Journal of the American College of Cardiology
© 2006 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 48, No. 10, 2006
ISSN 0735-1097/06/$32.00
doi:10.1016/j.jacc.2006.04.107

Improving Imaging

Our Professional Imperative

Pamela S. Douglas, MD, MACC
Durham, North Carolina

Many factors, including disproportionate growth rates and exciting new technologies, have focused attention on cardiovascular imaging. However, critical examination of the field reveals a surprisingly weak evidence base and inconsistent systematic attention to quality improvement. Remedies span research and practice. The optimal clinical continuum of care begins with ensuring a proper match between the diagnostic test and the individual's clinical question, and progresses to include image acquisition, image interpretation, and results reporting. Better research methodologies are needed to more tightly link imaging use to improved outcomes in non-biased community populations. To accomplish these lofty goals, alignment across stakeholders is needed to ensure the necessary human and capital investment in research and systems of care. (J Am Coll Cardiol 2006;48:2152–5) © 2006 by the American College of Cardiology Foundation

There's lip service to quality, but real commitment is in short supply.

Donabedian (1)

Knowing is not enough; we must apply. Willing is not enough; we must do.

Goethe (2)

Hailed as one of the top 11 medical advances in the past 1,000 years (3), imaging in general, and cardiovascular (CV) imaging in particular, has contributed significantly to the striking reduction in cardiovascular mortality over the last 40 years. However, growth rates of as high as 26% per year, more than any other component of medical care, have also captured the attention of payers and regulators (4,5). The appeal of imaging is obvious—we all love a pretty picture—and extends to patients as well as physicians. However, in this time of budgetary constraint, how can we be sure that imaging is providing value? When the rate of use of CV imaging varies as much as 3-fold to 4-fold in different regions across the U.S., as it does for echocardiography (6), how can we be sure that such testing is being performed well and to our patients' benefit?

Although most CV imaging is noninvasive, even such seemingly innocuous tests may cause harm; a patient with false-positive test results may subsequently have an unnecessary invasive procedure, or a patient with false-negative test results may not receive life-saving treatment. The evidence base supporting the clinical use or benefit of an imaging procedure is limited and problematic. Current imaging research is often performed in nonrandomized populations referred to academic centers, resulting in significant referral bias, and the usual comparisons to gold standards are plagued by verification bias. We generally evaluate tests, and not diagnostic strategies, so that imaging research is not patient oriented. There is a lack of consensus on the definition of quality in imaging, with the result that there are few quality standards. For example, of the 745 recommendations on imaging in the American College of Cardiology/American Heart Association (ACC/AHA) Clinical Guidelines, there is a striking disconnect between the class of the recommendations (51% are class 1) and the level of evidence (only 1% are level 1, whereas 54% are level 3), which supports these recommendations (Fig. 1). Finally, efforts to improve imaging quality are quite limited, especially in comparison to the national performance measures used in other areas of cardiovascular medicine (7,8), which have evolved to encompass nationally agreed-on standards, which in turn form the basis for hospital pay-for-performance programs and public reporting.

One reason for the lack of a robust evidence base in imaging is the federal approval process. Advances in imaging require few regulatory approvals to implement so that the requirements for U.S. Food and Drug Administration 510K approval are minimal compared with those needed to bring a new medication to market. As a result, there is little incentive for the imaging industry to support or academic investigators to perform extensive clinical research, much less the large randomized trials that form the basis for much of today's clinical CV care. Indeed, regulatory approval is driven by technology, rather than by clinical utility, and the current approval process too often fails to advance knowledge in the field. This situation critically constrains efforts to determine the proper place of existing imaging or of new technologies such as computed tomography angiography in the clinical armamentarium and in payers' coverage policies. Although extensive reform of this process is unlikely, small efforts, such as requiring a basic level of information technology interoperability for approval of new imaging equipment,

From the Cardiovascular Medicine Division, Department of Medicine, Duke University, Durham, North Carolina. Dr. Douglas has done research for Medtronic and is a consultant for GE Healthcare, Merck, and Northpoint Domain.

Manuscript received March 28, 2006, accepted April 12, 2006.

Abbreviations and Acronyms

ACC/AHA = American College of Cardiology/American Heart Association
CV = cardiovascular

would be both easier to implement and a welcome stimulus toward much-needed reform.

At the core of the problem is the difficulty in connecting performance of an imaging test to a health-related outcome. Patients rarely live or die on the basis of performance of a noninvasive test. Instead imaging outcomes (if assessed at all) are generally evaluated in a hierarchical fashion that includes the intermediate, but hard to measure, steps of impact on diagnostic and therapeutic thinking (9,10) (Table 1). In this schema, the initial step in imaging outcomes is technical capability, which generally includes engineering and equipment specifications. This is followed by test performance, which includes conventional measures of sensitivity, specificity, negative and positive predictive values, and overall accuracy, usually determined in reference to a gold standard. Both of these domains are commonly investigated as part of the evaluation of a new imaging test; however, most assessments stop at this stage. Higher levels of imaging outcomes include impact on diagnostic or prognostic thinking (e.g., the patient with a positive stress test result may now be diagnosed with coronary artery disease, and is stratified into a high or low risk group for a future ischemic event). This is followed by impact on diagnostic or therapeutic strategies (e.g., the patient with newly diagnosed coronary artery disease may or may not need additional testing, lipid lowering and other preventive medications should be added or avoided, a therapeutic procedure is indicated or not, and so on). Finally, the highest level involves financial, health-related, and patient and provider satisfaction outcomes (e.g., as a result of testing, will this patient live a longer and healthier life, was the performance of this imaging test a cost-effective strategy for this patient, was the patient's experience optimal).

One of the cornerstones of evidence-based medicine is a continuous cycle of improvement that links the introduction of new therapies to an evaluation process and to patient outcomes, which in turn informs further therapeutic development. There is no analogous cycle in imaging. Instead, the current "cycle" of imaging begins at technology development, moves to evaluation of technical capability (e.g., test performance characteristics), and then rapidly moves to reimbursement and clinical use (Fig. 2A). Instead, a true cycle would consist of technology development informing technical capability, which in turn would drive the assessment of diagnostic utility and therapeutic strategy, and only then move on to reimbursement. Once a test is reimbursed, further investigation is needed to track implementation and to develop guidelines and appropriateness criteria, which in turn impact patient outcomes and finally influence the next generation of technology development (Fig. 2B).

Clearly there is a need for substantial improvement in imaging research, including the development and adoption of a viable, evidence-based imaging cycle. Because researchers have not yet developed the appropriate analytic methodologies to properly evaluate imaging outcomes, we need to focus on developing pragmatic research methods. One such method has been proposed for the implementation of new technology that uses time-varying physician confidence and test referral patterns as independent judges of the new test's value (11). Academic centers should target the development of imaging evaluation centers that include outcomes and quality evaluation as well as analysis of test performance. Similarly, we need to develop and implement standards for using imaging in clinical trials (12). Imaging registries would also be highly desirable, particularly across modalities, and would require definition of key data elements and uniform structured reporting with concordance among different tests. Local ad hoc registries, unconnected to national data repositories, are already being developed as payers require participation as a condition of reimbursement for newer tests, such as computed tomography angiography. Imaging quality needs to be better defined, the methods to achieve it agreed on and implemented, and the impact on

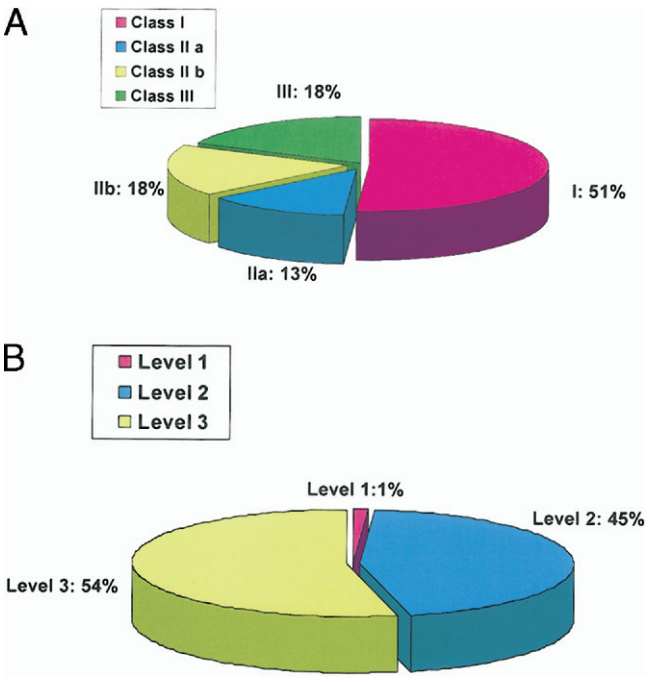

Figure 1. **(A)** Current American College of Cardiology/American Heart Association (ACC/AHA) Guidelines contain a total of 745 recommendations on the use of imaging, with just over one-half being class I, indicating that the procedure is beneficial, useful, and effective, and only 18% class II, indicating that the procedure is not useful or effective and may be harmful. **(B)** The level of evidence to support the use of imaging used in the ACC/AHA Guidelines is in contrast to the class of the recommendations. The majority are level 3, indicating that the recommendation is supported only by the consensus opinion of experts, case studies, or standard-of-care, rather than representing level 1 evidence derived from multiple randomized clinical trials.

JACC Vol. 48, No. 10, 2006
November 21, 2006:2152–5

Table 1. Measuring Imaging Outcomes: A Hierarchy of Value

- Technical capability
- Test performance, accuracy
- Diagnostic/prognostic thinking
- Diagnostic/therapeutic strategies
- Outcomes, cost effectiveness
- Patient satisfaction

Data from Guyatt et al. (9) and Fryback et al. (10).

outcomes measured. In general, all of these efforts will help to enable improvement in imaging effectiveness and efficacy as well as efficiency in clinical practice.

Quality efforts in CV imaging need to focus on critical components of imaging care. Beginning with the patient, the first step is ensuring an optimal match between the diagnostic test and the individual's clinical question. This is predominantly the responsibility of the ordering physician and can be guided by the new ACC appropriateness criteria series of documents (13,14). After an appropriate match is ensured, images that are complete and interpretable need to be acquired by a skilled technologist, with minimal harm to the patient. (Harm may come in the form of radiation or contrast agent use for some imaging tests.) Images need to be interpreted by a skilled physician, with quality controls and processes in place to minimize intraobserver and interobserver variability and to maximize comparability with standard image sets. Results need to be communicated in a timely, clinically relevant, and definitive manner to the referring physician so that they can be incorporated into clinical care planning and thereby impact patient outcomes. Reports should be complete and electronically accessible, with standardized data elements and cross-correlation across all imaging modalities. Current laboratory accreditation processes address some but by no means all of these issues. In addition, they represent a single "snapshot" of quality, often at 3-year intervals, rather than providing a mechanism for ongoing assessment and improvement.

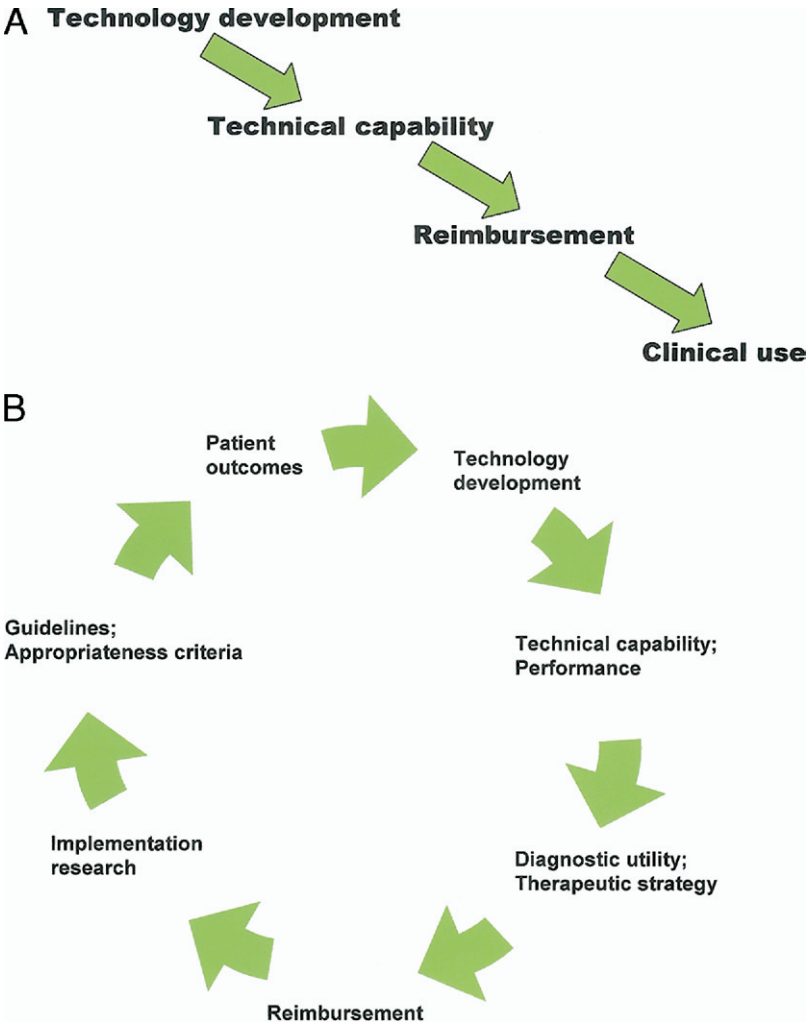

Figure 2. **(A)** The current process of imaging development requires only demonstration of technical capability or test performance for reimbursement and subsequent clinical adoption, without a need for demonstration of clinical utility. Further, there are few intermediate steps designed to assess the impact of such use and few guidelines directed at ensuring appropriate care. Finally, it is linear, with little feedback from clinical experience onto subsequent technology development. **(B)** An ideal cycle of imaging development would incorporate all of these steps into a continuous creation of evidence and incorporation into clinical care as well as the development of new imaging technology.

Although the need for change is apparent, there are also many barriers. We need to aim high with a concrete plan for reform, and coordinate our efforts. Research and data collection are critical to support the value of quality improvement programs in imaging and to provide momentum and justification for ongoing efforts. Hospitals, payers, and providers need to agree on uniform sets of metrics and to align their efforts accordingly. Improved information technology is an essential platform for communication between referring and interpreting providers with facilitation of a 2-way flow of vital information in a user-friendly, distributed, and timely way. Enhanced information technology is also necessary to implement ongoing monitoring and improvement of quality. Because there is as yet little regulatory or financial pressure for the required system redesign, committed leadership is critical, as is alignment of financing and funds flow to support quality and research efforts. We need to minimize the regulatory processes so that the burden of compliance is minimized. Physicians and hospitals need to discard the fears of litigation that often accompany contemplation of admitting to providing less than optimal care.

The path is clear. Creation of a robust body of clinical evidence regarding the value of imaging is long overdue. It is a necessary foundation for any quality improvement process, which can no longer be based on the educated guesses that inform our current consensus model. Without an explicit evidence base it will be impossible to build the guidelines, appropriateness criteria, and other performance measures that will form the core of quality programs that in turn are needed to drive improvement of real-world results. Partnerships of providers, hospitals, government, professional societies, payers, and industry are critical. All stakeholders need to recognize that imaging and imaging quality cannot be taken for granted any longer. They deserve the same attention to research and outcomes, enhancement of performance, and care delivery as other interventions. These are inescapable components of ensuring imaging's proper place in the clinical arena.

Reprint requests and correspondence: Dr. Pamela S. Douglas, Duke University Medical Center 3943, Duke North 7451, Durham, North Carolina 27710. E-mail: pamela.douglas@duke.edu.

REFERENCES

1. Best M, Neuhauser D. Avedis Donabedian: father of quality assurance and poet. Quality Saf Health Care 2004;13:472.
2. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press, 2001:364.
3. Ciccarelli EC, Jacobs AJ, Berman P, et al. Looking back on the millenium in medicine. N Engl J Med 2000;342:1365–7.
4. Koenig L, Dobson A, Book R, Smith A, El-Gamil A, The Lewin Group. Issues in the growth of diagnostic imaging services. A case study of cardiac imaging, prepared for the American College of Cardiology. May 3, 2005.
5. Miller ME. MedPAC Recommendations on Imaging Services. Washington, DC: Subcommittee on Health, Committee on Ways and Means, 2005.
6. Lucas FL, Wennberg DE, Malenka DJ. Variation in the use of echocardiography. Effective Clinical Practice 1999;2:71–5.
7. Krumholz HM, Anderson JL, Brooks NH, et al. ACC/AHA clinical performance measures for adults with ST-elevation and non–ST-elevation myocardial infarction. J Am Coll Cardiol 2006;47:236–65.
8. Bonow RO, Bennett S, Casey DE Jr., et al. ACC/AHA clinical performance measures for adults with chronic heart failure. J Am Coll Cardiol 2005;46:1144–78.
9. Guyatt GH, Tugwell PX, Feeny DH, Haynes RB, Drummond M. A framework for clinical evaluation of diagnostic technologies. Can Med Assoc J 1986;134:587–94.
10. Fryback DG, Thornbury JR. The efficacy of diagnostic imaging. Med Decis Making 1991;11:88–94.
11. Hunink MG, Krestin GP. Study design for concurrent development, assessment, and implementation of new diagnostic imaging technology. Radiology 2002;222:604–14.
12. Gottdiener JS, Bednarz J, Devereux R, et al. American Society of Echocardiography recommendations for use of echocardiography in clinical trials. J Am Soc Echocardiogr 2004;17:1086–119.
13. Brindis RG, Douglas PS, Hendel RC, et al. ACCF/ASNC appropriateness criteria for single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI): a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group and the American Society of Nuclear Cardiology endorsed by the American Heart Association. J Am Coll Cardiol 2005;46:1587–605.
14. Patel MR, Spertus JA, Brindis RG, et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. J Am Coll Cardiol 2005;46:1606–13.