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

National efforts to improve the quality of care were greatly enhanced by the Institute of Medicine’s landmark publication, Crossing the Quality Chasm. 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 inequality 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. This group and others have also shown wide geographic variations in the use of procedures such as coronary angiography and percutaneous coronary angioplasty (PCI). 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.

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. 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. 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 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. 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.

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 al examined the frequency of appropriate indications for PCI from >500 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 16.6% were inappropriate. Others studies have shown the rate of inappropriate procedures to range from 15% to 25% in stable ischemic heart disease. 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%. 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.

Studies have shown that appropriateness criteria are generally reliable and can predict outcome. 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.25 compared the
ratings between 2 separate expert panels considering the indica-
tions of coronary angiography for patients with angina. The study
found only moderate agreement between the panels with a κ of
0.58. The less the available evidence the greater the variability.

In addition, other important clinical factors were not consid-
ered 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 sev-
eral 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 consid-
ered.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% reduc-
tion in major adverse cardiac events at an average of 23 months
of follow-up in patients randomized to preventive (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 reduc-
ing unnecessary procedures and increasing appropriate pro-
cedures 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 unde-
ruse 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, mor-
bidity, and improving quality of life. To date, this is not clear.
Data from National Cardiovascular Data Registry with >200,000
patients showed that the rate of inappropriate procedures was
not associated with in-hospital mortality, bleeding, or optimal
medical therapy at discharge.23 Others have shown similar long-
term outcomes as well.24 However, 1 study suggested a reduced
incidence of death or acute coronary syndrome in patients with
an appropriate indication who had revascularization but no dif-
fERENCE in outcome in patients in the uncertain or inappropriate
category.25 These results leave us with concern that the appropri-
ateness 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 me-
asures, 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 Performance Improvement/National Committee
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 considera-
tions 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 fac-
tors and is truly inappropriate, some or most may be justified and
lack of understanding of the complexity of the patient or special cir-
cumstances justify deviation from guideline and AUC recommen-
dations. 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 modifi-
cation 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 appro-
piateness criteria, to improve quality by narrowing practice vari-
bility 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 out-
comes from SCAMP data are analyzed paying particular atten-
tion 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 vari-
a tions. 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 stakehold-
er’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 in the best interest of the patient or are likely to improve outcomes, reduce cost, and improve the quality of health care.

Disclosures
None.

References

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