Improving Quality and Patient Safety by Minimizing Unnecessary Variation

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Quality and safety in health care have proven difficult to precisely define and measure. In other fields, quality is defined as the absence of unnecessary variation and process improvement efforts are gauged by their ability to reduce variation. This article explores how this definition can be applied to various attributes of image-guided procedures.

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DESPITE continual increases in the resources devoted to health care, outcomes remain far less than optimal. Although perfection is an unattainable goal, there is every reason to believe there is substantial room for improvement. The first article in this series (1) reviewed process improvement strategies and illustrated how every data-driven strategy is based on the scientific method. The second article (2) offered a systematic approach to choosing process improvement projects. The third article (3) illustrated how system performance in health care remains tightly linked to human performance and how human performance can be measured, and introduced the topic of variation. This final article will examine how excessive variation diminishes quality and patient safety.

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Quality and Safety Are Linked

The frequency, severity, and cost of medical errors have made patient safety a high-profile issue (4,5). Quality and patient safety are clearly linked, as quality errors lead to unsafe practices and procedural complications are often linked to quality lapses. Although process improvement will never yield systems that are completely error-free, we can still strive to decrease the frequency, minimize the burden, and improve the early detection of errors (6).

High-reliability industries such as air transport, nuclear power, and electronics manufacturing have long understood how safety and quality add value (7). The previous articles in this series (1–3) advocated studying these industries and adapting their methods to medicine in general and interventional radiology in particular (8–10). We suggest that the principles that guide the quality control programs in these and other high-reliability industries can be applied to image-guided procedures.

The First Step Is to Define Quality in Measurable Terms

The medical literature contains numerous articles describing the need to develop measures of quality and how such metrics might improve quality (11–13). As shown in **Table 1**, quality involves multiple attributes of a product or process. Although one can consider numerous attributes, it is typical to focus on a few attributes that are considered critical to quality. High-reliability industries use operational definitions of these attributes to measure progress toward quality goals (19–21). The operational definitions focus on observable characteristics and include a description of how the characteristic is to be measured. For example, based on the knowledge that the performance of dialysis and other central venous catheter–related tasks depends on the position of the catheter tips relative to the right atrium (22,23), one might define catheter tip position relative to the cavoatrial junction as a metric that is critical to quality. Recent work by Baskin et al (23) illustrates how an operational definition of optimal catheter tip position was developed by examining the distance between the catheter tip and carina on supine radiographs.

It is crucial to realize that such metrics are at best faint reflections of quality. The metric is not quality *per se*, but rather a means of assessing the attribute considered critical to quality. It is clear that catheter tip position varies with respiration and patient position (22). It is also obvious that measuring the vertical distance between the carina and the catheter tip provides only indirect evidence of the relationship between the catheter tip and the cavoatrial junction (24). Such prob-

Table 1
Dimensions of Quality for Tunneled Dialysis Catheter Placement (14–18)*

	Process		Product	
Dimension	Query	Definition	Query	Definition
Performance	Will the process perform as planned?	Tunneled catheter placed in time for next dialysis appointment	Will the product perform as planned?	Catheter provides flow rates >300 mL/min
Reliability	How often does the process fail?	Unable to place tunneled catheter in time for dialysis appointment	How often does the product fail?	Frequency that flow rate is <300 mL/min
Conformance to standards	Does the process proceed as planned?	Catheter placed via jugular rather than subclavian vein	Is the product made as planned?	Catheter tip 2 cm below cavoatrial junction†

* Adapted from Montgomery et al (15). That text includes other dimensions of quality such as durability, serviceability, aesthetics, features, and perceived quality.
† The specification that the catheter tip should lie 2 cm below the cavoatrial junction was chosen to approximate the observed practice of many interventional radiologists. It is also congruent with the Kidney and Dialysis Outcomes Quality Initiative recommendation that the distal tip of the catheter should be within the right atrium (14). Catheter tip position is a controversial topic and some agencies recommend that no catheter tip should be positioned below the superior margin of the pericardium to minimize the risk of cardiac tamponade caused by the catheter tip eroding through the vessel wall (16–18).

lems are an inherent issue with any measurement, and indeed measurement theory states that it is impossible to measure any parameter with absolute precision (25). We should recognize that our measurements are merely an attempt to infer quality. Problems occur when one begins to believe that the metric directly reflects quality. Such mistaken beliefs will cause one to focus on the metric itself and lead to instances in which one aspect of quality is improved but other facets suffer (19,20). For example, one could use digital subtraction angiography or computed tomography to better assess how the central venous catheter tip is positioned relative to the cavoatrial junction in every patient, but these would clearly subject the patient to additional risk such as that incurred from exposure to more ionizing radiation.

Metrics and Tolerance Bands Are Frequently Used to Assess Quality

To illustrate these points, we ponder how a future pay-for-performance program (26) might use such critical-to-quality metrics to identify and reward exemplary performance. This hypothetical pay-for-performance program would assess catheter tip position with the aim of having dialysis catheter tips positioned 2 cm below the cavoatrial junction. The program designers would recognize that variation is part of any process and thus allow a ± 2 cm tolerance band around that target on the postprocedural supine radiograph. Equipped with this operational definition, the inspector arrives and audits your practice. The inspector collects radiographs from your procedures, extracts data, and compares his measurements to the pay-for-performance standard. Based on his measurements, the inspector makes a decision regarding the quality of each catheter placement. If the inspector judges the catheter tip to be within the specified tolerance band, the catheter passes inspection. If the audit reveals that you meet the quality target in a specified percentage of cases, you earn a bonus. If the inspector's measurement falls outside this tolerance band, the catheter fails inspection, and if this occurs frequently, you lose the bonus. This is a typical step-function approach to quality (**Fig 1a**).

Because you accept the notion that incorrectly positioned catheters can cause complications and you also wish to be identified as an exemplary supplier in the pay-for-performance program, you use the fluoroscopic image and redouble your efforts to insure that each catheter will pass inspection. If, toward the end of the procedure, it appears the catheter tip might fall outside the tolerance band, you are faced with a decision. You might decide to revise the catheter and monitor progress via fluoroscopy. Revision is associated with a small added cost attributable to the time and radiation dose needed to make the revision. For catheters that appear to fail by a large margin, you might decide to completely replace the catheter. Replacement is associated with a greater additional cost. The different costs of revision and replacement create a series of intermediate steps at the edges of the tolerance band (**Fig 1b**).

Errors in measurement introduce additional possibilities. The auditor may decide to define the carina or the catheter tip position slightly differently than you do. As a result, the auditor's measurements differ from yours by 10%–20%. You anticipate this potential problem and decide to improve your odds of passing inspection by revising catheters that appear to deviate from the pay-for-performance standard by 1.5 cm. Such problems with measurement and decision-making are common in nearly every human endeavor. This problem led Taguchi (27) to reconsider the traditional step-function approach to quality. He proposed the use of a U-shaped curve to best model how costs increase as one moves away from the target value (**Fig 1c**). This continuous value function suggests two strategies for maximizing the value of your efforts