JACC: CARDIOVASCULAR IMAGING
VOL. 5, NO. 6, 2012
© 2012 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
ISSN 1936-878X/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcmg.2012.05.001

iVIEW

EDITOR'S PAGE

Informed Consent and AUC: Bare It All...

Thomas H. Marwick, MBBS, PhD,* Y. Chandrashekhar, MD,† Jagat Narula, MD, PhD‡

Appropriate use criteria (AUC) have become widely accepted as a means of test selection, and their application has become an accepted alternative to other means of controlling test utilization, such as radiology benefit managers (1). Less widely known is the underlying emphasis on the balance of risk and benefit, "an appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication" (2). This issue of *iJACC* provides 4 papers that reflect the application of these criteria and perhaps how we should perceive them.

AUC are most commonly understood as a shorthand method for evaluating the adequacy of decision-making as it pertains to test selection. In a review of large cohort of patients undergoing transesophageal echocardiograms (TEE) before cardioversion for atrial fibrillation, Grewal et al. (3) report inappropriate use of the test in <3.0% of patients. Whereas 2.5% suffered stroke, and left atrial thrombus (or "sludge") was identified in 8.0% of subjects (especially in those at high stroke risk [18.0%] and symptomatic patients [14.0%]), neither stroke nor thrombus were documented in patients in the inappropriate category. While these results reassure that AUC are followed for the selection of atrial fibrillation patients for TEE, they also presage an era when AUC would be based on outcomes rather than expert opinion.

Cardiovascular imaging remains a major beneficiary of engineering innovation, and the AUC need to be sufficiently dynamic to incorporate new developments as they are validated. One such example relates to the interaction of echocardiography with computed tomography and magnetic resonance imaging as the former becomes a truly 3-dimensional (3D) technique. This development will allow echocardiography to fill a role in the accurate measurement of cardiac structures that was not feasible in the era of 2-dimensional imaging. Tamborini et al. (4) have documented the utility of 3D echocardiography in the measurement of aortic dimensions in patients undergoing transcatheter aortic valve replacement. The implication of this study is that 3D TEE could be reasonably added to transcatheter aortic valve replacement evaluation. The evolution of the indications for test use will assuredly continue between iterations of AUC, implying that unquestioning pursuit of an AUC target of 100% will delay the clinical application of new methodologies that improve care and save money.

AUCs are based on the premise that an appropriate test, when used appropriately, will generate data that will be of sufficient clinical use to significantly advance decision making in the clinical setting. This has generated a debate about what conditions can be covered in such an exercise and which test is most appropriate in such a condition. It is assumed that efficacy is the point of contention, and not safety. It is also presumed that all these tests are fairly safe, and both the clinician and the patient are clearly aware of the risks and benefits. Newer imaging methods and newer information about older imaging modalities may upend this assumed equation. It is becoming clear that some tests, especially those involving radiation, might have risks that may need additional qualification. In addition, often the clinician and most certainly the patient may not be completely

From the *Cleveland Clinic Heart and Vascular Institute, Cleveland, Ohio; †University of Minnesota, Minneapolis, Minnesota; and the ‡Mount Sinai School of Medicine, New York, New York.

JACC: CARDIOVASCULAR IMAGING, VOL. 5, NO. 6, 2012
JUNE 2012:665–7

aware of the cumulative risk of some common tests, especially when done repeatedly over a period of time. Further, even if the clinician is fully aware, a clear and concise communication to the patient, in the current informed consent practice, may remain inadequate. This important issue has received only passing attention so far (5), and needs to be explored further.

Two papers in this issue of *iJACC* address this topic of informed consent in the context of imaging procedures involving radiation and its readability. To most physicians, the performance of a noninvasive test is usually considered to be of low risk, unless it is associated with stress testing. However, the consequences of long-term exposure to diagnostic radiation, particularly in patients undergoing serial testing, the young, and especially women, are becoming matters of concern. In the European Union, the use of diagnostic radiation is subject to legislation that mandates that it should not be used in circumstances where there are alternative imaging strategies. In the United States however, no such legislation exists, and the decision to use radiation for diagnostic use is limited only by the fiduciary duty of the physician to select appropriate testing. While most clinicians are familiar with the assumption of linear risk without threshold that underlies the "as low as reasonably achievable" (ALARA) principle, the reality is that many physicians lack knowledge about either the amount of radiation exposure from diagnostic testing or the potential consequences (6). The paper by Paterick et al. (7) emphasizes that the principles about disclosure have moved away from the previous professional standard of what a reasonable physician would describe in similar circumstances, to what a reasonable person would want to know about the balance of risk and benefit inherent in this decision. Physicians should be able to discuss reasonable options regarding diagnosis and treatment, as well as the degree of benefit in symptomatic patients (which may involve a discussion about the improvement of quality of life and survival with appropriate diagnosis), and in asymptomatic patients (where the risk is justified on the basis of refining a prediction of cardiovascular risk).

Consent documentation is a vital component of this dialogue with the patient regarding risk and benefit. While the common adage that consent is a process rather than a document is undoubtedly true, the reality is that consent documentation provides an excellent opportunity to lay out risks and benefits of a procedure in the fashion that the patient should be able to rehearse and reconsider after a physician appointment. Terranova et al. (8) review the content, organization, construction, and layout of consent documents from Italy, the United Kingdom, and the United States. Based on the fact that patients do not have an ongoing relationship with the imaging physicians, and the limited time available for the consent process (9), not only readability but also understandability are vital components of this evaluation are attended to in the paper. As would be anticipated by most clinicians, they found that the readability of the original documents was poor. After revision based upon application of a checklist, there was improvement in readability, particularly in sentence shortening as well as a minor degree of improvement of word complexity. This improvement of readability was matched by improved description of risks, alternatives, limits, and disadvantages, and was thought by the patients to improve comprehension, though it has been acknowledged that this was also influenced by numerical literacy, education, and other demographic characteristics (10).

Much attention in the topic of appropriate use criteria has focused on test selection. The contents of this issue of *iJACC* should emphasize to readers that appropriate use also should most certainly involve an acknowledgment of risk, and that we all have work to do in facilitating the understanding of benefit and risk, which supports shared decision-making. The medical community will have to rapidly adapt their consent process to these newer realities. A well-informed patient, whose autonomy is acknowledged and respected, is the foundation of our ability to deliver the absolutely best care, and a well executed and comprehensive informed consent process is the cornerstone. It is important that we, as imaging society, engage in standardizing this process to enhance our patient care mission. Otherwise we run the risk of a restrictive legal process that might dictate burdensome external standards that would compromise excellence in patient care.

We would, therefore, suggest that both the AUC and the process of informed consent would need to evolve in this new reality. The new ground for informed consent process is largely uncharted and legal calisthenics would affect what will be considered to be "adequately informed patients." Merely listing potential adverse events would not suffice. It would be necessary to anticipate them and explain in sufficiently quantified and understandable terms what a patient would need to know to make a thoughtful decision about his or her care. Physicians take great care to follow AUC, which seem to be a clearly changing practice. The current way of emphasizing *efficacy of a test* in AUC, instead of a combination of *efficacy and safety*, might need to change as well. For example, while one always explains the risk and benefits of the test being performed, it is rare that the alternative test strategies are discussed and why one test was chosen over the other. One could see ramifications of not discussing the available choices that might violate the "information needed for a reasonable person to make a reasonable decision" standard. Thus, marrying safety of a test (not an overt emphasis in current AUC since it is assumed that the physician has already considered safety before choosing this particular test) into its efficacy will influence the way we think across the tests rather than being about a test. The new iteration of AUC might be condition based rather than test based and this will, hopefully, reflect better in our informed consent process too.

REFERENCES

1. Willens HJ, Hendel RC, Inhaber FR, et al. Appropriateness use criteria for transthoracic echocardiography: relationship with radiology benefit managers preauthorization determination and comparison of the new (2010) criteria to the original (2007) criteria. Am Heart J 2011;162:772–9.
2. Douglas PS, Khandheria B, Stainback RF, et al. ACCF/ASE/ACEP/ASNC/SCAI/SCCT/SCMR 2007 appropriateness criteria for transthoracic and transesophageal echocardiography. J Am Coll Cardiol 2007;50:187–204.
3. Grewal GK, Klosterman TB, Shrestha K, et al. Indications for TEE before cardioversion for atrial fibrillation: implications for appropriateness criteria. J Am Coll Cardiol Img 2012;5:641–8.
4. Tamborini G, Fusini L, Gripari P, et al. Feasibility and accuracy of 3DTEE versus CT for the evaluation of aortic valve annulus to left main ostium distance before transcatheter aortic valve implantation. J Am Coll Cardiol Img 2012;5:579–88.
5. Wong CS, Huang B, Sin HK, et al. A questionnaire study assessing local physicians, radiologists and interns' knowledge and practice pertaining to radiation exposure related to radiological imaging. Eur J Radiol 2012;81:e264–8.
6. Schenker Y, Meisel A. Informed consent in clinical care: practical considerations in the effort to achieve ethical goals. JAMA 2011;305:1130–1.
7. Paterick TE, Jan MF, Paterick ZR, Tajik AJ, Gerber TC. Cardiac imaging modalities with ionizing radiation: the role of informed consent. J Am Coll Cardiol Img 2012;5:634–40.
8. Terranova G, Ferro M, Carpeggiani C, et al. Low quality and lack of clarity of current informed consent forms in cardiology: how to improve them. J Am Coll Cardiol Img 2012;5:649–55.
9. Fink AS, Prochazka AV, Henderson WG, et al. Predictors of comprehension during surgical informed consent. J Am Coll Surg 2010;210:919–26.
10. Crepeau AE, McKinney BI, Fox-Ryvicker M, Castelli J, Penna J, Wang ED. Prospective evaluation of patient comprehension of informed consent. J Bone Joint Surg Am 2011;93:e114(1–7).