Variability in the Use of Invasive Services
Sign of Poor Quality of Care or an Opportunity to Improve Care?

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Variability is the law of life,…and no two individuals react alike and behave alike under the abnormal conditions which we know as disease.

—William Osler

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tional efforts to improve the quality of care were greatly enhanced by the Institute of Medicine’s landmark publication, Crossing the Quality Chasm.1 The report concludes that a fundamental redesign of the healthcare system is needed to achieve the core needs of health care to be safe, effective, patient-centric, timely, efficient, and equitable. One goal has been to reduce inequity in care by reducing sex, race, and socioeconomic and geographic variability because inequity was felt to represent lack of adherence to optimal standard of care.

The Dartmouth Healthcare Atlas project was the first to demonstrate significant regional differences in Medicare spending in the United States without an improvement in quality.2 This group and others have also shown wide geographic variations in the use of procedures such as coronary angiography and percutaneous coronary angioplasty (PCI).3–4 The causes for this large difference in practice are unclear, but it has been speculated that it is because of both underuse and overuse of these procedures.5,6 Several factors have been shown to relate to the variation in practice, including the operator, hospital, sex, race, the availability of a cardiac catheterization laboratory, the type of hospital, rural location, the type of health insurance, and socioeconomic class.3,7–9 Efforts to reduce the variability in care have focused on overuse through adoption of appropriate use criteria (AUC), performance measures, public reporting, and pay for performance.

The Rand Corporation first developed AUC in 1986 using a modified Delphi process. Based on guidelines, registry studies, and expert opinion, a panel of experts developed a consensus on several indications for common procedures including angioplasty.10 The goal of the AUC was to provide guidance on the optimal use of a procedure, to support efficient use of medical resources and to provide a means of assessing practice patterns. The American College of Cardiology Foundation/American Heart Association in collaboration with others have adopted AUC to help improve quality through a reduction in the variability in the use of procedures.

The American College of Cardiology Foundation/Society of Cardiac Angiography and Intervention/Society of Thoracic Surgery/American Association for Thoracic Surgery/American Heart Association/American Society of Nuclear Cardiology/Heart Failure Society of America/Society of Cardiovascular Computed Tomography AUC for coronary revascularization were published in 2009 and 2012, and the AUC for cardiac catheterization were published in 2012.11–13 The AUC indications for coronary revascularization is an extensive document that ranked >180 clinical situations using 5 key variables: clinical presentation (acute coronary syndrome or stable angina), severity of angina (Canadian Cardiovascular Society class), extent of ischemia on noninvasive testing, extent of medical therapy, and extent of anatomic coronary disease. Despite the large number of clinical situations evaluated, the criteria are estimated to cover only 5% of all potential scenarios.14

The benefit of the appropriateness criteria document is that it provides a more objective view of practice patterns, can quantify variations in practice, and assist in understanding of its cause. For example, Chan et al8 examined the frequency of appropriate indications for PCI from >500,000 PCI procedures in the National Cardiovascular Data Registry using the 2009 American College of Cardiology Foundation/American Heart Association appropriateness criteria. They found that the majority of patients with acute indications (largely acute coronary syndrome) were appropriate (98.6%), whereas only 50.4% of nonacute indications (largely stable ischemic heart disease) were appropriate and 11.6% were inappropriate. Others studies have shown the rate of inappropriate procedures to range from 15% to 25% in stable ischemic heart disease.15–18 The study by Chan et al also demonstrated great variability in the frequency of inappropriate indications from one hospital to another (range, 6%–16.7% interquartile range), suggesting that opportunities exist to improve quality.

One of the most common reasons for an inappropriate procedure was the presence of mild symptoms or no symptoms, absence of a noninvasive assessment or low risk, and no medical therapy. The lack of noninvasive tests or medical therapy may be because of lack of documentation or other factors that precluded testing or treatment. One study assumed the best-case scenario that the noninvasive test was present when it was listed as missing and the rate of inappropriate procedures dropped to 8%.18 In contrary to what one might assume, men, whites, and those with private insurance were more likely to have an inappropriate procedure in the National Cardiovascular Data Registry.5

Studies have shown that appropriateness criteria are generally reliable and can predict outcome.19,20 However, there are significant limitations to the process. The most important is that the vast majority of recommendations are based on expert opinion alone. This issue is not trivial because the consensus of 1 group of experts is not always consistent with another group of experts particularly when the evidence is not based on randomized clinical trials. In a
comparative study of 2 panels, Hemingway et al.20 compared the ratings between 2 separate expert panels considering the indications of coronary angiography for patients with angina. The study found only moderate agreement between the panels with a $\kappa$ of 0.58. The less the available evidence the greater the variability.

In addition, other important clinical factors were not considered in this study, such as patient preference, age, frailty, and comorbidities, to name a few. For instance, an active 45-year-old man with mild typical angina on 1 medication and a strongly positive family history for coronary disease who does not want medical therapy might be better served by cardiac catheterization and possible PCI than having a stress test, which would not increase the pre test probably of coronary artery disease. PCI in a low-risk lesion would give the same outcome as medical therapy. The primary difference is the cost of the procedure.

The rapid advances in practice also make it difficult for indications criteria to remain current. For instance, the current AUC do not consider fractional flow reserve or other coronary hemodynamic measurement in decision making, despite several trials demonstrating the value of this technique. The recent randomized trials, such as Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) and Preventive Angioplasty in Acute Myocardial Infarction (PRAMI), were also not considered.21 The latter trial demonstrated the difficulty AUC have in relying only on expert opinion. The appropriateness guidelines, in part reflective of the guidelines, classified multivessel PCI at the time of primary PCI for ST-segment-elevation myocardial infarction as a class III indication and as inappropriate in the AUC. The PRAMI trial, however, demonstrated a 65% reduction in major adverse cardiac events at an average of 23 months of follow-up in patients randomized to prevent (multivessel PCI) at the time of primary PCI compared with patients with culprit-only primary angioplasty.22 Previous meta-analysis of registry studies also showed no harm or benefit for this strategy.

Understanding whether AUC can improve quality by reducing unnecessary procedures and increasing appropriate procedures is important in the ultimate use of the criteria. If use of AUC reduces unnecessary procedures then healthcare cost may be reduced; however, if the identification of cases of underuse results in new procedures the cost saving might be lost.

For clinicians, an equally important question is whether use of the AUC can improve outcome by reducing mortality, morbidity, and improving quality of life. To date, this is not clear. Data from National Cardiovascular Data Registry with >200000 patients showed that the rate of inappropriate procedures was not associated with in-hospital mortality, bleeding, or optional medical therapy at discharge.23 Others have shown similar long-term outcomes as well.24 However, I study suggested a reduced incidence of death or acute coronary syndrome in patients with an appropriate indication who had revascularization but no difference in outcome in patients in the uncertain or inappropriate category.25 These results leave us with concern that the appropriateness criteria may not be helpful in deciding who benefits or who avoids harm, both are important aspects of quality. Also, we know nothing about the relationship to quality of life.

The other efforts to improve quality, such as performance measures, pay for performance, and public reporting, have similar problems as well.26–30 Performance measures have been in place since the 1990s. Many have been process measures such as door-to-balloon times. The recent American College of Cardiology/American Heart Association/Society of Cardiac Angiography and Intervention/American Medical Association-convened Physicians Consortium for Quality Assurance 2013 performance measures for adults undergoing percutaneous coronary intervention has proposed 11 performance measures for PCI. Six are process measures and 5 are not. The small number of variables with limited considerations for confounders raises concern about their effectiveness but they are a first step. If they prove to improve quality then they will be important contribution. However, current evidence does not show clearly that performance measures, pay for performance, or public reporting do improve quality beyond that which is occurring from other secular, hospital, and practice efforts.30

All of these quality efforts make the assumption that the wide variability in practice patterns is not good and while multifactorial are largely because of adverse hospital and physician decisions. This variability could be because of lack of following the guidelines and AUC because of bias or ignorance or to secondary financial gain. Although some of the overuse is likely because of these factors and is truly inappropriate, some or most may be justified and lack of understanding of the complexity of the patient or special circumstances justify deviation from guideline and AUC recommendations. Because <5% of clinical situations are included within the guidelines and AUC, physician judgment is critical in most cases. It could be argued that variation is in fact desired because it can help explain the nuances of care, provide new best practice guidance, and identify areas of needed randomized trials that could lead to modification of guidelines, AUC, and performance measures.

A novel approach to overcome these limitations of current quality efforts is the Standardized Clinical Assessment and Management Plan (SCAMPs).31,32 The goal is similar to appropriateness criteria, to improve quality by narrowing practice variability through more appropriate use of testing and treatment. The process begins by identifying areas where there is significant practice variability because of uncertainty caused by a lack of adequate observational and randomized trial data. A clinical care pathway is developed based on guidelines and expert opinion. The individual SCAMPs are intended to be brief and focused. The key component, which is distinctly different from all of the other quality efforts, is that deviations from the pathway are not discouraged but rather encouraged. When a deviation occurs, the physician is asked to document the rationale for the change. After a set time period, typically 6 to 12 months, the predefined outcomes from SCAMP data are analyzed paying particular attention to the reasons for practice variations. The SCAMP pathway is revised based on any new evidence and the SCAMP outcomes with special attention to the variations that occurred. This results in a continuously updated pathway that reflects new knowledge, the experience of the clinicians in the practice, and rational variations. Initial experience with 49 SCAMPs in 9 states has shown a decrease in practice variation, reduction in the unnecessary use of resources with reduced cost, and improvement in stakeholder’s engagement. Longer term studies are needed to determine whether clinical outcomes are also improved.

Variations in practice are not all bad and can be a powerful way to assess treatment options in areas of uncertainty. The national efforts to reduce variability should incorporate the concepts used
in SCAMPs to provide encouragement for variation so that we can improve quality. Continuing to develop punitive methods to make practice uniform and avoid creative new approaches is not can improve quality. Continuing to develop punitive methods to make practice uniform and avoid creative new approaches is not

### Disclosures

None.

### References


**Key Words**: quality of life
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_Circ Cardiovasc Interv._ 2014;7:133-135
doi: 10.1161/CIRCINTERVENTIONS.114.001477
_Circulation: Cardiovascular Interventions_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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