Monotoring health care and developing metrics to gauge optimum systems from suboptimum ones is a multidimensional effort that spans the spectrum of health services research and administration. The quality assessment tools for operative procedures range from policies requiring measurement of general compliance within medical society guidelines, in terms of medical indications and procedural techniques, to local hospital peer review and medical executive committee oversight focused on case review. Although these quality measures are certainly labor intensive and require the highest level of objective reasoning and judgment, simpler metrics have been proposed that offer better ease of use and objectivity. Probably the most practical of the simpler methods for operative procedures is the measurement of periodic operative count, usually by physician and hospital, and a comparison of this count to a specified number or threshold felt to signify the highest quality. Inherent in this comparison of volume and quality is the operation-specific assessment of volume and outcomes to support the notion of a positive or negative (ie, not flat) relationship. In virtually all analyses in which a significant relationship has been demonstrated, an inverse relationship between volume and adverse outcomes was seen. Such relationships have also been seen for percutaneous coronary interventions (PCI), and the American College of Cardiology and American Heart Association (AHA/ACC) Joint Task Force guidelines for PCI have recommended minimum threshold goals for hospitals and operators to ensure the highest quality of PCI care.

Volume-Outcomes Measures and Quality Assessment

Evidence supporting volume of procedures as a valuable metric for assessing quality of care is based on the reduction in variance of observed adverse outcomes by volume as an explanatory variable, first shown for several operations by Luft in 1979, and more recently for coronary bypass surgery. Overviews of the literature on volume-outcome relationships for cardiac and other procedures, considered to be at high risk, have shown consistent relationships between higher volume and lower adverse events. A recent study of surgery in 2.5 million Medicare patients also showed an inverse relationship between volume and adverse outcomes, in which the lowest volume-adverse events ratios were seen in some cancer operations such as pancreaticectomy and esophagectomy, whereas ratios for cardiac or carotid surgery were closer to unity. In contrast to proposed PCI thresholds, cutoff volume counts for esophagectomy and pancreaticectomy that demonstrated differential outcomes were 1 to 5 procedures per year versus >11 procedures per year. The evidence for significant volume-outcome relationships for cardiac procedures was first rooted in cardiac surgery,
which administrative databases (with limitations in adjustment methods) showed modest improvements in mortality reduction with increasing hospital volume. Hannan was the first to use more sophisticated risk adjustment techniques in a specialized database (New York Cardiac Surgery Reporting System), and showed a more striking differential in volume-outcomes: 7.25% mortality for hospitals performing <200 operations per year as compared with 2.85% mortality rate for hospitals performing >890 operations per year. Extension of this methodology to PCI in the balloon angioplasty era also demonstrated improved clinical outcomes with higher volumes. Thus, when assessing the quality of PCI based on the dimension of procedure volume-mortality, the findings of the present study by Hannan are consistent with the inverse volume-adverse event relationship already seen in other operative procedures, including cardiac surgery and nonstent PCI.

**Complexity of Volume Outcome Analyses in the Assessment of Healthcare Quality**

Given the wide range of healthcare delivery patterns that have direct implications on surgical volume by operator or hospital, dictated by local demographics, geography, payor mix and variable practice patterns, the assumption that high volume is always better for patients would have tremendous impact on attaining strategies for optimum health care. Hanan et al state that other process measures for quality should be explored and validated to understand the low volume-high adverse event rate relationship, and that one should act on these measures to improve outcomes for low-volume operators and hospitals. Alternatively, the inverse volume-outcome relationship may lead to the adoption of regionalized healthcare programs that concentrate surgical procedures at high-volume centers for high-volume operators. Such regionalization may be disruptive for many patients and healthcare providers. Therefore, with each additional study such as Hannan et al supporting the theme that higher PCI volume is associated with improved clinical outcomes, with its inevitable policy consequences, critical reviews of these reports are required.

The calculation of volume-outcome ratios is straightforward, but the inference made about the quality of surgical operations and procedures based on volume of cases is complex. The intuitive notion that practice makes perfect, often cited as a mechanism of observed inverse volume-outcome associations, may drive the expectation of an inverse volume-adverse outcome relationship for each new study. There are many confounders that may act to cause such a result, obscuring the real cause of higher adverse outcome rates. For example, some operators and hospitals may be more apt to take on complicated cases that are associated with higher inherent risk of the adverse event measured. Such a relationship may also be associated with volume, and thus confound the observed volume-outcome result. Hannan et al have used a uniquely comprehensive database and proper adjustment techniques to minimize this potential bias. Moreover, the use of 3 outcomes, in-hospital death, same day, and same stay coronary bypass surgery, help to corroborate the conclusion. Of course, the outcomes measured should have direct relationships with our understanding of quality of PCI. Furthermore, the measured thresholds in the present analysis by Hannan (75 cases for operators and 400 cases for hospitals) should be interpreted cautiously because an optimization analysis for the best thresholds was not formally conducted, and the variance inherent in low-volume sample sizes make analysis of thresholds difficult.

Shahian and Normand pointed out that in the analysis of volume-outcomes for operative procedures, the low-volume estimates of adverse event rates are associated with high variance because of shrinking sample sizes. Several figures from Hannon et al show smoothed regression curves with inflection points that are taken as meaningful thresholds for determining cutoffs for high-quality care. The X-on-Y local regression technique employed, however, is fraught with sufficient wobble because of high variability associated with low sample size that makes direct interpretations of these inflection points notoriously difficult. An example of this result is shown in the Figure, in which simulated data via a fixed complication rate of 0.91% across a wide range of case volume resulted in substantial wobble of the local smoother regressor, giving an apparent inflection point between 200 and 400 patients. Therefore, threshold inference made on such analyses should be interpreted with caution because of the noise associated with low-volume samples. Alternatively, the prespecified 2-group analyses based on the recommendations of the ACC/AHA task force guidelines are valid, but the exact number needed to provide competence is not likely summarized by a single cutoff or the ones used in this analysis. A principled approach to identification and estimation of a volume cutoff involves not only the estimation of the cutoff but also the uncertainty attached to such cutoff. Thus, the volume-outcome relationship should be viewed as a general concept, with cutoffs for quality that only approximate those analyzed.

**PCI and Outcomes of Interest**

PCI is likely one of the most evolving and changing fields in medicine. During its ≈28-year history, elective PCI has never been shown to extend life or prevent death—its value has been found in the improvement in quality of life through reduction of myocardial ischemia. Several hundred randomized controlled trials have been performed in the PCI arena. As evidenced in recent drug-eluting stent trials, the primary end points and principal secondary end points of elective coronary device trials are either composite end points that are mainly driven by clinical restenosis components or explicit measure of restenosis, such as angiographic renarrowing or target lesion revascularization. Virtually all new PCI devices have been valued on the basis of successful durability of the index revascularization, generally measured as freedom from restenosis. Likewise, trials of adjunctive medical therapy for elective PCI measure acute death and coronary bypass rates, but the principal end points are mainly driven by the rates of acute myocardial infarction. Such outcome analysis have caused the sea change in stent therapy, which has adopted the more expensive drug-eluting stent rather than the less expen-
sive bare metal stent as the treatment of choice in >80% of PCI cases in just 2 years.

Measurements of acute death and emergent bypass surgery are important end points that are carefully measured in contemporary elective PCI device trials but have been relegated as safety measures assumed to be equivalent between the standard and new promising treatment. In other words, the improvements in PCI stent technology during the past 10 years and our assumptions of consequential patient benefit have rarely been driven by reductions in acute death or emergent or urgent bypass surgery. Whether measurement of PCI operative competency and quality should be studied the same way as is contemporary coronary device and medication trials has challenged us in employing a research program to evaluate PCI at hospitals without cardiac surgery on-site in Massachusetts. That the other end points used in PCI device and drug trials may be of interest, in addition to in-hospital mortality and coronary bypass surgery, has been examined carefully. For this specific question of quality (elective PCI at hospitals without surgical backup), we feel that PCI quality may not be faithfully measured by acute in-hospital mortality and coronary bypass alone, as good- and poor-quality PCI can be performed without these events. An alternative measure of quality may be the level of safe and durable complete revascularization, manifested by freedom from downstream interventions. We have thus promoted a primary end point similar to that used in the coronary stent trials of freedom from major adverse cardiac events, which includes the need for late-term (1 year) repeat revascularization of both the index lesions and other lesions. Thus, a comparison of patients randomized to sites with and without surgical backup will be compared on such a composite end point, mainly driven by out-of-hospital late-term follow-up events. Similarly, one could advance the argument that other PCI quality endeavors may also be measured with a combination of similar acute and late-term outcomes.

The findings of Hannan et al.4 that the higher volume of cases for both operators and hospitals is associated with lower...
adverse events (in-hospital mortality and CABG) come from a well-designed study that adds to the general notion that operative procedure healthcare quality may be summarized by case volume. The thresholds used in this analysis provide rough guidelines for policy decisions about PCI, and future PCI quality analysis may be focused on determining optimum thresholds and their corresponding estimates of uncertainty rather than on proving the inverse volume-outcome relationship already shown by Hannan and colleagues.

**Disclosure**

Drs Kuntz and Normand are members of the Massachusetts Cardiac Care Quality Commission and Dr Normand leads a data-coordinating center that examines the quality of PCI care.

**References**


**Key Words:** Editorials ■ stents ■ angioplasty ■ catheterization ■ coronary disease
Measuring Percutaneous Coronary Intervention Quality by Simple Case Volume
Richard E. Kuntz and Sharon-Lise T. Normand

*Circulation*. 2005;112:1088-1091
doi: 10.1161/CIRCULATIONAHA.105.561126

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2005 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/112/8/1088

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