Patient Safety – Quality Improvement Strategies

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Quality healthcare has been 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”. According to the Institute of Medicine (IOM) report, *To Err Is Human*, the majority of medical errors result from faulty systems and processes, not individuals.

Processes that are inefficient and inconsistent, 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.

This paper will discuss strategies and tools that have been used to improve the quality and safety of health care, including:

* Failure Modes and Effects Analysis (HFMEA^{TM}),
* Plan-Do-Study-Act,
* Six-Sigma,
* Lean,
* Root Cause Analysis (RCA)

Quality Improvement Strategies

According to Ronda G Hughes (1), quality improvement projects and strategies differ from research in that research attempts to assess and address problems that will produce results. Quality improvement projects can include small samples, frequent changes in interventions, and adoption of new strategies that appear to be effective.

In a review of the literature on the differences between quality improvement and research, Reinhardt and Ray (2) 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 applicable to all similar organizations
(4) Data from quality improvement is organization-specific, while research data are derived from multiple organizations.

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.

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 (3) 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?
(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.

Six Sigma

Six-Sigma originally designed as a business strategy, involves improving, designing, and monitoring processes to minimize or eliminate waste while optimizing satisfaction and increasing financial stability.

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.

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 pre-analytic and post-analytic 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 define, measure, analyze, improve, and control (DMAIC) approach.

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.

Toyota Production System/Lean Production System

Application of the Toyota Production System—used in the manufacturing process of Toyota cars 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. 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 and blood banks 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. According to Spear (4), 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".

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", 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 and similar to critical incident technique (5), 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.

RCA is a technique used to identify trends and assess risk that can be used whenever human error is suspected with the understanding that system, rather than individual factors, are likely the root causes of most problems.

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.

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. 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.

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.

The final step of a traditional RCA is developing recommendations for system and process improvement(s), based on the findings of the investigation. 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.

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 (6) (7).

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.

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.

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.

In Health care, FMEA focuses on the system of care and uses a multidisciplinary team to evaluate a process from a quality improvement perspective.

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 sub-step 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)

(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.

References

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3) Langley JG, Nolan KM, Nolan TW, et al. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.
4) Spear SJ, Fixing Healthcare from the Inside, Today.
5) Kemppainen JK, The Critical Incident Technique and Nursing Care Quality Research
6) Joint Commission, Using Aggregate Root Cause Analysis to Improve Patient Safety
7) Bagian JP, Gosbee J, Lee CZ, et al. The Veterans Affairs Root Cause Analysis System in Action.

AIHC now offers an introduction to HFMEA packet which includes a pdf product and powerpoint presentation. For more information about this product or our 2010 certifications in Patient Quality, email us at info@aihc-assn.org!