in quality improvement techniques.[106] Another consideration was using a model that intervened at the hospital-community interface, coupled with an education program.[97]

The influence of teamwork processes enabled those within the team to improve relationships across departments.[89] Particular attention needed to be given to effective team building,[110] actively following the impact of using the rapid-cycle (PDSA) model, meeting frequently, and monitoring progress using outcome data analysis at least on a monthly basis.[86] Effective teamwork and communication, information transfer, coordination among multiple hospital departments and caregivers, and changes to hospital organization culture were considered essential elements of team effectiveness.[86] Yet the impact of team members that had difficulty in fully engaging in teamwork because of competing workloads (e.g., working double shifts) was dampened.[97] Better understanding of each other's role is an important project outcome and provides a basis for continuing the development of other practices to improve outcomes.[97] The work of teams was motivated through continual sharing of progress and success and celebration of achievements.[87]

Teamwork can have many advantages, but only a few were discussed in the reports reviewed. Teams were seen as being able to increase the scope of knowledge, improve communication across disciplines, and facilitate learning about the problem.[111] Teams were also found to be proactive, [91] integrating tools that improve both the technical processes and organizational relationships,[83] and to work together to understand the current situation, define the problem, pathways, tasks, and connections, as well as to develop a multidisciplinary action plan.[59] But teamwork was not necessarily an easy process. Group work was seen as difficult for some and time consuming,[111] and problems arose when everyone wanted their way,[97] which delayed convergence toward a consensus on actions. Team members needed to learn how to work with a group and deal with group dynamics, confronting peers, conflict resolution, and addressing behaviors that are detrimental.[111]

What Was Learned From Evaluating the Impact of Change Interventions?

As suggested by Berwick,[112] the leaders of the quality improvement initiatives in this review found that successful initiatives needed to simplify;[96, 104] standardize;[104] stratify to determine effects; improve auditory communication patterns; support communication against the authority gradient; [96] use defaults properly; automate cautiously; [96] use affordance and natural mapping (e.g., design processes and equipment so that the easiest thing to do is the right thing to do); respect limits of vigilance and attention; [96] and encourage reporting of near hits, errors, and hazardous conditions.[96] Through the revision and standardization of policies and procedures, many of these initiatives were able to effectively realize the benefit of making the new process easier than the old and decrease the effect of human error associated with limited vigilance and attention.[78, 80–82, 90–92, 94, 96, 102, 103, 113, 114]

Simplification and standardization were found to be effective as a forcing function by decreasing reliance on individualized decisionmaking. Several initiatives standardized medication ordering and administration protocols,[78, 87, 101, 103, 106–108, 109, 114–116] realizing improvements in patient outcomes, nurse efficiency, and effectiveness.[103, 106, 108, 109, 114–116] One initiative used a standardized form for blood product ordering.[94] Four initiatives improved pain

assessment and management by using standardized metrics and assessment tools.[80, 93, 100, 117] In all of these initiatives, simplification and standardization were effective strategies.

Related to simplification and standardization is the potential benefit of using information technology to implement checks, defaults, and automation to improve quality and reduce errors, in large part to embedding forcing functions to remove the possibility of errors.[96, 106] The effects of human error could be mitigated by using necessary redundancy, such as double-checking for certain types of errors; this was seen as engaging the knowledge and abilities of two skilled practitioners[61, 101] and was used successfully to reduce errors associated with dosing.[78] Information technology was successfully used to (1) decrease the opportunity for human error through automation;[61] (2) standardize medication concentrations[78] and dosing using computer-enabled calculations,[115, 116] standardized protocols,[101] and order clarity;[116] (3) assist caregivers in providing quality care using alerts and reminders; (4) improve medication safety (e.g., implementing bar coding and computerized provider order entry); and (5) track performance through database integration and indicator monitoring. Often workflow and procedures needed to be revised to keep pace with technology.[78] Using technology implied that organizations were committed to investing in technology to enable improvement,[85] but for two initiatives, the lack of adequate resources for data collection impacted analysis and evaluation of the initiative.[93, 97]

Data and information were needed to understand the root causes of errors and near errors,[99] to understand the magnitude of adverse events,[106] to track and monitor performance,[84, 118] and to assess the impact of the initiatives.[61] Reporting of near misses, errors, and hazardous conditions needs to be encouraged.[96] In part, this is because error reporting is generally low and is associated with organizational culture[106] and can be biased, which will taint results.[102] Organizations not prioritizing reporting or not strongly emphasizing a culture of safety may have the tendency to not report errors that harm patients or near misses (see Chapter 35. "Evidence Reporting and Disclosure"). Using and analyzing data was viewed as critical, yet some team members and staff may have benefited from education on how to effectively analyze and display findings.[106] Giving staff feedback by having a transparent process[39] of reporting findings[82] was viewed as a useful trigger that brought patient safety to the forefront of the hospital.[107] It follows then that not having data, whether because it was not reported or not collected, made statistical analysis of the impact of the initiative[115] or assessing its cost-benefit ratio not possible.[108] As such, multi-organizational collaboration should have a common database.[98]

The meaning of data can be better understood by using measures and benchmarks. Repeated measurements were found to be useful for monitoring progress,[118] but only when there was a clear metric for measuring the degree of success.[83] The use of measures could be used as a strategy to involve more clinicians and deepened their interest, especially physicians. Using objective, broader, and better measures was viewed as being important for marking progress, and provided a basis for "a call to action" and celebration.[106] When measures of care processes were used, it was asserted that there was a need to demonstrate the relationship between specific changes to care processes and outcomes.[61]

When multiple measures were used, along with better documentation of care, it was easier to assess the impact of the initiative on patient outcomes.[93] Investigators from one initiative put forth the notion that hospital administrators should encourage more evaluations of initiatives and that the evaluations should focus on comprehensive models that assess patient outcomes, patient satisfaction, and cost effectiveness.[114] The assessment of outcomes can be enhanced by setting realistic goals, not unrealistic goals such as 100 percent change,[119] and by comparing organizational results to recognized State, regional, and national benchmarks.[61, 88]

The cost of the initiative was an viewed as important factor in the potential for improvement, even when the adverse effects of current processes were considered as necessitating rapid change.[106] Because of this, it is important to implement changes that are readily feasible[106] and can be implemented with minimal disruption of practice activities.[99] It is also important to consider the potential of replicating the initiative in other units or at other sites.[99] One strategy to improve the chances of replication is to standardize processes, which will most likely incur some cost.[106] In some respects, the faster small problems were resolved, the faster improvements could be replicated throughout the entire system.[84, 106] Recommendations that did not incur costs or had low costs and could be demonstrated to be effective were implemented expeditiously.[93, 107] A couple of investigators stated that their interventions decreased costs and patients' length of stay,[103] but did not present any data to verify those statements. It was also purported that the costs associated with change will be recouped either in return on investment or in reduced patient risk (and thus reduced liability costs).[61]

Ensuring that those implementing the initiative receive education is critical. There were several examples of this. Two initiatives that targeted pain management found that educating staff on pain management guidelines and protocols for improving chronic pain assessment and management improved staff understanding, assessment and documentation, patient and family satisfaction, and pain management.[80, 93] Another initiative educated all staff nurses on intravenous (IV) site care and assessment, as well as assessment of central lines, and realized improved patient satisfaction and reduced complications and costs.[109]

Despite the benefits afforded by the initiatives, there were many challenges that were identified in implementing the various initiatives:

- Lack of time and resources made it difficult to implement the initiative well.[82]
- Some physicians would not accept the new protocol and thwarted implementation until they had confidence in the tool.[103]
- Clear expectations were lacking. [86]
- Hospital leadership was not adequately engaged.[86]
- There was insufficient emphasis on importance and use of measures.[86]
- The number and type of collaborative staffing was insufficient.[86]
- The time required for nurses and other staff to implement the changes was underestimated.[120]
- The extent to which differences in patient severity accounted for results could not be evaluated because severity of illness was not measured.[89]
- Improvements associated with each individual PDSA cycle could not be evaluated.[89]
- The full impact on the costs of care, including fixed costs for overhead, could not be evaluated.[89]
- Failure to consider the influence of factors such as fatigue, distraction, time pressures.[82]
- The Hawthorne effect may have caused improvements more so than the initiative.[118]
- Many factors were interrelated and correlated.[96]
- There was a lack of generalizability because of small sample size.[93, 119]
- Addressing some of the problems created others (e.g., implementing computerized physician order entry (CPOE)).[110]
- Targets set (e.g., 100 percent of admissions) may have been too ambitious and were thus always demanding and difficult-to-achieve service improvements.[119]

Despite the aforementioned challenges, many investigators found that it was important to persevere and stay focused because introducing new processes can be difficult, [84, 100] but the reward of quality improvement is worth the effort.[84] Implementing quality improvement initiatives was considered time consuming, tedious, and difficult for people who are very action oriented; it required an extensive investment of resources (i.e., time, money, and energy);[94] and it involved trial and error to improve the process.[91] Given theses and other challenges, it was also important to celebrate the victories.[84]

Other considerations were given to the desired objective of sustaining the changes after the implementation phase of the initiative ended.[105] Investigators asserted that improving quality through initiatives needed to be considered as integral in the larger, organizationwide, ongoing process of improvement. Influential factors attributed to the success of the initiatives were effecting practice changes that could be easily used at the bedside;[82] using simple communication strategies; [88] maximizing project visibility, which could sustain the momentum for change;[100] establishing a culture of safety; and strengthening the organizational and technological infrastructure.[121] However, there were opposing viewpoints about the importance of spreading the steps involved in creating specific changes (possibly by forcing changes into the redesign of processes), rather than only relying on only adapting best practices.[106, 121] Another factor was the importance of generating enthusiasm about embracing change through a combination of collaboration (both internally and externally)[103] and healthy competition. Collaboratives could also be a vehicle for encouraging the use of and learning from evidence-based practice and rapid-cycle improvement as well as identifying and gaining consensus on potentially better practices.[86, 98]

What Is Known About Using Quality Improvement Tools in Health Care?

Quality tools used to define and assess problems with health care were seen as being helpful in prioritizing quality and safety problems[99] and focusing on systems,[98] not individuals. The various tools were used to address errors and growing costs[88] and to change provider practices.[117] Several of the initiatives used more than one of the quality improvement tools, such as beginning with root-cause analysis then using either Six Sigma, Toyota Production System/Lean, or Plan-Do-Study-Act to implement change in processes. Almost every initiative included in this analysis performed some type of pretesting/pilot testing.[92, 99] Investigators and leaders of several initiatives reported advantages of using specific types of quality tools. These are discussed as follows:

Root-cause analysis was reported to be useful to assess reported errors/incidents and differentiate between active and latent errors, to identify need for changes to policies and procedures, and to serve as a basis to suggest system changes, including improving communication of risk.[82, 96, 102, 105]

Six Sigma/Toyota Production System was reported to have been successfully used to decrease defects/variations[59, 61, 81] and operating costs[81] and improve outcomes in a variety of health care settings and for a variety of processes.[61, 88] Six Sigma was found to be a detailed process that clearly differentiated between the causes of variation and outcome measures of process.[61] One of the advantages of using Six Sigma was that it made work-arounds and rework difficult because the root causes of the preimplementation processes were targeted.[59, 88] Additionally, investigators reported that the more teams worked with this strategy, the better they

became at implementing it and the more effective the results.[84] Yet it was noted that to use this strategy effectively, a substantial commitment of leadership time and resources was associated with improved patient safety, lowered costs, and increased job satisfaction.[84] Six Sigma was also an important strategy for problem-solving and continuous improvement; communicating clearly about the problem; guiding the implementation process; and producing results in a clear, concise, and objective way.[59]

Plan-Do-Study-Act (PDSA) was used by the majority of initiatives included in this analysis to implement initiatives gradually, while improving them as needed. The rapid-cycle aspect of PDSA began with piloting a single new process, followed by examining results and responding to what was learned by problem-solving and making adjustments, after which the next PDSA cycle would be initiated. The majority of quality improvement efforts using PDSA found greater success using a series of small and rapid cycles to achieve the goals for the intervention, because implementing the initiative gradually allowed the team to make changes early in the process[80] and not get distracted or sidetracked by every detail and too many unknowns.[87, 119, 122] The ability of the team to successfully use the PDSA process was improved by providing instruction and training on the use of PDSA cycles, using feedback on the results of the baseline measurements,[118] meeting regularly,[120] and increasing the team's effectiveness by collaborating with others, including patients and families,[80] to achieve a common goal.[87] Conversely, some teams experienced difficulty in using rapid-cycle change, collecting data, and constructing run charts,[86] and one team reported that applying simple rules in PDSA cycles may have been more successful in a complex system.[93]

Failure modes and effects analysis (FMEA) was used to avoid events and improve or maintain the quality of care.[123] FMEA was used prospectively to identify potential areas of failure[94] where experimental characterization of the process at the desired speed of change could be assessed,[115] and retrospectively to characterize the safety of a process by identifying potential areas of failure, learning about the process from the staff's point of view.[94] Using a flow chart of the process before beginning the analysis got the team to focus and work from the same document.[94] Information learned from FMEA was used to provide data for prioritizing improvement strategies, serve as a benchmark for improvement efforts,[116] educate and provide a rationale for diffusion of these practice changes to other settings,[115] and increase the ability of the team to facilitate change across all services and departments within the hospital.[124] Using FMEA facilitated systematic error management, which was important to good clinical care in complex processes and complex settings, and was dependent upon a multidisciplinary approach, integrated incident and error reporting, decision support, standardization of terminology, and education of caregivers.[116]

Health failure modes and effects analysis (HFMEA) was used to provide a more detailed analysis of smaller processes, resulting in more specific recommendations, as well as larger processes. HFEMA was viewed as a valid tool for proactive analysis in hospitals, facilitating a very thorough analysis of vulnerabilities (i.e., failure modes) before adverse events occurred.[108] This tool was considered valuable in identifying the multifactoral nature of most errors[108] and the potential risk for errors,[111] but was seen as being time consuming.[107] Initiatives that used HFMEA could minimize group biases through the multidisciplinary composition of the team[78, 108, 115] and facilitate teamwork by providing a step-by-step process,[107] but these initiatives required a paradigm shift for many.[111]

Evidence-Based Practice Implications

From the improvement strategies and projects assessed in this review, several themes emerged from successful initiatives that nurses can use to guide quality improvement efforts. The strength of the following practice implications is associated with the methodological rigor and generalizability of these strategies and projects:

1. The importance of having strong *leadership* commitment and support cannot be overstated. Leadership needs to empower staff, be actively involved, and continuously drive quality improvement. Without the commitment and support of senior-level leadership, even the best intended projects are at great risk of not being successful. Champions of the quality initiative and quality improvement need to be throughout the organization, but especially in leadership positions and on the team.
2. A *culture of safety and improvement* that rewards improvement and is driven to improve quality is important. The culture is needed to support a quality infrastructure that has the resources and human capital required for successfully improving quality.
3. Quality improvement teams need to have the right *stakeholders* involved.
4. Due to the complexity of health care, *multidisciplinary teams and strategies* are essential. Multidisciplinary teams from participating centers/units need to work closely together, taking advantage of communication strategies such as face-to-face meetings, conference calls, and dedicated e-mail listservs, and utilize the guidance of trained facilitators and expert faculty throughout the process of implementing change initiatives when possible**.**
5. Quality improvement teams and stakeholders need to *understand the problem and root causes*. There must be a consensus on the definition of the problem. To this end, a clearly defined and universally agreed upon metric is essential. This agreement is as crucial to the success of any improvement effort as the validity of the data itself.
6. Use a *proven, methodologically sound approach* without being distracted by the jargon used in quality improvement. The importance given to using clear models, terms, and process is critical, especially because many of the quality tools are interrelated; using only one tool will not produce successful results.
7. *Standardizing care processes* and ensuring that everyone uses those standards should improve processes by making them more efficient and effective—and improve organizational and patient outcomes.
8. *Evidence-based practice* can facilitate ongoing quality improvement efforts.
9. Implementation plans need to be *flexible* to adapt to needed changes as they come up
10. Efforts to change practice and improve the quality of care can have *multiple purposes*, including redesigning care processes to maximize efficiency and effectiveness, improving customer satisfaction, improving patient outcomes, and improving organizational climate.
11. *Appropriate use of technology* can improve team functioning, foster collaboration, reduce human error, and improve patient safety.
12. Efforts need to have *sufficient resources*, including protected staff time.
13. *Continually collect and analyze data and communicate results* on critical indicators across the organization. The ultimate goal of assessing and monitoring quality is to use findings to assess performance and define other areas needing improvement.
14. *Change takes time*, so it is important to stay focused and persevere.

Research Implications

Given the complexity of health care, assessing quality improvement is a dynamic and challenging area. The body of knowledge is slowly growing in this area, which could be due to the continued dilemma as to whether a quality improvement initiative is just that or whether it meets the definition of research and employs methodological rigor—even if it meets the requirements for publication. Various quality improvement methods have been used since Donabedian's seminal publication in 1966,[27] but only recently has health care quality improvement used the Six Sigma methodology and published findings; when it has, it has been used only on a single, somewhat isolated component of a larger system, making organizational learning and generalizability difficult. Because of the long standing importance of quality improvement, particularly driven by external sources (e.g., CMS and the Joint Commission) in the past few years, many quality improvement efforts within organizations have taken place and are currently in process, but may not have been published and therefore not captured in this review, and may not have necessarily warranted publication in the peer-reviewed literature. With this in mind, researchers, leaders and clinicians will need to define what should be considered generalizable and publishable in the peer-reviewed literature to move the knowledge of quality improvement methods and interventions forward.

While the impact of many of the quality improvement projects included in this analysis were mentioned in terms of clinical outcomes, functional outcomes, patient satisfaction, staff satisfaction, and readiness to change, cost and utilization outcomes and measurement is important in quality improvement efforts, especially when variation occurs. There are many unanswered questions. Some key areas are offered for consideration:

- How can quality improvement efforts recognize the needs of patients, insurers, regulators, patients, and staff and be successful?
- What is the best method to identify priorities for improvement and meet the competing needs of stakeholders?
- What is the threshold of variation that needs to be attained to produce regular desired results?
- How can a bottom-up approach to changing clinical practice be successful if senior leadership is not supportive or the organizational culture does not support change?

In planning quality improvement initiatives or research, researchers should use a conceptual model to guide their work, which the aforementioned quality tools can facilitate. To generalize empirical findings from quality improvement initiatives, more consideration should be given to increasing sample size by collaborating with other organizations and providers. We need to have a better understanding of what tools work the best, either alone or in conjunction with other tools. It is likely that mixed methods, including nonresearch methods, will offer a better understanding of the complexity of quality improvement science. We also know very little about how tailoring implementation interventions contributes to process and patient outcomes, or what the most effective steps are that cross intervention strategies. Lastly, we do not know what strategies or combination of strategies work for whom and in what context, why they work in some settings or cases and not others, and what the mechanism is by which these strategies or combination of strategies work.

Conclusions

Whatever the acronym of the method (e.g., TQM, CQI) or tool used (e.g., FMEA or Six Sigma), the important component of quality improvement is a dynamic process that often employs more than one quality improvement tool. Quality improvement requires five essential elements for success: fostering and sustaining a culture of change and safety, developing and clarifying an understanding of the problem, involving key stakeholders, testing change strategies, and continuous monitoring of performance and reporting of findings to sustain the change.

Search Strategy

To identify quality improvement efforts for potential inclusion in this systematic review, PubMed and CINAL were searched from 1997 to present. The following key words and terms were used: "Failure Modes and Effects Analysis/FMEA," "Root Cause Analysis/RCA," "Six Sigma," "Toyota Production System/Lean," and "Plan Do Study Act/PDSA." Using these key words, 438 articles were retrieved. Inclusion criteria included reported processes involving nursing; projects/research involving methods such as FMEA, RCA, Six Sigma, Lean, or PDSA; qualitative and quantitative analyses; and reporting patient outcomes. Projects and research were excluded if they did not involve nursing on the improvement team, did not provide sufficient information to describe the process used and outcomes realized, nursing was not directly involved in the patient/study outcomes, or the setting was in a developing country. Findings from the projects and research included in the final analysis were grouped into common themes related to applied quality improvement.

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Evidence Table. Quality Methods

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Failure Modes and Effects Analysis (FMEA)						
Adachi 2005[78]	Medication safety	Quality improvement	Medication errors, targeting wrong dose errors (Level 4)	422-bed hospital in California	FMEA used to develop strategies – Standard order sets were revised, items from the formulary were removed, and the use of unapproved abbreviations was eliminated. – Used IV pumps with enhanced safety features.	1 year after medication strategies were implemented, medication errors associated with IV infusion were reduced slightly (from 59 to 46), and error related to IV pumps decreased from 41% of dosing errors to 22%. Errors related to wrong drug concentration were completely eliminated.
Apkon 2004[115]	Medication safety	Quality improvement	Infusion drug errors (Level 4)	11-bed pediatric intensive care unit (ICU) in a children's hospital	None	Standardization of the infusion delivery process, with the combined effect of prolonging infusion hang times from 24 to 72 hours, shifting preparation to the pharmacy, and purchasing premanufactured solutions resulted in 1,500 fewer infusions prepared by nurses per year; process changes preferred by nurses and patients.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Burgmeier 2002[94]	Blood transfusion	Quality improvement	Errors associated with blood products administered to patients (Level 4)	1 hospital in Ohio	Following the FMEA, implemented the following changes: a standardized form listing choices for blood products and documenting medical necessity, form is faxed to the blood bank; used a blood-barrier system; required staff training; and changes in policies and procedures.	Following the new process changes for blood transfusions, no outcome errors were reported within the first 3 months. New process continued to be assessed, finding more failures to be addressed, and data are aggregated and reported monthly. Flowcharting before beginning the FMEA process itself was important. FMEA process was time consuming, tedious, and difficult.
Day 2006[124]	Dialysis treatment	Quality improvement	Risks for error in the process of administering dialysis (Level 4)	1 hospital in Utah	None	Risk factors included inconsistent nephrology consult/dialysis communication process; dialysis technicians performing beyond their scope of work; scheduling treatments for chronic dialysis patients without a formal consult/order; nurses inconsistently involved in dialysis process; nurses not reviewing dialysis orders or treatment plan before treatment; and lack of a formal handoff report before treatment.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Esmail 2005[107]	Medication safety	Quality improvement	Systematic analysis for improvement in the ordering and administration of potassium chloride and potassium phosphate using HFMEA (Level 4)	4 adult ICUs in 3 hospitals in Canada	Implemented standardized protocol for potassium chloride and potassium phosphate.	Using the HFMEA, recommendations were made for the hospital and ICUs, including who, where, and how the drugs should be mixed, and identifying and developing standard labels for look-alike and sound-alike products. HFMEA helped prioritize the critical steps of a complex medication process (from ordering to administration), making it more objective. While the process took time to conduct, it was instrumental in discovering that the vials of intravenous potassium needed to be stored and packaged differently.
Gering 2005[123]	Patient transfer	Pretest and post-test, quality improvement	Adverse events (Level 3)	2 VA medical centers	A series of strategies to merge patients into one facility	Nurses were critical in the actual move of patients from one hospital to the next. After integration, there were no disruptions in patient care, operating room (OR) cancellations decreased, there were no MRSA infections, and clinic wait times decreased.
Kim 2006[116]	Medication safety, CPOE	Pretest, post-test study	Medication order errors (Level 3)	Pediatric oncology patients in 1 academic medical center in Maryland	Implementation of a CPOE system	After CPOE implementation, there was a decrease in improper dosing, incorrect dosing calculations, missing cumulative dose calculations, and incomplete nursing checklists. There was no difference in the likelihood of improper dosing on treatment plans, and a higher likelihood of not matching medication orders to treatment plans.
Papastrat 2003[111]	Medication safety	Changing practice project	Error detection associated with medication administration (Level 4)	First-semester baccalaureate nursing students at 1 university in Pennsylvania	New teaching method	Problem-based learning enabled students to use findings from topic-specific research to develop solutions for clinical problems. Students applied knowledge to clinical settings.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Semple 2004[92]	Patient monitoring	Quality improvement	Response time (Level 4)	1 unit with telemetry in a hospital in Connecticut	Procedure changes to enable nurse to respond to telemetry alarms	Problem areas were identified as the nurses' inability to see critical alarm screen color change, hear critical alarms, and to know when their patient's alarm is sounding. A series of changes were implemented to enable nurse response. Response to telemetry alarms decreased from 12 minutes to 1.57 minutes.
Singh 2004[107]	Error risk detection	Pretest, post-test study	Perceived type/cause of error (Level 3)	1 academic rural primary care practice with 32 staff members	Implementation of electronic medical record	Perceived risk of errors decreased in nurse-physician and physician-chart interactions, but hazards increased in physician-patient interaction in the assessment stage as well as nurse-chart interactions.
Singh 2007[99]	Error risk detection	Quality improvement	Perceived type/cause of error (Level 4)	2 primary care practices serving rural populations in New York	None	Nurses perceived being in a hurry, fatigued, stressed, or ill as well as not using available resources for help as the most prevalent type and cause of errors. Hazard scores at site 2 were consistently higher, indicating that staff perceived greater frequency and/or severity of the errors in their practice.
Smith 2005[87]	Medication safety	Quality improvement	Medication errors and adverse drug events (ADEs) (Level 4)	1 hospital in Illinois	Pharmacist staffing on patient care units to review orders and stock medications reduced errors by 45%; adult IV medications were standardized, and nonstandard doses were prepared by the pharmacy.	There was a significant (a 66% drop in the FMEA score) reduction in ADEs.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
van Tilburg 2006[108]	Medication safety, CPOE	Quality improvement	Errors associated with chemotherapy (Level 4)	Pediatric oncology patients in a hospital in the Netherlands	None	Because changes in ordered prescriptions could be made without being noticed by the nurse, a standardized procedure for changes in chemotherapy treatment schedules was made. Because of administration errors, the procedure was changed so that only pediatric oncologists were allowed to administer vincristine via peripheral IV access.
Weir 2005[101]	Medication safety	Quality improvement	ADEs associated with patient-controlled analgesia (PCA) (Level 4)	1 hospital and clinics in California	None	Areas needing change included using a standard IV PCA dosage or concentration protocol; adding the patient's age to CPOE medication order screen; handwritten orders; PCA pumps programmed incorrectly; and monitoring patients using PCAs. 71% of ADEs were associated with PCA programming error, followed by human factors (15%), equipment problems (9%), and ordering errors (5%).
Plan-Do-Study-Act (PDSA)						
Baird 2001[103]	Medication safety	Quality improvement	Patient outcomes and reduced costs in the ICU (Level 4)	Physicians, nurses, and clinical pharmacists in a 115 adult ICU beds in 1 large medical center in Texas	Using a new heparin administration protocol in ICU	Initial findings with 10 patients found that 90% of patients received optimal bolus doses (compared to 8.6% of the historical patients) and all received optimal infusion doses (compared to 3.4% of historical patients). Patients received better heparin therapy because they received the right loading dose, reached a therapeutic level of the drug more quickly, and maintained the therapeutic level. Nursing efficiency improved with fewer dose changes and laboratory tests. Medication and laboratory test costs decreased as did the patient's length of stay.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bolch 2005[97]	Care transitions	Quality improvement	Patients having a documented discharge plan, patients screened for risk, patients receiving followup care within 10 days of discharge (Level 4)	Patients ages ≥ 65, admitted to a hospital in South Australia	Modified the nursing assessment/risk assessment tool	Improvements in the initiation and followup of discharge planning resulted in more documented discharge plans, increased risk assessment, increased referrals to community services, and improved communication between hospital staff and community providers.
Buhr 2006[80]	Pain management	Quality improvement	Improved assessment and management of chronic pain (Level 4)	Patients and nurses (licensed practical nurses (LPNs), certified nursing assistants (CNAs), and registered nurses (RNs)) in 1 nursing home in North Carolina	Increased knowledge of chronic pain assessment and management through education. Implemented updated policies and procedures, and used new tools for pain assessment and management. Revised standing orders for pain management.	Pain assessment and management understanding improved in staff, especially in the CNAs. Patient and family satisfaction increased, and feeling that pain was adequately addressed increased.
Docimo 2000[89]	Throughput in emergency department (ED)	Quality improvement	Time in ED for minor illnesses and injuries (Level 4)	1 ED in 1 hospital in Maryland	Improved both the processes and relationships of hospital staff using PDSA cycles	Nonacute patients were fast-tracked to an average time of 1 hour, 47 minutes by not waiting behind higher-acuity patients for registration. Physician assistants, nurses, and technicians reported improved working conditions and team spirit.
Dodds 2006[119]	Practice variation	Quality improvement	Length of stay, reduced variation in process of care (Level 4)	Patients with chronic obstructive pulmonary disease (COPD)	Redesigned service delivery by using a continuous quality improvement methodology and PDSA cycles	Decrease in average length of stay. Increase in the numbers of patients admitted directly to the emergency medical unit and transferred to the respirator department. Improved the management of patient information and communication with patients.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dunbar 2006[100]	Pain management Practice variation	Quality improvement	Frequency of painful procedures, managing pain associated with painful procedures (Level 4)	11 neonatal ICUs	Implemented evidence-based practices for pain management and sedation in neonates using PDSA cycles	The combination of using collaborative quality improvement techniques and local quality improvement efforts resulted in better patient outcomes.
Eisenberg 2002[109]	IV incidents	Quality improvement	IV care patient outcomes (Level 4)	4 community hospitals	Education of all staff nurses on IV site care and assessment, as well as assessment of central line, total parenteral nutrition (TPN**)**. Revised 35 IV policies into 5, revised documentation flow sheets, and provided a resource manual.	Reductions in complications and costs. Improved patient satisfaction. No formal complaints about IV care.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Erdek 2004[93]	Pain management	Prospective study	Pain management and assessment (Level 4)	2 surgical ICUs in 1 hospital in Maryland	Implemented 4 PDSA cycles, including educating staff on pain management, modifying pain scales at patients' bedsides, residents documenting pain scores for past 24 hours, and creating expectation that pain > 3 is a defect.	Pain assessment improved from 42% to 71%, and pain management improved from 59% to 97%. Documentation of pain assessment improved among nurses.
Farbstein 2001[106]	Medication safety	Quality improvement	Types of medication administration errors (Level 4)	6 improvement projects in hospitals in Massachusetts	Implementation of best practices, using PDSA to assess impact	The results presented from the 6 improvement projects included faster therapeutic anticoagulation for patients receiving heparin; fewer look-alike/sound-alike errors; fewer PCA administration adverse events; safer administration of coumadin; improved patient information on their medication; and improved processing of the morning dispensing of medications in the pharmacy. The investigators described success factors of medication safety projects as using data to measure outcomes; using forcing functions built into the process; pacing changes sequentially, not all at one time; low cost of changes; using a consultant to mentor team leaders; and using reported errors to assess implementation impact.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Horbar 2003[98]	Neonatal intensive care	Quality improvement	Improved quality and safety of neonatal intensive care (Level 4)	34 centers	Implemented, applying 4 key habits for improvement using rapid-cycle PDSA	Developed 51 potentially better practices that were implemented by multidisciplinary neonatal ICU teams in identifying, testing, and implementing change in practice.
Horner 2005[117]	Pain management	Pretest and post-test study	Improved pain assessment and management of residents (Level 3)	9 nursing homes in North Carolina	Chart audit and data feedback on quality indicators, provider education, and technical support for systems change using PDSA	The number of residents receiving pain assessments increased from 8% to 29%. Residents receiving nonpharmacological pain treatments increased from 31% to 42%. Residents with daily moderate or excruciating pain had increased probability of pain medication use.
Leape 2006[86]	Medication reconciliation, communicating critical test results	Quality improvement	Implementation of safe practices (Level 4)	58 hospitals (88%) in Massachusetts	Institute for Healthcare Improvement model for improvement to care practices	Participating hospitals did so because of the following factors: the intrinsic appeal of the practice, access to experts, and the availability of implementation strategies. Project success was associated with active engagement of senior management, physician engagement, increased use of PDSA cycles, participation in collaborative meetings.
Pronovost 2000[83]	Access to care	Quality improvement	Number of ambulance bypass hours (Level 4)	1 hospital in Maryland	PDSA to act on identified root causes, targeting bed sharing for patients needing ICU care that were managed in the ED	Significant reduction in hours with an estimated $6 million in additional hospital revenue. Success was achieved by teams integrating tools that improved processes and collaborative relationships.
Salvador 2003[114]	Medication safety	Quality improvement	Safety of hospital-based antenatal home care for high-risk women (Level 4)	Physicians, nurses, and clinical pharmacists in 115 adult ICU beds in 1 large medical center in Texas	Using a new heparin administration protocol in ICU	New heparin protocol resulted in better patient care, improved nursing efficiency and work satisfaction, and reduced costs by $885 on average. There were no differences in maternal or newborn health outcomes.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
van Tiel 2006[118]	Health care associated infections	Quality improvement	Compliance with infection control measures (Level 4)	1 ICU and OR in a 715-bed university hospital in the Netherlands	Instruction and training of nursing and medical staff on PDSA cycles	Not wearing a face mask during procedures decreased to 0%; not wearing jewelry decreased to 33%. Improved compliance with wound care, including hand washing before and after wound care and the use of disposable surgical wound sets.
Warburton 2004[120]	Adverse outcomes in EDs	Quality improvement	Detect patients at risk for adverse outcomes, provide a plan of care, and target care services (Level 4)	1 small hospital in Canada	Implementation of the Elder Alert program using PDSA cycles	Process evaluation audits and regular meetings of providers and academic collaborators were essential improvement tools. Screening criteria had to be adapted to the patient population.
Wojciechowski 2006[122]	PDSA	Quality improvement	Increasing access to patient education resources (Level 4)	1 rehabilitation facility in a city in the Midwest	Implementation of a new patient education system for medication and disease information using PDSA cycles	Designing a new Web-based patient education system benefits from a process promoting change incrementally and collaboration.
Root-Cause Analysis (RCA)						
Gowdy 2003[90]	Patient falls	Quality improvment	Incidence of inpatient falls (Level 4)	1 hospital in North Carolina	Implemented an action plan to prevent patient falls	RCA identified risks for falls associated with confusion, gait disturbance, and self-toileting. Inpatient fall rate decreased from 6.1 to 2.6 falls per 1,000 patient days (a 43% decrease during the study period).
Luther 2002[104]	Adverse events	Quality improvement	Incidence of ADEs, ventilator-acquired pneumonia, central-venous-catheter-related bloodstream infections (Level 4)	2 hospitals in Texas	Increased staffing levels and improved education. Conducted RCA to identify issues needing to be addressed by leadership and staff.	Adverse events targeted by nurses using protocols decreased ADEs by 45%, ventilator-acquired pneumonia from 47.8/1,000 ventilator days to 10.9/1,000, and decreased central-venous-catheter-related bloodstream infections from the 90th to the 50th percentile of the National Nosocomial Infection Surveillance System. Implementation of protocols decreased length of stay from 8.1 to 4.5 days.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Middleton 2007[105]	Root causes of errors	Cross-sectional study	Adoption of recommendations detected from RCA (Level 4)	12 physicians (86% response rate) and 17 nurses (100% response rate) in Sydney, Australia	None	Nurses were more likely than physicians to view RCA recommendations as "relevant to the causal statement," "understandable," "achievable," and "measurable." Physicians and nurses involved in the RCA were significantly more likely to believe that the RCA recommendations would "eliminate" or "control" future risks. Some recommendations rated as "relevant to the causal statement" by nurses were significantly less likely to also be rated as "achievable."
Mills 2005[82]	Patient falls	Quality improvement	Incidence of falls and major injuries due to falls (Level 4)	100 VA acute and long-term care facilities	Aggregate RCA was used to support implementation of fall prevention strategies.	61.4% of strategies were fully implemented, and 20.9% were partially implemented. 34% of the facilities reported a reduction in the number of falls, and 38.9% reported a reduction in major injures related to falls. The impact of the interventions could have been hampered by making specific clinical changes without changing policies and providing staff education.
Mutter 2003[95]	Medication safety	Quality improvement	Frequency of medication administration errors (Level 4)	1 451-bed acute care hospital in New Jersey	After assessing causes of errors, established a nonpunitive environment to encourage error reporting and interviewed providers who reported errors.	Improvement requires constant and continual assessment of errors. Rapid-cycle improvement was used to decrease medication administration errors and to inform changes.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Plews-Ogan 2004[102]	Voluntary reporting of near miss/adverse events	Cross-sectional study	Error reporting (Level 4)	1 ambulatory site of a large teaching hospital	System analysis and redesign using RCA.	Two-thirds of the 70 recommended recommendations were level 1, 23% level 2 (i.e., involving more complex interventions usually requiring significant groundwork), and 10% level 3 (i.e., involving other services). Using RCA increased error reporting as system issues were addressed, not through individual blame. RCA identified the underlying causes of reported errors, and improvements were made on an ongoing basis.
Rex 2000[96]	Medication safety	Quality improvement	Rates of ADEs (Level 4)	1 hospital in Texas	Implemented policy changes to use forcing or constraining functions and better personnel support	RCA identified environmental factors (e.g., patient acuity, change of shit) and staffing issues (e.g., new staff). ADEs decreased by 45%. Implementing blame-free RCA enabled identification and prioritization of performance improvement initiatives and focus on systems issues.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Willeumier 2004[85]	Medication safety Health care associated infections	Quality improvement	Rates of medication error reporting and ventilator-associated pneumonia (VAP) rates (Level 4)	8-hospital system in northern Illinois	Improved medication availability, standardized nursing reassessment of medications, reinforced the 5 rights of medication administration, provided medication information, revised medication policies, and standardized nursing documentation of medication administration. Redesigned oral hygiene processes, used head positioning, and used collection and culture techniques for better diagnosis.	Identified strategies based on proactive risk assessment (a composite of RCA and FMEA). Medication error reporting increased and VAP rates decreased. Greatest challenges were implementing and sustaining a culture of safety, the complexity of the health care system, underreporting of patient safety events, and medical staff's acceptance of the disclosure policy. Improvement is dependent upon the involvement of leadership, communication with staff, and the use of the appropriate technology.
Six Sigma						
Germaine 2007[91]	Surgical site infections OR patient throughput	Quality improvement	OR turnover (Level 4)	1 hospital in Michigan	Implemented OR turnaround protocol	Turnover decreased from 34 minutes to an average of 18 minutes, allowing volume to increase by 5%. Surgical site infections decreased from 2.14% to 1.07%.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Guinane 2004[81]	Groin injury in cardiac catheterization patients	Quality improvement	Groin injury rates (Level 4)	A team of physicians, nurses, and administrators involved in the care of cardiac catheterization patients in 1 hospital	Implemented groin management process to decrease injury rates, reduce the cost of care, and improve customer satisfaction	Groin injuries decreased from 4% to less than 1% (e.g., 41,666 defects to 8,849.5 defects) – sigma value improved from 3.23 to 3.87. Length of stay that exceeded the specified upper limit decreased from 16% of the time to only 3% of the time. Operating costs that exceeded the specified upper limit decreased from 18% to 3% of the time.
Johnson 2005[125]	Chest pain management	Quality improvement	Time for diagnosis and evidence-based treatment of patients with chest pain	1 hospital in New York	Implemented an algorithm, preprinted orders, and use of cardiac nurse practitioners from presentation in ED through discharge	Increases in diagnosis of cardiac disease, cardiac catheterization, and stenting/bypass surgery, especially in women, Latinos, and patients > 60 years old.
Pexton 2004[113]	Surgical site infections	Quality improvement	Rate of colon and vascular surgical site infections (Level 4)	1 medical center in West Virginia	A preoperative order set with a checklist including recommended antibiotics and weight-based dosages, education of team members, physician report cards, and anesthetists and nurses prompting surgeons to use antibiotics.	Surgical site infection rates decreased by 91% (2.86 sigma), with an estimated potential annual savings of more than $1 million.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Toyota Production System (TPS)/Lean						
Aldarrab 2006[126]	Emergency care of patients with ST-elevation myocardial infarction (MI)	Quality improvement	Patients with appropriate reperfusion and adjunctive pharmacological treatment (Level 4)	3-site tertiary/quaternary facility in Canada	Implementation of evidence-based guidelines for ST-elevation in MI patients	An RCA was used to understand current processes and to assess what could be standardized. Targets were achieved in terms of using the appropriate reperfusion strategy, meeting the median time of < 30 minutes for thrombolytic therapy and 90 minutes for percutaneous coronary intervention, appropriate thrombolytic and adjunctive treatment use. It was noted that without continued reinforcement of the new protocol, the process would regress to prior levels of performance.
Furman 2007[39]	Error reporting	Quality improvement	Near-miss error reports (Level 4)	1 medical center in Virginia	Implemented an error reporting system, including a 24-hour hotline	Nurses reported 44% of the near misses, physicians 8%, managers 20%, nonclinical staff 23%. Over a period of 3 years, the number of error reports increased because there was a transparent discussion and feedback process.
Jimmerson 2005[88]	Medication safety Access to medical equipment	Quality improvement	Efficiency of testing patient's glucose level at the bedside (Level 4)	1 medical-surgical ICU in a hospital in Utah	Installed glucometers in each room in the ICU	Reduced time to do glucose check from 17 to 4 minutes. Improved ability to consistently implement the protocol. No unlabeled specimens at risk of erroneous identification. Fewer RN interruptions and frustration.
Nowinski 2006[121]	Medication administration	Quality improvement	Medication administration errors (Level 4)	1 hospital in Pennsylvania	Revised and streamlined medication administration process based on finding from an RCA	Rapid, substantial, and continuing improvements in patient care were achieved. Nursing staff reported higher levels of satisfaction.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Printezis 2007[59]	Using TPS in health care	Literature review	Reviewed five quality improvement projects to reduce medical errors in hospitals (Level 4)	Improvement projects in hospitals	None	Simple pathways of root causes lead to better operational performance. Organizing principles of TPS improve reliability and effectiveness of health care delivery systems. Problem-solver on projects should not be a consultant, but someone who is a stakeholder. Many problems are associated with relationships with other departments. TPS makes work-around and rework difficult to continue. TPS helps staff learn and identify waste in daily activities. Front-line staff need to be enthusiastic about making improvements. Clear, concise, and objective communication is key.
Thompson 2003[84]	Medication administration	Quality improvement	Missing medications Complexity of the medication administration process (Level 4)	Pharmacy and nursing units at 1 hospital in Pennsylvania	Implemented: specific	Rapid, substantial, and continuing improvements in medication administration processes were achieved. Nursing staff reported higher levels of satisfaction, associated with workflow improvements.