IR Safety Rounds

Strategies for Choosing Process Improvement Projects

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THE first article in this series illustrated how errors during medical care are a serious problem (1). Error rates of 1% are common when humans perform simple tasks (2,3) and increase to 30% or more during complex multi-step procedures such as cardiac surgery or caring for hospitalized patients (4,5). Despite the prevalence of human error, well-designed systems such as those used in aviation and nuclear power diminish the rate of serious errors to less than one in a million. Although medical errors will always be inevitable, much can be done to reduce their burden. We suggested that it would be impractical and impossible to simultaneously tackle all types of medical errors. Rather, a systematic approach is needed. The ideal approach would examine any health care process and create a prioritized list of error reduction or quality improvement projects. Herein, we describe how the scientific method can be applied to this problem.

APPLYING THE SCIENTIFIC METHOD TO PROCESS IMPROVEMENT

The scientific method uses five basic steps to help solve any problem (Table 1). For process improvement, one first gathers information about the process by observing it. Those observations are then used to predict how the process might be improved. Next, the predicted improvement is tested and the results analyzed. On the basis of those results, one must decide whether there is sufficient evidence to conclude the prediction is correct. If the evidence is not sufficient, one must decide if this occurred because the prediction is correct but the evidence is lacking or if the evidence is correct and the prediction requires revision. Those with a background in process improvement might structure their project by using the Define Measure Analyze Improve Control model of Six Sigma (6) or the Plan Do Study Act paradigm introduced by Shewhart (7). However, because both follow the scientific method’s general theme of observe, predict, test, and decide, we see little reason to reinvent the wheel. Rather, we contend that because the scientific method drives every process, improvement should be promoted to the same status as molecular biology, clinical trials, and the other branches of stamp collecting.

OBSERVATIONS FROM A MACROSCOPIC VIEWPOINT

The overriding theme is that any process can be improved. This implies that every aspect of interventional radiology contains opportunities for improvement. Even if one’s practice is devoted exclusively to a single procedure, one could still improve the results by changing the processes used to screen and schedule patients, perform the procedure, and care for patients after the procedure. Developing a list of quality improvement projects requires a comprehensive survey of the field and a means to map out all the different job processes. Job analysis techniques such as observational studies, customer surveys, and record review provide data that encompass the entire scope of job-related activities and allow one to begin mapping the process improvement landscape (9, 10).

When analyzing the data provided by such studies, one is soon faced with choosing between two different process improvement strategies. The first is a “hitting for power” strategy in which one focuses on projects that offer a large potential impact. The second is a “hitting for average” strategy in which one attempts to make a series of small incremental improvements. The first strategy offers discrete and dramatic results. It fosters a sense of completion and can minimize the need for detailed statistical analysis. However, over the long term, the opportunities for quick dramatic fixes soon diminish. As a result, most quality improvement programs favor the hitting for average strategy of small incremental improvements (6,11). Even though some of those projects might provide dramatic results, the long-term goal is to continually improve the underlying processes. This viewpoint recognizes that the value of small changes in high-volume processes quickly aggregates and can soon ex-
ceed the results obtained with big
changes in high-profile but less-com-
mon processes.

To help identify high-volume pro-
cesses and prioritize them, one can use
tools such as Pareto analysis (6,12). Pa-
reto analysis is a process of ranking
opportunities to help one decide
which of many potential opportunities
should be pursued first. We used this
process to analyze current procedure
terminology (CPT) coding data from
our billing records. This analysis re-
vealed that, during a 21-month period,
two interventional radiologists used
188 unique CPT codes to describe the
work performed. Common proce-
dures were reflected by multiple bill-
ing records containing the same CPT
code, and these billing records con-
tained more than 15,000 codes. As
shown in **Figure 1**, CPT code usage
was severely skewed, with just nine
CPT codes accounting for nearly 50%
of the total billed codes. These nine
codes described central venous access
and abscess drainage procedures. The
CPT data were then converted into rel-
ative value units to begin estimating
how workload was distributed be-
tween various procedures. This analy-
sis (Fig 2) confirmed that the workload
for these two interventional radiolo-
gists was heavily skewed toward cen-
tral venous access and abscess drain-
age.

Although central venous access
might lack the appeal of more complex
procedures, a series of high-profile
agencies have identified central ve-
 nous access as a high-priority target
for process improvement. The Agency
for Healthcare Research and Quality
(AHRQ) critically reviewed the exist-
ing evidence on practices relevant to
improving patient safety and reported
11 practices that, if widely imple-
mented, would have the greatest im-
 pact (13). This list included prophy-
laxis of venous thromboembolism,
antibiotic prophylaxis in surgical pa-
tients, and three recommendations
with regard to central venous access.

For central venous access, the AHRQ
recommended using real-time ultra-
sonographic (US) guidance for central
venous access, maximum sterile barri-
ers, and antibiotic-impregnated cathe-
ters (13). Agencies such as the Joint
Commission and the Centers for Med-
icaid and Medicare Services are using
their considerable leverage to imple-
ment those recommendations. The
Centers for Medicare and Medicaid
Services has identified vascular cathe-
ter—related bloodstream infection as
a potentially avoidable complication

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**Table 1**

<table>
<thead>
<tr>
<th>Scientific Method</th>
<th>Define Measure Analyze Improve Control (DMAIC—Six Sigma)</th>
<th>Plan Do Study Act (PDSA—Shewhart)</th>
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<tbody>
<tr>
<td>1. State the problem and collect background information.</td>
<td>1. Define the goals of improvement activity and measure the existing process.</td>
<td>1–2. Plan – study the current process and plan how it might be improved.</td>
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<td>2. Propose a hypothesis.</td>
<td>2. Analyze the system to identify how the process might be improved.</td>
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<td>3. Design an experiment that tests the hypothesis.</td>
<td>3–4. Improve the system by varying the process and measuring the results.</td>
<td>3. Do – test the predictions by conducting experiments.</td>
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<td>4. Collect and analyze the data.</td>
<td>4. Study the result of those experiments.</td>
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<td>5. Draw a conclusion regarding the hypothesis. Report these conclusions.</td>
<td>5. Control the new system. Lock in the improvements by reporting the results.</td>
<td>5. Act on the results by drawing a conclusion and reporting that new knowledge.</td>
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**Figure 1.** Pareto analysis of CPT data. CPT data from two interventional radiologists were collected during a 21-month period. The data set included a total of 188 unique CPT codes, and the relative frequency of each code was determined. The figure illustrates how the distribution is highly skewed toward a small number of codes.
and is planning to implement a rule whereby hospitals are denied payment for treating such complications (14). As a step toward this goal, the Centers for Medicare and Medicaid Services created a new International Statistical Classification of Diseases and Related Health Problems (ICD-9) code, 996.62, to begin tracking such cases. This analysis highlights the importance of improving central venous access. Although most interventional radiologists have already made the improvements recommended by the AHRQ, we suggest two reasons for continuing to improve central venous catheter placement. First, further improvements in the efficiency and reliability of central venous catheter placement will allow interventional radiologists to free up resources that can be shifted to other portions of their practices. Second, interventional radiologists have a “head start” because they have already implemented these recommendations and, thus, interventional radiologists are well positioned to take a leadership role in a high-profile segment of the patient safety field.

OBSERVING PROCESSES IN MORE DETAIL

Task analysis is a strategy for studying processes in greater detail (10). Task analysis creates models that help us understand procedures such as US-guided central venous catheter placement (Fig 3). These models include flow charts and other symbolic representations that force us to explicitly describe the process and the system. Even a simple procedure like central venous access can be broken down into numerous smaller pieces for analysis in greater detail (Fig 4). As the level of detail increases, one typically simplifies the process so as to maintain an ability to comprehend the system being studied. The result, hierarchical task analysis, exploits the same drill-down strategy that has been effectively employed throughout molecular biology and other fields.

The aim of task analysis and these models is to reveal predictions that can then be tested. As shown in Figures 5 and 6, we have created a series of models for physician decision-making and action during central venous access. These models are clearly incomplete and almost certainly contain multiple flaws. Still, because these models describe the process and system in explicit terms, they take us a step closer to improving the process because they help reveal how errors occur.

PREDICTING HOW PROCESSES GO AWRY

Both Murphy’s Law and probability theory contend that every process
is prone to failure. The models created by using task analysis provide a detailed analysis of the system and allow us to begin predicting the possible modes and causes of failure. Failure Mode and Effects Analysis (FMEA) contends that although these failures are inevitable, the system can be improved by taking steps that decrease the frequency of failure, minimize the consequence of failure, and identify failures before they lead to catastrophe (15,16). FMEA is now required by the Joint Commission. The first goal of FMEA is to create a comprehensive list of failure modes and their potential causes. As shown in Figure 6, even a seemingly straightforward step such as using US to identify the jugular vein has multiple failure modes.

The second goal of FMEA is to rank these failure modes. For this, the frequency and severity of each failure mode is rated. The ability of the existing system to detect each failure mode is also considered. These ratings might be extracted from existing data sets or estimated from experience. When attempting to apply the rating schemes used in other fields, we found that the broad range of event frequency and severity created difficulties for analysis of medical procedures. The problem was further compounded by the tendency of each rater to base the rating on different criteria. This led us to propose the system outlined in Figure 7. In this system, the broad range of event frequency and severity is compressed by using a logarithmic scale.

Furthermore, the event frequency is expressed in terms of failure probability on any given day. The event severity is based on the costs associated with the failure. The frequency and severity scores are readily combined to estimate the average daily cost for any failure mode. The detection factor serves to highlight those failure modes that tend to slip through the system’s current defenses.

When compared with root cause analysis, FMEA is substantially more robust. Root cause analysis is a retrospective tool that is used only after a problem is found (17). FMEA is a forward-looking exercise that attempts to predict the potential harm caused by any failure mode. Aviation and other industries routinely use FMEA during the early design stages so as to improve the reliability of the resulting process. FMEA also lends itself to continuous process improvement because any attempts to improve the system can be monitored by their effect on the frequency, severity, and detection of the system’s various failure modes.
Process improvement is an attempt to gain knowledge about a system. W. Edwards Deming observed that “Information is not knowledge. The world is drowning in information but slow in acquisition of knowledge” (18,19). One gathers information from a system by observing its processes. One then uses that information to predict how the system operates, and the result is a mental model of the system. That model explains the relationship between process inputs and outputs. The model can also be used to begin predicting how the inputs might be altered so as to improve the output. It is not enough to make a prediction; one must then test the model by altering the inputs and capturing data on the resulting process outputs. This information is then analyzed and used to drive decisions. If the output information agrees with predictions, then one might conclude that the mental model is correct. If the output disagrees with predictions, then one must discard either the model or the data. An accurate model is valued because it allows one to predict the future. This predictive capability enables one to optimize the system.

An appointment scheduling problem provides a simple example. Suppose one observes that one group of patients (group A) always arrives 30 minutes early for their scheduled appointments and another group (group B) is always 30 minutes late. This information provides an opportunity to optimize the system so that neither patients nor procedure teams have to wait. One simply instructs the scheduler to determine the patient’s group (input variable) and then add or subtract 30 minutes from the desired time (input variable 2). The result is the time that is communicated to the patient (output). This improvement requires that the scheduler is able to correctly differentiate between groups A and B, the patients continue to follow their prior patterns of behavior, and procedure teams are able to adhere to the predetermined schedule. In reality, errors will occur. But if those errors are random events, the revised process will, on average, be an improvement over telling patients their actual scheduled time.

Choosing a process improvement project is itself an attempt to predict the future. One invests current resources with the hope of obtaining a future return. Accordingly, one should consider how to maximize the return on that investment (Table 2). This
analysis transforms what was once a single prediction into three separate predictions, and each of the three in turn relies on correctly interpreting prior data. As each level of analysis reveals more uncertainty, one ultimately arrives at the realization that there is no sure bet in a world that is ultimately governed by the summed probabilities of events occurring on a quantum scale (20). Even carefully chosen and well-designed process improvement projects will fail; these failures, however, should be viewed as learning opportunities. Both experience and information theory tells us that careful analysis of a single failure can provide more information about a system than a series of successes (21–23). The inevitability of failure should not dissuade us from investing in the future because the alternative assures mediocrity. Rather, we should continually invest in improving our collective future.

Acknowledgments: We thank David Hovsepian, MD, and Dan Picus, MD, for reviewing the manuscript and providing helpful comments.

References