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The Intersection of Evidence-Based Practice With 5 Quality Improvement Methodologies

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In this department, the authors highlight hot topics in nursing outcomes, research, and evidence-based practice relevant to the nurse administrator. The goal is to discuss the practical implications for nurse leaders in diverse healthcare settings. Content includes evidence-based projects and decision making, locating measurement tools for quality improvement and safety projects, using outcome measures to evaluate quality, practice implications of administrative research, and exemplars of projects that demonstrate innovative approaches to organizational problems. In this article, the authors describe the intersection of various quality improvement methodologies with the evidence-based practice process. Five quality improvement approaches, plan-do-check-act, Six Sigma, Lean, root cause analysis, and failure mode effects analysis, are described and are used to frame examples.

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Nurses play an important and significant role in promoting positive patient outcomes. Because of this direct effect on patients, nurses must have a constant awareness and a diligent effort to identify and correct problem-prone processes. Quality improvement (QI) skills and engagement are central to the nurse's responsibility in healthcare settings. Quality improvement is a process by which individuals work together to improve systems and processes with the intention to improve outcomes.[1] Quality improvement uses data-based methods to bring about immediate improvements in healthcare delivery.[2] Central to these efforts is informing strategies for improvement by both research and experiential evidence.

Evidence-based practice (EBP) is a problem-solving approach to clinical decision making in a healthcare organization that integrates the best available scientific evidence with the best available experiential (patient and practitioner) evidence, considers internal and external influences on practice, and encourages critical thinking in the judicious application of such evidence to care for the individual patient, patient population, or system.[3] There are many models for EBP, but they all include 5 distinct steps: (1) asking important questions, (2) acquiring the evidence, (3) appraising the evidence, (4) applying the evidence to practice, and (5) assessing the results and adjusting the processes if needed.[4,5]

Past departments have focused on distinguishing between QI, research, and EBP.[6] This department focuses on the intersection of QI methodologies with the EBP. Five QI approaches will be described (plan-do-check-act [PDCA], Six Sigma, Lean, root cause analysis [RCA], and failure mode effects analysis [FMEA]) and then used to frame examples of how EBP is central to the improvement methodologies. A summary of each methodology and

its intersection with EBP is listed in Table 1.

QI Approaches

Plan-Do-Check-Act

Plan-do-check-act, also known as plan-do-study-act, is the most commonly used QI methodology in healthcare. The PDCA model was originally introduced by Shewart and Deming as a model for continuous QI in business, but it gained popularity in healthcare when the Institute for Healthcare Improvement (IHI) recommended its use as the model for improvement and accelerating change.[7] The PDCA model is based on the scientific process in considering an assessment of original data, the introduction of an intervention or change, a prediction about the outcome of the intervention, and finally, development of a conclusion about the intervention based on evidence and data. Although modeled after the steps in the scientific process, the PDCA process is unique in that it is intended to be iterative and continuous. The 4-step process is cyclic in nature and models the real-life nature of ongoing action and appraisal.[8]

In the "plan" phase, a specific change aimed at improvement is designed and a strategic plan for implementation is recommended. The PDCA model does not limit or recommend the size or scope of the change; the plan can refer to an organizational-wide change or to a smaller scale test of change. However, it has been noted that change is more successful when tested on a small scale 1st.

The do phase of the PDCA model refers to the actual implementation of the planned change. The completion of the do phase is easier and typically more successful if a detailed implementation plan is developed during the "plan" phase. The check phase of the PDCA model requires an analysis or examination of results. Questions typically asked in this phase include the following: Did the implementation plan go as expected? What was learned during the implementation phase? Did anything unexpected occur? This is the stage of the model where an assessment of the change is made based on quantitative or

Table 1. Summary Table

	Brief Definition	Steps	Intersection With EBP
PDCA	Flowchart for process improvement	Plan Do Check Act	Apply Assess Adjust
Six Sigma	Minimization of variation in process; 3.4 defects per million	Define Measure Analyze Improve Control	Ask Apply Assess Adjust
Lean	Process development method with focus on value-added steps and elimination of non–value-added steps	Voice of the customer Value stream mapping Determination of value-added and non–value-added steps Create or revise process	Ask Apply Assess Adjust
RCA	Retrospective analysis of an untoward event	Ask a series of why questions Determine root causes	Ask
FMEA	Prospective risk assessment	Process map current state Identify all potential process failures Estimate the effect of each identified failure Identify top 1 or 2 failures and prospectively mitigate risk	Apply Assess

Abbreviations: EBP, evidence-based practice; FMEA, failure mode effects analysis; PDCA, plan-do-check-act; RCA, root cause analysis.

qualitative data. In the act phase of the model, a decision to adopt, adapt, or abandon the planned change is made. Data obtained in the check stage should drive this decision.

The PDCA model was originally designed to be used continuously, as knowledge gained in the 1st cycle should fuel more questions or present more opportunities for improvement. Ideally, multiple PDCA cycles are used in succession, with the easiest changes being made in the initial cycle, followed by implementation of the more difficult changes. For example, during the development of an evidence-based falls prevention strategy, there are multiple tests of change that should be implemented and evaluated. During the 1st PDCA cycle, it is reasonable to implement universal armbands that identify patients as being at high risk to fall; in the next cycle, a hospital may decide to implement a new fall risk assessment tool; in the next cycle, the hospital may choose to implement a new fall prevention competency for ancillary staff. The easiest changes to make are planned and implemented 1st, followed by the changes to the more complex processes.

Six Sigma

Six Sigma was developed as a QI strategy by Motorola in the 1980s.[8] The term Six Sigma is derived from the Greek term sigma, which statisticians use to measure variation, and the degree to which almost perfect production occurs. If a process is operating at the Six Sigma level, one can expect 99.9996% perfection or 3.4 defects per million opportunities. For example, if a company that manufactures syringes is operating at the Six Sigma standard, 3.4 of every 1 million syringes manufactured will be defective. In contrast, most manufacturing companies operate at the 3 or 4 sigma performance level, which results in over 66,000 defects per every 1 million opportunities.[8]

Like PDCA, the Six Sigma process is also based on the scientific method, but instead of 4 steps, there are 5 steps in the Six Sigma process: define, measure, analyze, improve, and control. These steps are often referred to by their initials, DMAIC. There is some overlap between DMAIC and PDCA, but the primary difference is in the measure and the control phases. The "define" step refers to defining the goals of the improvement activity and defining who the customers, process owners, and stakeholders are. There are multiple tools and strategies that are typically used in this phase, such as focus groups, process mapping, and the creation of cause-and-effect diagrams. The "measure" phase involves the quantitative measurement of the current system or process. This phase can be challenging because data that measure the specific processes of interest are not always readily available. In this case, manual data collection during a specific time frame may be necessary. Data analysis typically involves descriptive statistics, run charts, and Pareto analysis. Once the objective data are available, the analyze phase focuses on identifying ways to eliminate the gaps between the current state and the desired state. The statistical tools used in the measure phase help team members understand the data and assist in guiding the improvement plan. The improve stage is analogous to the "do" and "check" stages of the PDCA cycle. In this phase, the planned change is implemented and evaluated. Quantitative data are again collected and used to evaluate the outcome of the implemented change. The control phase is the final and perhaps the most important stage of the DMAIC process. This phase requires the identification and articulation of formal plans and processes for maintaining and controlling the new system or process. A robust control plan usually includes an ongoing plan for data collection and evaluation, as well as the development of new policies and procedures if needed.

Although the term defects per million is easily understood as applicable to the manufacturing industry, it is not always immediately clear how the term Six Sigma applies to the healthcare industry. The goal of Six Sigma is to limit process variation, thereby improving efficiency and outcomes. The tools and methodologies used during the DMAIC process help to identify standard measurements to continuously monitor performance and achieve significant long-term improvements. The define and measure steps of the Six Sigma process can lead to clinical practice questions that require a review of the evidence, or evidence can be used to help design process changes or to identify strategies for maintaining sustainability of process. For example, while undergoing a Six Sigma project to improve perioperative patient flow, the scientific evidence that addresses best practices associated with the diagnosis and management of patients with obstructive sleep apnea[9] can be

integrated into the "improve" phase of the DMAIC process.

Lean

Lean methodology was developed by Toyota in the 1940s, but the term *Lean* was not introduced until the 1990s.[8] The basic principles of Lean are to minimize waste, whether that is waste associated with product defects, overproduction, and excessive inventories or the unnecessary movement or actions of people. The goal of a Lean process or a Lean organization is to eliminate non–value-added steps and processes. The critical components of Lean include identifying exactly what defines "value" to the customer and then creating a value stream map.

A value stream map is similar to a process map, but it identifies not only the flow of the work but also the value associated with each step in the process. Each step in the value stream map is identified as a value-added or a non–value-added step from the perspective of the customer. In the most simplistic of descriptions, the goal of Lean is to eliminate as many non–value-added steps as possible. As with Six Sigma, there are various terms and tools that are used when an organization is working toward becoming a Lean organization. A key term includes the word *Kaizen*, which means continuous QI, and frequently used tools include A3, a standardized project management and reporting tool, Kanban, a visual cue, and Poka-Yoke, any tool that is designed to prevent human errors. The IHI has published a white paper about the Lean methodology as it applies to healthcare, and a full glossary of Lean terms can be found there.[10]

The terms Lean and Six Sigma are often used together. Although they are 2 different approaches to QI, they are complementary to each other and are therefore often used simultaneously. The Six Sigma methodology is helpful for identifying variation in practice and for helping the team identify not only what data are useful to measure to describe the scope of the problem but also what data are useful to measure for the purpose of evaluating change sustainability. Lean provides a methodology that focuses on value to the customer, as well as tools for eliminating waste and creating efficient processes. Therefore, the early steps of the Lean process that involve identifying the voice of the customer and defining value can inform the exact clinical questions that should be asked. Value stream mapping and the use of Lean tools such as visual cues are helpful when developing new processes during the application phase of EBP. In the previous example of caring for patients with obstructive sleep apnea in the perioperative setting, implementation of a visual cue such as a STOP sign, which represents the STOP questionnaire that assesses for sleep apnea,[9] can be placed on the chart of all patients who screen positive for obstructive sleep apnea. This Kanban, or visual cue, will alert care providers to the presence of obstructive sleep apnea and will serve as a reminder to implement the evidence-based pathway that has been developed.

Root Cause Analysis

Root cause analysis is a retrospective, systematic process that uses information obtained during the investigation of an event to identify and understand the underlying causes of an event.[11] Like many of the QI strategies discussed, RCA also has its roots in the manufacturing industry and was originally used as a way to evaluate industrial accidents. In healthcare, RCA has been widely adopted as a tool to review and understand the underlying system deficiencies that contribute to medical errors and adverse events. In fact, the Joint Commission as well as state hospital associations require that hospitals submit an RCA and subsequent action plan for all sentinel events. As a result, several healthcare professionals in an institution are often trained in RCA, and resources for how to conduct a thorough RCA are now widely available.[12]

The goal of RCA is to understand the contributory factors that create an environment where an error is likely to happen. The RCA process is designed to focus on systems and processes, not individuals. The RCA process should consider both active and latent factors. Latent factors can be described as conditions that result from organizational actions and decisions, such as poor maintenance of equipment, creation of policies that are not clear, and tolerance for complacency. In the EBP process, RCA is useful for identifying clinical problems and questions that can be answered using EBP. For example, during the RCA process for a hospital-acquired stage 4 pressure ulcer in a cardiac surgery patient, it may be determined that there was no standardized process in either the operating room or the cardiothoracic intensive care unit (ICU) for caring for cardiac surgery patients considered at extremely high risk for the development of a pressure

ulcer. The results of this RCA should be used to prompt an EBP project aimed at identifying the best intraoperative and postoperative care processes for the cardiac surgery patient at high risk for pressure ulcer development.

Failure Mode Effects Analysis

Unlike RCA, which is a retrospective tool, FMEA is a prospective risk assessment tool. This tool was developed by the military and the National Aeronautics and Space Administration to evaluate potential failures and unrecognized hazards[11] and has been adapted for use in healthcare by the Department of Veteran Affairs and the National Center for Patient Safety.[13] Failure mode effects analysis involves identifying all the potential failures within a specific process and anticipating the effect that each failure might have on the process outcome. The estimated effect of each process failure is determined by how likely the failure is, how visible the failure is, and how catastrophic the failure would be if it occurred. The goal of FMEA is to identify the process failures that are most problematic and attempt to correct or mitigate the failures before they occur. This tool is most effective when new processes are being designed; therefore, it is a useful tool during the application and assessment phases of EBP. Like RCA, tools and resources for conducting an FMEA are widely available.[14]

Case Study

Although discreet examples of the intersection between QI methodologies and EBP have been given, the following fictional, case study demonstrates how these 5 QI methodologies can work synergistically to enable and support the EBP process.

A 48-year-old woman receiving immunosuppressive therapy for systemic lupus erythematosus presented to the emergency department (ED) with fever 3 days status post laparoscopic cholecystectomy; the patient was admitted to rule out sepsis. The patient was given a dose of antibiotics in the ED at 10 am and was ordered for routine antibiotics every 8 hours. At 3 pm, a request for transfer form was faxed from the ED to the surgical unit and the patient was transferred by transportation personnel. At 10 pm, the patient became febrile, tachycardic, hypotensive, and oliguric. The patient was transferred to the ICU but ultimately died of septic shock. Upon review of the case, it was determined that the patient never received her 6 pm dose of antibiotics. A multidisciplinary team including staff members from the ED, the surgical unit, the ICU, and the pharmacy was convened to discuss the case. Using QI methodologies, this case is considered within the EBP framework described in the Introduction section: ask, acquire, appraise, apply, assess, and adjust.

An RCA of the event was conducted and 2 root causes associated with the omitted antibiotic dose were identified: communication failure at the time of patient transfer from the ED to the surgical ward and a faulty medication timing function within the computerized order entry system that timed the antibiotic dosing schedule 8 hours after the time of transfer, not 8 hours after the time of the 1st dose. These 2 root causes then became the critical clinical questions that made up the "ask" phase of EBP. To address the root cause of communication failure at handoff, nurses from the ED and the surgical unit conducted a literature review and consulted organizations such as the IHI to determine the best practices for handoff communication. Once the evidence was acquired and appraised, the nurses conducted a gap analysis to determine what best practices are included in the current handoff process and what best practices are lacking. The nurses proposed a new handoff communication tool that requires a nurse-to-nurse verbal handoff, and together with the ED physicians, they developed a better process for transfer medication reconciliation. Using PDCA, the new handoff tool was implemented. Staff satisfaction with the tool was assessed using focus groups and adjustments to the new tool were made based on staff feedback.

To address the root cause associated with the computer order entry system, pharmacy staff, nursing staff, and information technology (IT) staff met to define the current process and process failures. Using the Six Sigma and Lean tools of Pareto analysis and value stream mapping, it was determined that the medication timing issue is a problem only at the time of patient transfer and that during the current transfer process, the pharmacy staff is required to complete a manual data entry step to accommodate the deficiency in the computerized medication timing function. Retrospective analysis of antibiotic medication administration over the previous year revealed that although this specific case was the first death attributed to this system failure, the issue of missed medication doses

has been a significant problem for patients transferring from the ED to the acute care units.

Although the published scientific evidence surrounding this specific issue is virtually nonexistent, the IT staff engaged in dialogue with the vendor and other hospitals about this issue and possible solutions. In the meantime, the clinical staff searched the scientific evidence for best practices around computerized order entry principles and processes. After acquiring information from 3rd parties and appraising the current literature, a solution that requires a software upgrade was recommended. Because objective data regarding the significance of the problem were discovered, hospital leadership approved a budget adjustment so that the needed software could be purchased immediately. While waiting for the software to be installed and tested, a multidisciplinary group of staff conducted an FMEA on the newly proposed process. After identifying 1 potentially significant failure related to default timing of medications, a forcing function (ie, Poka-Yoke) that requires a manual attestation of timing was instituted for all antibiotic medications that are ordered at the time of transfer. The software was implemented (applied) and pharmacy staff is now responsible for assessing and tracking the incidence of missed antibiotic doses at the time of patient transfer.

Conclusion

In the field of QI, there are multiple different tools available for use to improve care delivery and patient and system outcomes. As with any type of tool, the QI tools described here are not interchangeable, and each tool is not appropriate for every clinical problem. As described, each QI method has the ability to inform and guide various stages of the EBP process. Quality improvement and EBP are 2 different methodologies that are fundamental to nursing practice, but they are synergistic and complementary. Evidence is fundamental to solving quality problems; therefore, neither methodology should be viewed in a vacuum. Root cause analysis can identify the clinical questions that require a thorough review of the evidence. Six Sigma and Lean methodologies and tools can be used to define measurement strategies, design new processes that add value, and establish plans for ensuring control and sustainability of change. Failure mode effects analysis can be used to identify potential problems that might arise from proposed clinical practice changes, and PDCA can be used as the model to implement small steps of change. The EBP process is informed and supported by the application of QI methodologies, and the QI process is strengthened by the use of evidence.

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