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HEALTH POLICY STATEMENT

ACC/AHA/ASE/ASNC/HRS/IAC/Mended Hearts/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SNMMI 2014 Health Policy Statement on Use of Noninvasive Cardiovascular Imaging

A Report of the American College of Cardiology Clinical Quality Committee

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Author Recusals: Writing committee members are required to recuse themselves from voting on sections to which their specific relationship with industry and other entities may apply; see Appendix 1 for recusal information.

This document was approved by the American College of Cardiology Foundation Board of Trustees in August 2013 and endorsed by the governing bodies of the American Heart Association (AHA), American Society of Echocardiography (ASE), American Society of Nuclear Cardiology (ASNC), Heart Rhythm Society (HRS), Intersocietal Accreditation Commission (IAC), Mended Hearts, North American Society for Cardiovascular Imaging (NASCI), Radiological Society of North America (RSNA), Society of Atherosclerosis Imaging and Prevention (SAIP), Society for Cardiovascular Angiography and Interventions Foundation (SCAI), Society of Cardiovascular Computed Tomography (SCCT), Society for Cardiovascular Magnetic Resonance (SCMR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in January 2014. For the purpose of complete transparency, disclosure information for the ACCF Board of Trustees, the board of the convening organization of this document, is available at: http://www.cardiosource.org/ACC/About-ACC/Leadership/Officers-and-Trustees.aspx. ACC board members with relevant relationships with industry to the document may review and comment on the document but may not vote on approval.

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Preamble

This document has been developed as a health policy statement by the American College of Cardiology (ACC), American Heart Association (AHA), American Society of Echocardiography (ASE), American Society of Nuclear Cardiology (ASNC), Heart Rhythm Society (HRS), Intersocietal Accreditation Commission (IAC), Mended Hearts, North American Society for Cardiovascular Imaging (NASCI), Radiology Society of North America (RSNA), Society of Atherosclerosis Imaging and Prevention (SAIP), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Cardiovascular Computed Tomography

(SCCT), Society for Cardiovascular Magnetic Resonance (SCMR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI). This document is an ACC health policy statement and is intended to promote or advocate a position, to be informational in nature, and to offer guidance to the stakeholder community regarding the ACC's stance on healthcare policies and programs. Health policy statements are not intended to offer clinical guidance and do not contradict existing ACC clinical policy. They are overseen by the ACC Clinical Quality Committee (CQC), the group responsible for developing and implementing all health policy statement policies and procedures related to topic selection, commissioning writing committees, and defining document development methodologies. The CQC brings together various areas of the College such as the Advocacy Committee, the National Cardiovascular Data Registry, the ACC/AHA Task Forces on Guidelines and Performance Measurement, and the Appropriate Use Criteria Task Force. The CQC recommended the development of this Health Policy Statement to document the College's official position on improving the effectiveness of diagnostic cardiovascular imaging to achieve better patient outcomes.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC CQC reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. On the basis of this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry (RWI), led by a chair with no *relevant* RWI. Authors with *relevant* RWI are not permitted to draft or vote on text or recommendations pertaining to their RWI. RWI is reviewed on all conference calls and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices 1 and 2, respectively. Additionally, to ensure complete transparency, authors' *comprehensive disclosure information*—including RWI not pertinent to this document—is available online (see Online Appendix 3). Disclosure information for the ACC CQC is also available online at www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx, as well as the ACC disclosure policy for document development at www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx.

The work of the writing committee was supported exclusively by the ACC without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and attended only by committee members.

Joseph P. Drozda, Jr., MD, FACC, Chair
ACC Clinical Quality Committee

1. Introduction

1.1. Document Development Process

1.1.1. Writing Committee Organization

The writing committee consisted of a broad range of members representing 15 societies and the following areas of expertise: general cardiology, interventional cardiology, pediatric cardiology, echocardiography, atherosclerotic imaging, cardiac computed tomography (CT), cardiac magnetic resonance, nuclear cardiology, electrophysiology, radiology, practice administration, primary care, and patients/consumers in order to provide an appropriate balance of perspectives. Geographic distribution of members crossed most U.S. time zones and included Canada. Authors represented both academic and private practice settings. This writing committee met the College's disclosure requirements as described in the Preamble.

1.1.2. Policy Statement Development

The writing committee convened by conference call and e-mail to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately sign off on the document for external peer review. All participating organizations contributed to peer review, resulting in 37 reviewers representing 320 comments. Comments were reviewed and addressed by the writing committee. A CQC liaison served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and the CQC approved the final document to be sent for board review. Organizations reviewed the document, including all peer review comments and writing committee responses. The ACCF Board of Trustees approved the document August 2013. The AHA, ASE, ASNC, HRS, IAC, Mended Hearts, NASCI, RSNA, SAIP, SCAI, SCCT, SCMR, and SNMMI endorsed the document January 2014. This document is considered current until the CQC revises it or withdraws it from publication.

2. Purpose of This Health Policy Statement: Overview of the Issues

Medical imaging is an exemplar of the power of scientific understanding to revolutionize the diagnosis and treatment of disease. Using modern diagnostic techniques, physicians can peer deeply into the body to gain insights into the structure and function of any organ without the risks of surgery or invasive procedures. Cardiovascular imaging methods, including echocardiography, nuclear cardiology

(including single-photon emission CT and positron emission tomography scanning), magnetic resonance imaging (MRI), and CT are all now routinely employed in the care of patients. These developments would be viewed as strong empirical evidence of the benefits society can reap from investment in medicine but for 2 factors. First, although imaging technologies offer the promise of more rapid and precise diagnosis, which may result in improved patient management, the pace of innovation and its dissemination into practice has outstripped the ability of researchers to define the associated incremental value clearly and persuasively. Second, rates of growth have previously been documented in the use of most common imaging studies performed in the United States, particularly between 1999 and 2006, which appeared to have been driven by something other than changes in the healthcare needs of the patient population. These high rates of diagnostic imaging test use coincide with a growing intensity of concern nationally about the overall growth in the rate of medical spending in the United States. Some of the most common cardiovascular imaging procedures, including echocardiography and SPECT nuclear cardiac scans, have consistently ranked in recent years in the top 200 codes billed to Medicare each year (1). The purpose of this document, in part, is to contend that policy decisions based on simplistic causal models connecting these sorts of trends will yield bad policy that may harm patients. Instead, we contend that, in order for policy reforms to achieve their intended goals without major off-target consequences, policy makers must take account of the complex interplay between medical care quality (of which proper use of diagnostic testing is an integral part), patient health outcomes, and medical costs.

2.1. Current Understanding of Patterns of Cardiovascular Diagnostic Imaging Use

Our understanding of the changes that have occurred over time in patterns of care employing imaging is incomplete. The current share of spending devoted to medical imaging is small (about 3% of the Medicare budget in 2007), and recent figures show declines since 2006 in the volume of imaging services provided (2,3). In the context of a growing belief by policy makers and payers in the need for aggressive reductions in the level of growth in health care spending in the United States, however, other statistics showing a disproportionate growth in the use of diagnostic imaging procedures starting in 1999 has led to intensified scrutiny (4). As in many other areas of medicine, this scrutiny has revealed substantial unexplained geographic variation in imaging use in the United States. Such variation (typically expressed in terms of unadjusted testing rates) is not, in itself, proof of overuse or inappropriate care. However, the suggestion these data offer, that some regions are able to provide care using less resource-intensive patterns of imaging without evident harm to patients, has been interpreted by some to show that higher-use areas are employing too much care with little incremental benefit (4). Although intuitively appealing to those tasked with reducing overall U.S. health spending, this line of reasoning provides insufficient insight to be used as the basis for shaping good policy decisions (5). Recent investigations into the deceleration in the rate of advanced imaging use that started in 2006 have suggested that imaging rates are best understood as the product of a complex interplay of healthcare system structural factors and incentives (both positive and negative) (6,7).

2.2. Drivers of Physician Use of Diagnostic Testing

Although direct evidence is scant, some sources asserted in 2006 that 20% to 50% or more of advanced imaging studies performed each year provided little or no benefit to the patient (8). Other sources have reported higher use of imaging when the treating physician also bills for the professional or technical fee associated with the testing (9,10). The conclusion often drawn from such data is that financial gain was a primary driver of the overuse of imaging in the United States. However, a more nuanced analysis shows that the drivers of physician test-ordering behaviors are complex and include technological, patient, physician, payer, and health system factors, including: the improved ability of newer imaging techniques to answer clinically relevant questions (independent of the question of whether ultimate patient outcomes are affected); changing patient demographics; greater patient awareness of and demand for the objectivity and higher certainty that imaging seems to offer; fragmentation of care with duplication of testing at different points in the healthcare network for a given patient; fear of lawsuits; diminishing confidence of practitioners in their abilities to make clinical assessments without imaging confirmation; and the incentive to do more in a fee-for-service reimbursement context (11–14).

More evidence that a financial incentive is not the only, or even the dominant factor at play in explaining varying national imaging rates, comes from a recently reported pooled analysis of 6 large health maintenance organizations (15). Between 1996 and 2010, use of CT studies increased 3-fold, use of MRI increased almost 4-fold, and use of ultrasound increased by 70%, whereas nuclear medicine studies decreased by a third starting around 2008. Thus, even in an integrated health system without a financial incentive for testing, use of some types of imaging studies has increased substantially over the last 2 decades.

"Defensive medicine" has been cited in numerous surveys of physicians as a major justification for overuse of imaging studies. A Massachusetts Medical Society study in 2008 demonstrated through a statewide physician survey that 22% of plain x-rays, 28% of CT scans, 27% of MRIs, and 24% of ultrasounds were ordered for "defensive" reasons (16). Separating explicit concerns about vulnerability to malpractice claims from the desire to achieve diagnostic certainty, however, is difficult. To the extent that the latter is a significant driver of physician behavior, medical malpractice tort reform may have only a modest effect on the

amount of "defensive medicine" practiced (17). Research to date on the effects of malpractice tort reform on physician behavior and "defensive medicine" costs is very mixed (18–23). In addition to defensive medicine and issues of diagnostic uncertainty, the effect of patient expectations, informed by news media and internet sources, on rates of test use should be considered, but such effects are very difficult to study empirically or indeed to quantify in any other way.

Another important, but often overlooked, driver of greater use of testing is the shift, over the last few generations of physicians, away from reliance on the history and physical examination and towards more reliance on "objective" data. Medicine has, in recent decades, evolved to an "imaging intensive" practice style or culture in which use of imaging is routine and unquestioned rather than selective and focused. In some clinical contexts, this increased imaging use provides higher quality care, but in other contexts more use of imaging may be disconnected from measurable improvements in patient care and outcomes. In addition, in the U.S. healthcare system, the physician performing imaging tests has the role of a service provider, with incentives (both financial and non-financial) to provide imaging services as requested. In contrast, in countries with more constraints on healthcare spending and limited medical ability, imaging physicians are often given the potentially more adversarial role of gatekeeper (24).

2.3. Imaging and Patient Safety: The Issue of Cumulative Diagnostic Radiation Exposure

Recently, the issue of patient risk/safety following exposure to ionizing radiation from CT, nuclear medicine, and invasive angiographic studies has been added to the debate about the use of medical imaging (25–30). For imaging modalities where the FDA has granted approval for clinical use, implying adequate safety at the individual test level, the clinicians ordering those diagnostic tests, in the past, had not given much attention to the estimated cancer risk from cumulative diagnostic test radiation exposure. Reasons for this include physician unfamiliarity with the issues, lack of accurate methods for tracking cumulative radiation exposures, and the very long time intervals involved between exposure and any detectable signs of disease (31).

These logistical difficulties, along with the millions of subjects that would need to be followed to accumulate a sufficient number of incident cancer cases, have hampered attempts to define empirically the possible impact on lifetime cancer risk following exposure to different levels of diagnostic ionizing radiation. As a consequence, the field has been forced to rely on extrapolations from data outside the diagnostic radiation imaging field (particularly studies of the Japanese atom bomb survivors), to lower exposure doses used in medical imaging and on modeling based on largely untestable assumptions. The "linear no-threshold" (LNT) hypothesis has been endorsed as the model that best fits the fragmentary data available (32). This model assumes that there is no safe dose of ionizing radiation, when safety is defined in terms of future cancer risk. The model suggests, therefore, that even with the low doses used for medical testing, projected cancer risk is a linear function of dose. A challenge to the LNT hypothesis is that projections as to the health impact of radiation exposure below 50 mSv have a large degree of uncertainty. Accordingly, there has been tremendous controversy regarding the projected cancer risk following radiation exposure to cardiac imaging. For clinical purposes, the incremental cancer risk projected following radiation exposure from medical imaging has been small (i.e., <1% incremental cancer risk). Although observational evidence is lacking as to whether low dose exposure, such as that with medical imaging is associated with an increase in incident cancer, there are data on the growing cumulative exposure of the population to diagnostic imaging. One recent study (15) used 15 years of patient-level data from 6 large integrated health systems (covering 1 to 2 million member-patients per year), to estimate that from 1996 to 2010, patient per capita radiation dose doubled (1.2 mSv versus 2.3 mSv), while the proportion of patients who received radiation doses greater than 20 mSv also doubled (1.2% versus 2.5%) (15). The LNT hypothesis predicts that this trend will be associated with a projected increase in cancer cases, although the timeline to develop new cancers and what sort of cancers will develop are still difficult to predict. To estimate these cancer risks, a model-based approach such as that developed by the National Cancer Institute (33) has been developed.

In the last several years, imagers have focused increasingly on making diagnoses with the lowest dose of radiation. In some cases, this has allowed testing with >50% reductions in the radiation dose while maintaining image quality (25,27,34,35). Clinicians, sensitized to these concerns, may also be able to substitute a study using magnetic resonance or ultrasound for one using radiation, particularly if there is comparable diagnostic evidence to support the use of alternative test modalities.

2.4. Overview of What Follows

Physicians, payers, and policy makers agree in principle that growth in medical imaging use without reasonable evidence of proportionate clinical benefits cannot be defended as responsible stewardship. Healthcare leaders further agree in principle that medical imaging should be used in a safe and efficient manner while fostering continued technological innovation and preserving equitable, high-quality patient care. Less agreement currently exists, however, on how to put those principles into practice. The purpose of this document is to provide a brief exposition of the issues involved and the possible ways in which the medical care system can balance responsible use of imaging with patient safety concerns while maintaining or even enhancing quality of care. The concepts, tools, and major options for achieving those goals are the subjects of the next 2 sections. We then consider the application of these tools for identifying and reducing underuse (Section 5) and overuse (Section 6) of

imaging. We conclude with some thoughts about possibilities for future initiatives.

3. Improving Imaging Use: Conceptual Overview

The current debate on the value, safety, and quality of medical imaging is not the product of recent insights by clinicians, payers, or policy makers. The concerns reviewed in the preceding section have appeared in literature dating back more than 25 years. If nothing else, this history serves as a warning that the issues involved are not amenable to easy solutions. It is tempting to propose that the goal in the field of diagnostic imaging should be to define the "optimal" level of imaging use in practice, neither too much (which is wasteful by definition) nor too little (which may be harmful to patients who fail to receive the correct diagnosis or treatment). This goal is captured in the aphorism "the right test on the right patient at the right time" (36). However, optimization of the sort referred to here, essentially the "best" solution possible, only becomes operationally tractable after creating clear boundaries for the problem at hand: a limited and explicitly specified healthcare budget allocated to improve the health of a well-defined population, with high-quality information on the incremental costs and benefits of all relevant management options. In such a context, it may be possible to identify the most efficient patterns of testing to use in maximizing well-defined health goal(s) with the funds available. Without such constraints, the problem has no meaningful "optimal" solution. The United States is clearly not willing to spend an unlimited amount of money on health care overall, or on diagnostic imaging in particular, but the real limits on spending and resource allocation are not clear. For this reason, calculation of optimal use rates for a given region or health system, or the country as a whole, is not possible without first reaching agreement on a large number of key assumptions.

Two general approaches have been developed to address the questions raised by the clinical deployment of more and better diagnostic tests: technology assessment and appropriate use. Both assume that imaging in question is performed well and interpreted accurately. Technology assessment examines the impact of healthcare technology in a broad policy context built around the question "what do we know?" from all the evidence available about a particular test or type of care. Appropriate use addresses the question "what should we do (and not do)?" Quality improvement integrates information from both these areas to ask a third question "how can we improve what we do so as to provide patients the full benefit of what we know?" In the next section, we will examine how these 3 elements interact to produce an operational path toward understanding "optimal" imaging use. However, to place this discussion in proper context, we first review the unique challenges presented by the clinical context in which diagnostic testing takes place.

As medicine has moved from a cottage industry of independent physician practitioners to an increasingly corporate industry accounting for 17% of the U.S. economic output, business concepts have been imported into the medical world with varying degrees of success. In the part of the business world concerned with producing consumer goods, quality is typically achieved through rigorous standardization of production methods, minimizing variation in the resulting product. From such a business perspective, therefore, variations in medical care chosen for the same patient group are viewed as evidence of poor quality. However, what this business-inspired analysis fails to account for is the pivotal role of uncertainty in every aspect of medical practice (37). Uncertainty is present when the physician first encounters the patient, and it remains present throughout every aspect of the diagnostic and treatment phases. Although uncertainty may be reduced, it can never be eliminated. Physicians spend their professional lives dealing with risks and benefits that can be measured only in terms of probabilities. Variations in the use of testing, therefore, are a likely consequence of the physician's search for a subjectively sufficient level of certainty (which includes the desire to avoid diagnostic mistakes that might be the basis for malpractice allegations), coupled with variable inefficiency in the use of test information (for example, when heuristics or simple rules of thumb are used to simplify complex decisions), and the local availability of different testing technologies and expertise. Many of these factors taken collectively can be conceptualized as "practice styles" that help clinicians make complex decisions efficiently in situations characterized by high uncertainty and insufficient high-quality evidence (38). Patient expectations, and physician understanding of those expectations, may also exert a powerful influence on testing patterns. Recognizing this, when new policies are proposed to address perceived overuse of diagnostic imaging, we must ask whether such policies adequately confront the central importance of managing uncertainty in patient care and the role that diagnostic tests serve for physicians and patients in that function.

4. Improving Imaging Use: Approaches and Tools

As discussed in the previous section, we can approach the general problem of improving imaging use through 3 related questions: what do we know from the available evidence? (technology assessment), what should we do (and not do)? (appropriate use), and how can we improve what we do so that patients can benefit from what we know? (quality improvement). In this section, we will examine each of these questions and the associated pathways to answering them in more detail. One caveat should be offered at the outset. Each of these topics is complex and has generated an

extensive literature of work. Our intention is to provide some general guidance through this area without any claim to being exhaustive.

4.1. Technology Assessment

Technology assessment in the healthcare context refers to a comprehensive, systematic evaluation of all relevant outcomes (including clinical, economic, social, organizational, and ethical) consequent to deploying a given health technology in a particular health system. It includes, but is not limited to, what is now referred to as "comparative effectiveness." Diagnostic imaging technologies pose particular problems for technology assessments because they have few direct effects on patient health outcomes (aside from immediate test-related complications). More often, diagnostic tests provide clinicians with information that sometimes, but not always, affects patient outcomes. Such a multilink chain of causation stretching from the imaging tests to patient outcomes highlights the many events that must occur sequentially for the potential of diagnostic testing to be realized in practice. That events chain is tightest in the acute care setting when diagnostic testing is used to make treatment decisions that are highly time sensitive. Of course, even a very accurate diagnostic test is of limited value to patients if physicians do not have the understanding or the tools to use its results to improve care.

A 6-level hierarchical technology assessment framework was first proposed by Fineberg et al. in 1977 for studying the impact of imaging technology on the healthcare system and was refined by Fryback and others several years later (39,40). In the ideal world of "rational" health care envisioned in this model, a comprehensive technology assessment of a new diagnostic technology would be performed covering all 6 levels before the technology was released into general medical practice. Such information would then help clinicians, payers, and policy makers understand how best to use the new technology to provide more clinically effective, more cost effective, higher-quality care. Nonetheless, that ideal has never been achieved, perhaps in part because the cost of generating the evidence to achieve such an understanding before general dissemination of the technology would make innovation prohibitively expensive. The counterargument is that failure to properly evaluate new technology before widespread dissemination can lead to excessive costs and reduced health outcomes despite the superficial appearance of being both compassionate and innovative. Regardless of one's perspective on this issue, the technology assessment framework is useful for its organizing concepts and for pointing out the important gaps in our current understanding (Table 1). Level 1 of this evaluation system addresses the technical quality of the images (including spatial and temporal resolution where relevant). Level 2 provides evidence on the diagnostic accuracy of the test relevant to appropriate reference standards, assessed using parameters such as sensitivity and specificity, post-test probabilities, receiver-operating curves, likelihood ratios, and interrater reliability estimates.

Table 1. Hierarchical Model of Diagnostic Test Evaluation

Level 1	Technical efficacy
Level 2	Diagnostic accuracy efficacy
Level 3	Diagnostic thinking efficacy
Level 4	Therapeutic efficacy
Level 5	Patient outcome efficacy
Level 6	Societal efficacy

A sizeable proportion of the voluminous literature on evaluation of diagnostic testing falls into this category. Level 3 deals with the effect of the test on the clinician's thinking, particularly the incremental value of the test information in arriving at a diagnosis. The fourth level of this evaluation framework is concerned with the incremental effects of the test results on the clinician's therapeutic decision making in the face of other available clinical information. Research in this area is difficult to design and perform due to difficulties in determining in what ways the physician's reasoning process, which cannot be directly observed, is affected by any specific information derived from an imaging test. The final 2 levels of this technology assessment hierarchy framework evaluate the effects of testing on incremental patient outcomes (including safety-related outcomes) and whether the use of the test is cost effective from a societal perspective. Effects of testing strategies on patient outcomes should be ideally assessed in a randomized trial, but such trials are difficult to perform, expensive, and have been very rarely attempted. Several randomized trials have recently evaluated the effects of coronary computed tomography angiography on management of patients with acute chest pain. The focus of these initial studies has been on efficiency and cost of care, and data on long-term patient outcomes have not typically been included, although additional outcome-based studies are currently underway (41–43). Cost-effectiveness models of diagnostic testing strategies are simpler to perform than randomized trials, but modeling by itself does not resolve the underlying uncertainties involved in translating data on test performance into an understanding of the comparative effectiveness of alternative testing strategies, for which there is usually only limited and lower-quality evidence (44,45).

4.2. Appropriate Use of Testing

The concept of appropriate use applied to medical care shares many of the conceptual and operational difficulties encountered in defining an "optimal" rate or pattern of medical care (46). All the definitions in the literature make reference to positive health benefits for the patient, but without further specification, this is of limited utility. The RAND/UCLA Appropriateness Methodology was originally developed in the 1980s as part of a series of studies on the overuse and underuse of medical and surgical procedures (47). According to RAND: "An appropriate procedure is one in which "the expected health benefit (e.g., increased life expectancy, relief of pain, reduction in anxiety, and

improved functional capacity) exceeds the expected negative consequences (e.g., mortality, morbidity, anxiety, pain, and time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost" (47). This method employs a panel of experts who are instructed to apply their professional clinical judgment while taking account of the available research evidence to rate appropriateness on an ordinal scale, ranging from 1 (very rarely appropriate) to 9 (most appropriate). A 2-round "Delphi process" is used to generate expert appropriateness ratings of medical and surgical procedures performed in briefly defined clinical scenarios. The expert panel is asked to base their ratings on an "average patient" presenting to an "average clinician" in an "average" medical care setting (47). The method seeks to identify when consensus exists but does not force consensus. The median scores and levels of group disagreement are used to classify the final ratings into 3 groups: rarely appropriate, uncertain, or appropriate.

RAND appropriateness methods were first applied to medical imaging by the American College of Radiology starting in 1993 (48). The ACC, in conjunction with the ASNC, applied these methods to cardiovascular nuclear stress tests in 2005. To adapt the RAND appropriateness methods to the problem of diagnostic imaging, an ACC expert panel proposed a modified definition of appropriate use: "an appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences [including the risks of the procedure and the downstream impact of false-positive and false-negative test results] by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication" (49). Appropriate use of testing is thus acknowledged to rest heavily on the clinical judgment that performing the test in question for the indication in question would "be an acceptable step in providing good clinical care." More recently, the ACC also adapted the 3 categories of appropriate use to clarify their intent and emphasize their application to populations. The new category labels are: appropriate, maybe appropriate, and rarely appropriate (50).

The initial ACC appropriate use criteria document included ratings for 52 possible indications for myocardial perfusion imaging (49,51). Empirical testing of these criteria in an academic medical center using patients enrolled before the appropriate use criteria were published found that 64% of tests were appropriate, 11% were uncertain, 14% were rarely appropriate, and 11% were not classifiable (52). A follow-up study from the same laboratory reflecting the period after the appropriate use criteria were published showed lower rates of rarely appropriate studies to 7%, but could not identify the cause of this improvement (53). In that academic center, the specialty of the ordering provider did not affect the rate of appropriate testing (54); but in earlier studies, physician specialty, experience, and practice environment did affect appropriate use of coronary angiography (55).

Although much current attention is directed to overuse of advanced imaging studies, 1 of the original motivations for the RAND appropriateness work was to identify underuse of effective care. The RAND investigators introduced the concept of necessity, defined as "care that must be offered," to assist in the identification of underuse (47). Underuse has been identified as a problem disproportionately affecting minorities, women, and the poor, and is likely to result in worse health outcomes (56–58). Underuse of appropriate coronary revascularization, for example, has been associated with higher cardiac event rates and worse angina control (59,60). Demonstrating that underuse of advanced imaging has had a negative effect on health outcomes would be substantially more difficult because, as noted earlier, these effects are indirect. Thus, although some observational data suggest that lower use of echocardiography among patients with newly diagnosed heart failure is associated with lower use of evidence-based medications, the nature of the connection between the performance of the diagnostic test and the treatment decisions remains uncertain in the absence of a randomized trial (61–63).

Appropriate use criteria have been critiqued for having only fair reproducibility among different rating panels, particularly in areas where evidence is weaker (64). Reproducibility of appropriate ratings, however, appears to be comparable to reproducibility of interpretations for cardiac imaging tests (65). The Delphi approach used in developing the criteria is reasonable for common conditions where all the important elements can be easily summarized, but would not be expected to capture important nuances of care that might modify decisions for individual patients. The pervasive uncertainty that characterizes medical practice creates unresolvable ambiguities in what will and should be considered appropriate care (66). Appropriate use criteria, therefore, are best considered "rules of thumb" that work reasonably well in groups of patients but may fail to capture important aspects of testing decisions for individual patients (6). For this reason, "rarely appropriate" should not be viewed rigidly as synonymous with negligent care or malpractice. A useful distinction, therefore, may be made between appropriate use criteria applied to individual patients versus a large group of patients. Individual deviations from "appropriateness" are to be expected and should not be viewed on this basis alone as evidence of poor-quality care. A good decision process that led to a choice for "rarely appropriate" care should be explainable and reasonably transparent so that the unique features of the case are evident and it is clear that no major reasoning error was involved. Some level of "rarely appropriate" care is to be expected in even the best practices, and elimination of these cases may harm patients with less common presentations and features.

Early investigations on the relationship between appropriate use ratings and geographic variations in patterns of

care revealed the surprising finding that areas of higher use did not usually have higher rates of rarely appropriate care (67). In fact, much of geographic variation in care occurs within the category of appropriate care and presumably reflects different assessments by physicians about the incremental value of that care for individual patients. Other important drivers of geographic variations in care include differences in practice "styles" (shaped by heuristic patterns of care used to simplify and speed up complex decision making, as well as peer practice norms for the community in question) and technology diffusion (66,68). Little work has been done to date on the relationship between appropriate use ratings and cost effectiveness (incremental health benefits as a function of incremental medical costs). Cost was excluded from consideration in the RAND appropriateness method, although implicitly considered in ACC efforts. The contention, by payers and some policy makers, that 20% to 50% of advanced imaging studies provide little to no benefit implies that they are including in that estimate not only the 10% to 20% of studies that typically are judged as not being appropriate but a significant proportion of other studies that are currently deemed reasonable. However, since this issue has not been studied, the actual amount of cardiovascular imaging that would fall into this latter category (appropriate but for which its value is highly variable based on context) is currently unknown (69).

4.3. Quality Framework for Diagnostic Imaging

Quality of care as it relates to imaging refers to the use of available best evidence to provide safe and effective management for patients with clinical problems where imaging has an important role to play. Quality in this context is most often operationalized using the 3-element model first proposed in 1966 by Donabedian: structure, process, and outcome (70–72). Applied to imaging, the specific components of each element are chosen for their relationship to safety or to clinical management. **Structure** includes the infrastructure that is required to support the performance of imaging studies, such as properly functioning state-of-the-art equipment and facilities, certified staff and physicians, continuous quality initiatives/maintenance of certification/training/continuing education for all members of the team, and use of imaging society standard imaging protocols and standardized reporting software. **Process** starts with patient evaluation and referral, and includes clinical decision making, standardized imaging acquisition, standardized test interpretation and report generation, communication of meaningful results, and test result–guided patient management. **Outcomes** include all the consequences of testing, both direct and indirect, that affect patients, including morbidity, mortality, quality of life, satisfaction, and cost. Traditionally, quality assessment in imaging has been limited to considering structure and some elements of process alone. New models of imaging quality seek to improve the entire processes of care, and consequently health outcomes, through a systematic focus on each link in the diagnostic imaging chain from test ordering to the communication of and use of the results (Figure 1) (8). Selected elements in this chain are considered in greater detail in the following text.

4.3.1. Quality Improvement of Imaging: Laboratory Accreditation

Accreditation of laboratories and certification of personnel who perform and interpret imaging (considered in the next section) are structural quality elements in the conceptual quality model presented in the previous section. The U.S. Congress, in its Medicare Improvements for Patients and Providers Act of 2008, mandated that as of January 1, 2012, all non-hospital entities supplying the technical component of advanced imaging services (defined as MRI, CT, nuclear medicine, and positron emission tomography) must be accredited by an approved organization in order to receive reimbursement. The 3 accreditation organizations approved by the Centers for Medicare and Medicaid Services (CMS) for this purpose are the Intersocietal Accreditation Commission (IAC), the American College of Radiology (ACR), and the Joint Commission (5). For other imaging modalities, such as echocardiography, accreditation is currently still voluntary for CMS reimbursement. However, some private payers have had similar payment policy requirements in place for several years and have included echocardiography (73).

With respect to IAC accreditation, the process of obtaining and maintaining accreditation requires a commitment to continuous compliance with peer-derived imaging standards. Representatives of those professional societies who are stakeholders in the specific imaging modality being

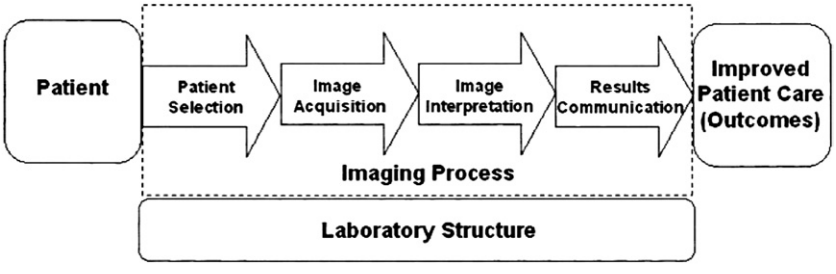

Figure 1. Dimensions of Care Framework for Evaluating Quality of Cardiovascular Imaging

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assessed create the standards by which IAC evaluates laboratories. Depending on the baseline level of laboratory organization, the initial accreditation process for some may prove to be a time consuming and labor intensive process, Specific protocols must be written, implemented, and monitored to meet and maintain compliance with accreditation standards. Once obtained, the process of maintaining accreditation requires commitment to continuous compliance with imaging accreditation standards thus making future accreditations relatively simple.

The application requirements covering structure include 1) a facility overview; 2) estimates of annual procedure volumes; 3) details of staff experience, training, and credentials; and 4) an imaging equipment list. The facility overview involves documentation of administrative policies for patient confidentiality, patient complaints, infection control, drug and contrast administration policies, emergency equipment, medication control, and other safety policies specific to the imaging modality (e.g., cardiac life support certification). The application for accreditation also assesses critical elements of **process** such as, patient identification and pregnancy screening (e.g., what steps are taken to ensure that the correct patient is tested), radiation and other safety protocols (as applicable), quality control protocols and quality improvement for the imaging equipment, and the use of standardized and timely reporting. **Outcome** of imaging is assessed in a limited way through documentation of ongoing quality improvement activities. These activities include measurement of appropriate use and patient satisfaction, technical and interpretative review, correlation with other imaging modalities, and patient outcomes.

The final step of the application process includes the submission of case studies (generally ranging from 3 to 6 cases [but up to 12 for large echocardiography or general nuclear medicine laboratories] performed within 1 year of the application). Independent peer review assessment of the interpretive and technical quality of the laboratory is performed. Once submitted, the application review typically takes 10 to 14 weeks (74).

IAC accreditation reflects demonstrated adherence to comprehensive imaging standards, authored by professionals within the imaging community. Detailed internal examination, coupled with external peer feedback, constitute IAC's foundational approach to quality, assessment, and improvement. Active engagement in these processes is expected to improve laboratory quality. That stated, it must be recognized that IAC (or any accrediting organization) is not a governmental agency and does not hold regulatory authority.

Potential weaknesses of IAC's approach to accreditation include its reliance on self-selected cases and limited audits of data submitted. Furthermore, because accreditation is a 3 year process with 1 mid-cycle audit, compliance cannot be assessed on an ongoing basis at this time. Efforts are currently underway within IAC to review solicited cases rather than self-submitted cases. Expansion of standards to include collection of prospective data on appropriate use, ensuring a more robust internal peer review process, and specific radiation safety practices represents efforts to keep accreditation robust and relevant. Further, IAC has initiated a program of research to demonstrate the value of accreditation in improving clinical quality). Standardized reporting, with emphasis on consistency and clarity has been shown to help avoid redundant testing (8). Recent literature has suggested that IAC requirements for standardized reporting have increased accuracy rates and created a more uniform performance among laboratories in subsequent accreditation cycles (9). Data are not yet available on the impact of reduced reimbursement and increased administrative burden from pre-authorization/notification requirements on laboratory quality.

4.3.2. Quality Improvement of Imaging: Physician Certification and Credentialing

Physician certification is another structural method of addressing imaging quality. Imaging societies, including the ASE, ASNC, ACR, SCCT, and SNMMI, have created physician board certification for specific imaging modalities. The first cardiac MRI certification examination is anticipated in 2015. The American Board of Radiology is pilot testing a focused practice evaluation in cardiac CT as part of their maintenance of certification program. In the future, these societies are expected to broaden their curricula to include more emphasis on appropriate use of imaging and on basic principles underlying the use of multiple modalities.

4.3.3. Quality Improvement of Imaging: Integration of Care and Accountability

Efforts to assess quality and appropriate use have typically focused on the imaging laboratory, but use of cardiac imaging depends on actions taken by referring physicians and patients, as well as by imaging laboratory staff. Prior to testing, the referring physician must correctly identify which patients need imaging, and in those patients, he or she must select a specific test. After the test is ordered and the patient appears in the laboratory for testing, the physician who oversees the imaging assumes responsibility, which includes standardized image acquisition and protocols, processing, and reporting. The reading physician must interpret the images, generate a report, and convey the test results and their relevance to the referring physician. At this point, the responsibility returns to the referring physician who must incorporate the results into the care of the individual patient and formulate patient management strategy based on test results.

The process of ordering, performing, and interpreting imaging tests and acting upon the results underscores the concept that quality improvement must address the entire process of care and not focus only on the imaging laboratory. Thus, development of metrics reflecting performance at each of the steps of the process is needed, but, at present,

numerous hurdles exist that may preclude success, including the complex factors that influence post-test management practices by referring physicians (Figure 1). The burden and cost of additional data collection, however, must be carefully weighed against its incremental value. At the step of initial physician referral, metrics capturing information regarding the clinical profile of patients referred to testing (e.g., primary reason for referral, distribution of patient pre-test likelihoods of coronary artery disease) could characterize patient selection and choice of imaging method and be used to calculate appropriate use criteria. However, a detailed clinical history is often not collected at the time of patient referral to an imaging laboratory. Thus, such data are usually not available in imaging databases. The second step could assess quality metrics for image acquisition and reporting established by the various imaging societies, which is the most readily available electronically stored data. The final step could involve determining how test results were used to guide the clinical management of patients (e.g., changes in medical therapy, referral for invasive catheterization). Currently, most practice sites lack the needed infrastructure to make routine tracking of outcomes that result from testing feasible. Eventually, patient outcomes could also be documented. The ability to link patient baseline characteristics with test performance and result data and patient outcomes would allow for the construction of longitudinal databases. Such data resources could be used to examine some comparative effectiveness questions related to the association between testing strategies and long-term outcomes.

Nevertheless, sizeable challenges exist for the development of integrated longitudinal registries incorporating imaging with other patient information. As an example, ASNC's ImageGuide™ registry is proposing to rely on interpretive software programs that are based on standardized reporting for data elements. Yet, the clinical data will be insufficient for documentation of the gamut of AUC indications. As such, adaptations are required to minimize data entry and limit AUC to those rarely appropriate indications that have been highlighted in the American Board of Internal Medicine's Choose Wisely program. Although plans are underway to link ImageGuide to the ACC's CathPCI registry and possibly to payer databases, the inclusion of long-term outcomes has not been proposed due to the excessive burden that this would place on participating laboratories. Expansion of the ACC's data registries into the outpatient area, along with the increase in health system based electronic health records will provide the basis for future such efforts.

5. Identifying and Reducing Underuse of Cardiac Imaging

Underuse of imaging is an extremely difficult concept to operationalize. As a practical matter, if the role of a diagnostic test is to reduce the uncertainty of a clinician to the point where she or he is able to decide on a course of management most likely to relieve suffering and improve outcomes, identifying when a test should have been done but was not becomes very difficult, inasmuch as it depends on the unobservable reasoning processes of the clinician as well as their unspecified, personal tolerance for diagnostic uncertainty. When applied to the problem of underuse, the RAND Appropriateness Method had to be adapted by the introduction of the concept of necessity: procedures and therapies that *must* be offered (47). The difference between appropriateness and necessity is that the latter reflects the judgment that patients have a clinically important probability of being harmed by the failure to perform the test or administer the treatment in question. By contrast, appropriateness only indicates a judgment that a course of action has a favorable risk/benefit ratio, but it is possible that not doing the test or doing a different test may also be appropriate by the same benchmark. Failure to administer aspirin to an acute coronary syndrome patient can be expected to be harmful on average, based on a large body of clinical trial evidence (75,76). Failure to perform an exercise myocardial perfusion single-photon emission computed tomography or a cardiac MRI scan in a certain circumstance has consequences that are much harder to define, in part because they are conditional on a large number of other factors. The consequences, for example, may be different if the alternative being considered is no testing versus performance of exercise treadmill testing or a cardiac stress transthoracic echo. There are few empirical data that persuasively document harms from the omission of imaging studies. Consequently, defining clinical scenarios that meet the RAND necessity criteria in the case of diagnostic imaging is quite difficult. A second method of identifying underuse employs selection of benchmarks from observational data. By comparing groups assumed to be similarly situated in terms of opportunity for benefit and assuming that greater rates of use are beneficial, it can be inferred that lesser rates are therefore harmful. For example, if the rate of cardiac imaging in white males is assumed to reflect a reasonable benchmark for necessary care, lower rates observed in women and minorities would be interpreted as underuse and would be expected to lead to poorer health outcomes. The difficulty with this approach is that there is often little justification supporting the benchmark upon which the whole analysis rests.

True underuse of cardiac imaging occurs for at least 3 general reasons: 1) reduced access to care due to economic, geographic, or cultural barriers; 2) inadequate understanding by physicians of the potential value of cardiac imaging to guide therapy and thereby improve quality of care; and 3) poor integration of the healthcare delivery system. Determination of left ventricular function by imaging in patients with heart failure has been recognized in practice guidelines as an important step in

patient management likely to affect outcome and is tracked as a quality measure, but few other uses of noninvasive imaging have established a direct connection to patient outcomes supporting the case for harm from less testing. At present, there are no large-scale systematic efforts to quantify underuse of medical imaging and identify potential remedies. Large clinical trials (e.g., the PROMISE [Prospective Multicenter Imaging Study for Evaluation of Chest Pain] [77] and ISCHEMIA [International Study of Comparative Health Effectiveness With Medical and Invasive Approaches] [78] Trials) could provide a path to identifying underuse by defining the clinical circumstances in which specific testing strategies improve outcomes. Underuse could then be operationally defined as the absence of testing in those clinical circumstances, without need to refer to the physician's level of uncertainty or to select unproven benchmarks. However, most clinical decisions involving imaging are unlikely to be the subject of large-scale clinical trials. Consequently, inferences about the best role of testing (including when failure to test would be harmful to patients) will still often need to be made from careful analyses of suitable observational data.

Cardiovascular imaging to assess the structure and function of the heart is often critical to the successful management of many cardiovascular disorders. Despite an understanding of the 3 potential causes of underuse as described above, it is important that future systems of care employ current and emerging technology to assist consultants in their use of imaging. Such technologies might include electronic health record and clinical decision support systems that review patient data and provide alerts and reminders concerning diagnostic tools available based on the current diagnosis and clinical course. Emerging office-based and hospital-based systems may allow practitioners in the future to better serve disparate populations and those where language and cultural barriers remain an obstacle to appropriate and timely care.

6. Identifying and Reducing Overuse of Cardiac Imaging

Payers and policy makers have focused on overuse of advanced cardiac imaging because managing it is a way to reduce medical costs: by definition, overuse is care that adds cost but little or no benefits to patients. However, by considering cost as well as net clinical benefit when discussing "overuse" of imaging, payers and policy experts are using a different concept from the one most commonly used by physicians and patients, which considers only net clinical benefit. Greater conceptual clarity about exactly what constitutes overuse and how it should be measured will be necessary in order to assess the degree to which different strategies are successful in controlling it.

6.1. Payer Efforts to Control Imaging Costs: Administrative Efforts

Payers for health care have over the last 2 decades developed and implemented 3 main strategies to control expenditures associated with the use of diagnostic imaging: 1) requiring physicians to obtain prior authorization from a "radiology benefits manager" (RBM) before performing the test in question—favored by many private payers; 2) requiring prior notification before performing select "high end" or advanced diagnostic imaging tests, such as MRI and PET (the notification process is believed by its proponents to encourage thoughtful test selection and does not require a formal approval step prior to testing); and 3) reduced payments for imaging services—favored by CMS and discussed in the next section. These strategies have evolved in response to the perceived absence of self-regulation by the clinical community.

RBMs are typically independent companies that are hired by payers to help control imaging costs. About half of all privately insured patients currently have coverage that requires prior authorization by an RBM (6). The RBMs assert that their algorithms are based on professional society appropriateness criteria and guidelines, but these claims can be difficult to verify because the algorithms used are often proprietary, and generally not available for peer review or validation. Because of this lack of transparency, some clinicians view RBMs as a blunt tool to reduce costs by the indiscriminate refusal of services, rather than an effort to improve quality of care (79). Recent congressional and state investigations have, in fact, found that some contracts between payers and RBMs have explicitly tied the RBM fees to the degree of savings to the payer (80). The legality of such direct financial incentives has been challenged in a number of states. Use of RBMs has indeed been associated with slower growth of utilization (81), but there are few data assessing the effect of these programs on quality of care. Furthermore, the effects of these programs on patient access to appropriate services remain undefined. Prior authorization and notification adds layers into care processes, but the net effects on the healthcare system, including downstream costs and patient outcomes, cannot be judged without empirical data (82). A recent study comparing appropriateness use criteria for transthoracic echocardiography with RBM preauthorization decisions found moderate to poor agreement (83). Recently in Delaware, RBMs denied approval of nuclear stress testing in 25% of cases, but only two-thirds of these denials were concordant with ACC appropriate use criteria for nuclear stress testing (80). A large proportion of the denials in this case involved a decision by the RBM that a stress treadmill, or in a smaller number of cases a stress echo, was sufficient. Currently, CMS is legally prohibited from using preauthorization of imaging, but periodically there are discussions in Congress to eliminate this restriction. In 2011, CMS initiated a 5-center, 2-year demonstration project to determine the

effect of decision support systems on appropriate use of advanced selected CT, MRI, and nuclear medicine studies (84). Cardiac imaging is represented in this project by single-photon emission CT myocardial perfusion imaging.

6.2. Payer Efforts to Control Imaging Costs: Use of Payment Reforms

In 2005, CMS started reducing physician payments for some imaging services in the Medicare program. Attempts to use reimbursement incentives to control healthcare costs through alterations in the care process are perennially appealing to payers, but the track record of such efforts, going back to the price controls of the Nixon administration (1971), is mixed at best. In addition, piecewise manipulations of the healthcare system, an extraordinarily complex interdependent sector of the economy, often induce unanticipated and undesirable consequences. Reducing payment for office-based tests relative to hospital-based tests, for example, might seem like a logical way to reduce wasteful spending in low-risk patients, but may have the unintended consequence of shifting testing to a less efficient, more expensive hospital-based laboratory (85). Similarly, reducing payment for stress echo might cause patients to be referred more often for stress nuclear studies, which are typically more expensive. Reducing physician fees for testing in the past has been associated with a subsequent increase in the volume of patients being tested (11). Finally, there is some evidence that reduced payments for imaging studies in physician practices have played an important role in the major and relatively abrupt shift in the relationships between physicians and health systems. Increasing numbers of physicians, unable to generate sufficient revenues to stay in practice due to changes in reimbursement, have become employees of large corporate entities rather than remaining independent small business owners (85). The full consequences of this tectonic shift in the structure of medicine on patient outcomes and healthcare costs will take decades to define clearly. The likelihood that physicians employed by a hospital system will be less subject to incentives to maximize revenue than if they were in a physician practice group seems small in the current U.S. healthcare environment.

6.3. Appropriate Use Criteria

The challenges involved in adapting appropriate use criteria to diagnostic imaging technologies have already been discussed. As noted earlier in this document, the development of the RAND Appropriateness Method was motivated by the hypothesis that empirically observed geographic variations in care were due primarily to variations in appropriateness of care. Empirical investigations using this method, however, found that appropriateness of care was not the primary driver of geographic variations (87). Rather, most of the variation was seen in care rated appropriate. A major goal of many payers and policy makers is to reduce costs. To achieve that goal without harming patient health, they can reduce inappropriate use as far as possible. However, since inappropriate use rates in many studies are relatively low, payers seeking to save substantial amounts of money must also reduce the use of inefficient care, namely that care classified as "appropriate" but which provides essentially no health benefits (so called "flat of the curve medicine"). While it may be surprising to some, appropriateness and cost effectiveness do not measure the same thing. Thus, care may be appropriate but not cost effective. Thus, to achieve more efficiency in care (increased proportion of care that is "cost effective" by conventional benchmarks), greater use of appropriate use criteria alone will be insufficient. Further, decision making based only on short-term costs (e.g., the cost of imaging tests) without considering longer-term costs and outcomes (e.g., procedures avoided, adverse events prevented) may have the paradoxical effects of reducing both the quality and cost effectiveness of care. At present, however, the amount of imaging care that is "appropriate" but low value from a cost effectiveness perspective is unknown (14).

6.4. Clinical Decision Support Tools

As noted earlier, diagnostic testing is an adjunct to the physician's clinical reasoning, used primarily to reduce uncertainty in ways that facilitate reaching a decision about a diagnosis and consequently a management strategy most likely to restore/maintain health and quality of life for a given patient (88). Attempts to use computers to create or deliver tools that will improve clinical decision-making have been ongoing for over 40 years. These tools have taken a variety of forms, including statistical models and prediction rules, decision support systems, and decision analysis. Decision models require explicit structuring of a decision problem and population of the model with the best data available in order to identify key uncertainties, evaluate options and identify the one with the best outcomes. Sensitivity analyses allow for evaluation of the extent to which that preferred strategy is sensitive to key starting parameters and assumptions in the model. Decision models are a powerful way of examining complex choices under uncertainty but are generally too labor intensive to be practical for real-time patient care. In the future, a library of such models covering common clinical problems and embedded in an electronic medical record platform could be used to provide patient-specific support in even relatively complex decisions. Statistical models and other prediction rules are tools that "inform" the testing decision by estimating either diagnostic probabilities or patient risk. These tools, unlike decision models, do not directly identify the preferred decision.

Outside cardiology, there is moderate evidence for the utility and effectiveness of qualitative and quantitative "clinical decision support" rules for several specific conditions, such as a traumatic headache (89), knee pain (e.g., Ottawa Knee Rule) (90), and low back pain (91). The Framingham Risk Score (92), the CHADS2 score in atrial fibrillation (93), the Thrombolysis In Myocardial Infarction (94), and

the Global Registry of Acute Coronary Events (95) scores in acute coronary syndrome are examples of cardiovascular risk scores widely used to support specific treatment decisions. These aids are typically based upon empirical or regression model weighted scoring rules that contain elements of the patient's history, physical findings, and initial laboratory tests selected for their ability to accurately estimate the pretest probability of a diagnosis or outcome of interest. Such models are, at least theoretically, more flexible than the RAND Appropriateness Method in their ability to relate patient-specific characteristics to the need for specific types of testing based on risk. However, the appropriateness approach addresses the decision directly (and the risk level indirectly) whereas the models estimate the risk directly but do not explicitly make a testing or treatment recommendation.

Patient-specific risk assessments based on validated models can also be used as part of an appropriateness approach, with appropriateness of testing defined in terms of the individual patient's predicted risk and the tests already performed (96). However, not all the clinical situations in which cardiac imaging is currently used have adequately validated models available for this purpose. In addition, as discussed with appropriate use, connecting a certain level of risk with the necessity of a specific strategy of testing requires evidence that, for the most part, currently does not exist. A given test in an intermediate-risk patient may be "appropriate" in the sense already discussed, but it would be difficult to define it as necessary without a full specification of the decision problem. Finally, although this risk model–based approach is more adaptable to specifics of individual patients than RAND or guideline-based appropriateness measures, uncommon patient characteristics or circumstances will not be adequately reflected in the models and will still require clinical judgment.

Clinical decision support systems are programs designed to combine knowledge and patient-specific data to enhance healthcare processes and outcomes (97). They are often, but not always, computer-based and support disease monitoring, treatment monitoring, and/or diagnosis. Between 2000 and 2010, 33 clinical trials tested various forms of decision support on diagnostic testing outcomes (36). Fifty-five percent improved testing behavior overall. Four of the tested systems attempted to reduce testing rates, and all succeeded (none involved cardiac imaging) (98). A systematic review of the effect of computerized provider order entry systems with decision support on physician use of medical imaging services suggested that such systems could improve adherence to test ordering guidelines (99). Interventions generally took the form of either education (recommended imaging strategies) or decision support (structured imaging request forms assessing adherence to accepted diagnostic testing strategies). The magnitude of effect in these standalone applications was generally modest (100). One system designed to support the decision for CT pulmonary angiography in suspected pulmonary embolism in the emergency department found that the use of CT decreased with the decision support (by 20%), whereas the rate of detection of pulmonary embolism increased modestly (101). In the outpatient setting, use of a computerized test order entry system with decision support substantially decreased the growth rate of CT and ultrasound testing with a lesser effect on MR (102). Preventing nonclinical support staff from using the system resulted in a significant improvement in appropriateness and a reduction in low-yield tests (103).

A recent 6-center pilot study demonstrated the feasibility of online point-of-care/referral tracking and identification of appropriateness of practice referral patterns for radionuclide myocardial perfusion imaging (104). In this population, 14% of the studies were rarely appropriate based on the ACC appropriate use criteria, and 5 indications accounted for almost all of those rarely appropriate tests. Further demonstration of the feasibility of this approach came from a single-center pilot study on the use of a Web-based appropriateness tool for transthoracic echo (105). Patient-specific data were entered into the point-of-care/referral application before testing. The data entry took about 55 seconds (range 25 to 280 seconds). Agreement between the real-time, Web-based appropriateness assessment and subsequent blinded manual assessment using medical records was excellent. Similar findings have been reported in a multicenter study involving 100 physicians and 472 patients (98). An appropriate use criteria-decision support tool took an average of 137 seconds to provide an assessment of appropriateness of three different forms of cardiac imaging, and its use was associated with improved rates of appropriate use and decreased rates of rarely appropriate use. Such integrated evaluations of appropriate use appear to offer a much more efficient and less expensive process than RBM preapproval for identifying and possibly reducing some of the overuse in current practice while also providing feedback and education for performance improvement.

CMS has attempted to control the initial usage of some new imaging technologies of uncertain clinical benefit through the use of mandatory participation in standardized registries (e.g., fluorodeoxyglucose positron emission tomography for solid tumor management). One important goal of obtaining such registry data is to accelerate the process of studying the interrelationships of the patient risk level, test findings, as well as, in some cases, recommended treatment decisions, and consequent clinical outcomes. Another goal is to compare the ability of competing imaging techniques to produce accurate diagnoses and to monitor the response to treatment. Both of these goals depend on observational strategy-of-care comparisons. Even with a rich data resource, the challenge of such work is considerable, due to the lack of any theoretical or operational basis for defining when the analysis has achieved sufficient control of confounding variables and when it has not. Unfortunately, use of multivariable adjustment tools, such as propensity scores, does not guarantee that adequate control for testing selection bias has been achieved.

6.5. Performance Measurement for Cardiac Imaging

CMS has recently begun public reporting of a number of new standardized performance measures and comparative benchmarking of imaging study usage for U.S. hospitals for a variety of clinical issues (106), which will include cardiac imaging for perioperative risk assessment for noncardiac low-risk surgery beginning in 2014 (107). Such a move may portend the possibility of financial rewards and/or punishments for performance by CMS in the near future, which may also be used by commercial payers. However, there is little evidence that public reporting efforts by CMS have had any real effect on patient outcomes, particularly because the time lag in reporting data is such that opportunities to intervene have long passed when the data appear. With the institution of new payment methods that utilize financial risk for shared savings with providers, such as Medicare-sponsored Accountable Care Organizations, bundled payments for specific diseases (such as heart failure, cardiac surgery, and acute myocardial infarction), physicians will likely seek to more carefully monitor and manage their use of diagnostic imaging for the populations of patients for which they provide clinical care. Such direct incentives for physicians to avoid overuse of imaging studies will enhance the demand for low-overhead point-of-care implementation of management tools such as appropriate use criteria. Newer methods of imaging may require evaluation and close monitoring through special registries that track and better define direct linkages to patient-centered outcomes through comparative effectiveness research supported by such entities as the newly established Patient-Centered Outcomes Research Institute (108,109).

6.6. Physician Professional Organization Initiatives

Importantly, physician groups are involved in multiple initiatives to promote more efficient and accountable use of cardiovascular imaging in clinical practice. The ACC has an ongoing Formation of Optimal Cardiovascular Imaging Utilization Strategies (FOCUS) program with the goals of the program being 2-fold: 1) reduce geographic variation in cardiovascular imaging through the application of the appropriate use criteria; and 2) reduce rarely appropriate testing rates. FOCUS provides an opportunity for health plans to work with local ACC chapters on appropriate use of imaging as part of payment reform and/or as an alternative to use of RBMs. The current FOCUS initiative has expanded to over 800 practices/hospitals, and preliminary data suggest that it has produced meaningful reductions in rates of rarely appropriate testing (110,111). A number of state initiatives, including mandatory participation in FOCUS in Delaware, are underway that use the FOCUS program as a means to drive more appropriate testing patterns. Additionally, the ACC, ACR, ASE, ASNC, and the SNMMI have also partnered with the American Board of Internal Medicine and Consumer Reports in the "Choosing Wisely" initiative, which engages patients and physicians to discuss the appropriateness of testing, including cardiovascular imaging. Further, the American Medical Association Physician Consortium for Performance Improvement is working to define performance measures that include the quality and appropriate use of cardiovascular imaging procedures. Continuing to develop and implement these initiatives, and studying their effectiveness (as reflected by outcomes and cost) is an important direction for physician groups to pursue to maximize high-quality health care. As part of this, ASNC is currently embarked on registry efforts to track appropriate use and/or radiation safety practices. An important complementary effort is needed to develop useful tools for shared decision making around the use of imaging studies (109).

7. Future Directions

A national consensus has developed around the need to improve quality and accountability in cardiovascular imaging. In this document, we have reviewed the challenges involved in finding the "optimal" rate of advanced cardiovascular imaging for a given region, practice environment, or patient population. The improvement of imaging use policy could likely benefit from an iterative process, requiring relevant, high-quality data to guide continued efforts. Clearly, policy interventions in clinical practice with the objective of reducing overuse, underuse, and misuse need to be supported by collection of high-quality data, from both randomized trials and prospective registries, that capture the complex multifactorial influences on test use in clinical practice and how test use affects patient outcomes, and how test use impacts both short- and long-term costs of care. As the country moves toward universal use of electronic health records, creating and sustaining high-quality data registries may become more feasible but concerns regarding the cost and labor burden on imaging laboratories remain. An imaging registry would have the greatest value if it extends beyond the boundaries of individual payers, health systems, and clinical specialties. Such a resource could be used to support both quality improvement efforts and comparative effectiveness research.

The technology clearly now exists to permit integration of computerized appropriate use into the processes of care so as to create minimal provider burden and patient delay in receiving needed care. For example, the use of automatic data extraction from an electronic reporting system that would seamlessly populate data elements is one means to craft an imaging registry. However, the proper incentive structure to promote such efforts is still not in place. In addition, development of consensus-based data standards is necessary before effective data pooling and analysis can take place. The new generation of computerized decision support tools should have the capability to create databases at each site that can be periodically uploaded to a national cardiovascular imaging registry. Beyond the basic imaging data

elements, future registries should include clinical outcomes of patients, along with resource use data and medical costs (not charges).

Development of computerized appropriate use tools would be efficient and also greatly enhance transparency by linking appropriateness ratings to a well-defined process in which professional societies combine available evidence with expert opinion to generate ratings that are then subject to extensive peer review. Ideally, a computerized physician order entry and approval process (also referred to as point-of-care or point-of-referral tools) could automatically generate an accountability dataset, in as much as each imaging decision will be documented by relevant clinical information entered by the clinician responsible for the decision to test. Such point-of-care tools would also serve an educational function as clinicians learn by experience what indications are rated as "appropriate" or "rarely appropriate" and why. In addition, these tools would efficiently support imaging laboratory quality improvement initiatives related to appropriate test use. The first generation of these tools would be built on professional society–published appropriate use criteria and clinical practice guidelines along with performance and/or quality of care measures. Future generations of the tools should be able to incorporate the option for using patient-level risk predictions and other decision support programs to further customize appropriate use ratings, once these have been properly validated for clinical practice. Such tools would also support enhanced shared decision making discussions by giving patients and physicians patient-specific data to consider in the decision making process.

Data collected via the point-of-care systems for the dynamic imaging registry would support both the goals of quality improvement and technology assessment. Evidence-based understanding of the comparative effectiveness of new imaging methods and technologies could be significantly accelerated with such a resource. In addition, the relationship between clinical decision making, appropriate use, clinical outcomes, and cost effectiveness of different imaging strategies could be empirically defined by analysis of data in the registry. Subsequent iterations of the point-of-care imaging support tools could then be evidence-based and provide clinicians with real-time guidance about both appropriate use (risk versus benefit) and value for money. Only by integrating the best available evidence, while explicitly acknowledging economic realities, can we move toward real value-based medicine. This paradigm forms the essential underpinnings of health technology assessments whose overarching goal is to find the most efficient ways to employ limited medical resources so as to maximize health benefits for the population.

Financial and political forces are dramatically reshaping the practice of medicine. The resulting changes represent both a threat and an opportunity. Many clinicians and patients fear that imaging policy decisions will continue to be driven primarily, if not exclusively, by cost considerations without adequate consideration of clinical benefit and value. Professional societies should offer a critical counterweight to such policies by leveraging their role as custodians of excellence in clinical care with support for innovations that empower physicians to better integrate quality of care with societal value.

8. Conclusions

Use of advanced cardiac imaging raises two related policy challenges for the profession, achieving the volume of testing that balances patient needs and benefits with responsible use of societal resources (i.e., cost effectiveness), and continued improvement in the quality of care involving such imaging tests. While frequently quoted statistics on the disproportionate growth in rates of imaging suggests that we have not always been responsible stewards of the technology tools of our profession, more recent data shows that the growth of advanced cardiovascular imaging has substantially slowed since 2006, likely due to a combination of professional society and payer initiatives. Because of doubts of payers and policy makers about the extent to which the profession can govern itself, blunt instruments such as reduced reimbursement and prior notification and authorization have been often used. These, unfortunately, can lead to unintended consequences, such as limiting patient access to necessary services and greater administrative inefficiencies in the healthcare economy. New approaches and tools are needed that put the focus back onto medical imaging quality of care. Validated patient-specific point-of-care/referral appropriateness tools, and other decision support tools are examples of innovations that could support a higher quality, more accountable use of cardiovascular imaging. These tools would allow physicians to exercise expert clinical judgment, yet maintain transparency and accountability in their use of advanced cardiac imaging tests. Patients could be confident of getting the most appropriate care for their individual circumstances (i.e., patient-centered care), and that any radiation exposure required would clearly have a favorable risk benefit relationship, while payers and policy makers would be able to differentiate patterns of care that provide good value for money versus patterns of care that add expense with little or no attendant clinical benefits.

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Key Words: ACC Health Policy Statement ■ cardiovascular imaging ■ noninvasive imaging ■ optimizing imaging

APPENDIX 1. AUTHOR RELEVANT RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Daniel B. Mark (Chair)	Duke Clinical Research Institute—Professor of Medicine	None	None	None	None	None	None
Jeffrey L. Anderson	Intermountain Medical Center—Associate Chief of Cardiology	None	None	None	• AstraZeneca • Toshiba	• ICON Clinical Research	None
Jeffrey A. Brinker	Johns Hopkins Hospital—Professor of Medicine and Radiology	None	None	None	None	• Care Core Cardiology*	None
James M. Brophy	McGill University Hospital Centre, Royal Victoria Hospital—Professor of Medicine & Epidemiology	None	None	None	None	None	None
Donald E. Casey Jr.	Atlantic Health—Vice President of Quality, Chief Medical Officer	None	None	None	None	None	None
Russell R. Cross	Children's National Medical Center—Director Cardiology Quality and Outcomes Program	None	None	None	None	None	None
Daniel Edmundowicz	University of Pittsburgh Medical Center—Professor of Medicine, Section Chief of Cardiology	• Merck/ Schering-Plough	None	None	None	None	None
Rory Hachamovitch	Cleveland Clinic—Staff Cardiologist, Section of Cardiovascular Imaging, Department of Cardiovascular Medicine	None	None	None	None	None	None
Mark A. Hlatky	Stanford University School of Medicine—Professor of Health Research & Policy, Cardiovascular Medicine	• Blue Cross Blue Shield Association Technology Assessment Committee*	None	None	None	None	None
Jill E. Jacobs	NYU Langone Medical Center—Professor of Radiology	None	None	None	None	• None	None
Suzette Jaskie	West Michigan Heart—Chief Executive Officer	• MedAxiom (with an "m" on the end)† • Medtronic	None	None	None	• MedAxiom	None
Kevin G. Kett	Cardiology Associates of Waterbury—Medical Director	None	None	None	None	None	None
Vinay Malhotra	Cardiac Study Center—Director, Cardiac Catheterization Laboratory	None	None	None	None	None	None
Frederick A. Masoudi	University of Colorado, Denver—Associate Professor of Medicine, Division of Cardiology	None	None	None	None	None	None
Michael V. McConnell	Stanford University Medical Center—Associate Professor of Medicine and Co-Director Noninvasive Imaging Section, Division of Cardiology	None	None	None	None	• GE Healthcare†	None
Geoffrey D. Rubin	Duke University Medical Center—George B. Geller Professor and Chairman, Department of Radiology	• Fovia†	None	• HeartFlow • TeraRecon	None	None	None
Leslee J. Shaw	Emory University School of Medicine—Professor of Medicine	None	None	None	None	• Astellas Pharma† • Bracco Diagnostics†	None
M. Eugene Sherman	Aurora Medical Associates University of Colorado Denver School of Medicine—President; Clinical Professor of Medicine	None	• AstraZeneca	• ABIO–Arca Biopkarm†	None	• None	None
Steve Stanko	Mended Hearts—Cath Patient Outreach Chair	None	None	None	None	None	None

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
R. Parker Ward	University of Chicago Medical Center—Associate Professor of Medicine	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were reported by authors to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted.

*No financial benefit. †Indicates significant relationship.

DSMB = Data Safety Monitoring Board, HFSA = Heart Failure Society of America; and NASCI = North American Society of Cardiovascular Imaging.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES

Peer Reviewer	Representation	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
W. Patricia Bandettini	Official Reviewer—Society for Cardiovascular Magnetic Resonance	Advanced Cardiovascular Imaging Lab National Heart, Lung, and Blood Institute National Institutes of Health; Suburban Hospital—Director of Cardiovascular MRI; Staff Clinician	None	None	None	None	None	None
Thomas A. Barringer, III	Official Reviewer—Society of Atherosclerosis Imaging and Prevention	Presbyterian Novant Heart & Wellness—Co-Medical Director	None	• Abbott Laboratories* • GlaxoSmithKline*	None	None	None	None
Marco A. Costa	Official Reviewer—Society for Cardiovascular Angiography and Interventions	Professor of Medicine Interventional Cardiovascular Center—Director; Center for Research and Innovation—Director; Harrington Heart and Vascular Institute; University Hospitals, Case Western Reserve University	• Abbott Vascular* • Boston Scientific • Cardiokinetix* • Cordis • Medtronic • NIH-CCTRN* • OrbusNeich • Scitech* • St. Jude	• Daiichi Sankyo • Eli Lilly • sanofi-aventis	• Genae Americas* • StemMed*	• Abbott Vascular* • Aastrom Biosciences* • Baxter* • Cardiokinetix† • Direct Flow • Medtronic* • NIH* • St. Jude	• 48 Biomedical* • A-Care/Masaryke University* • Abbott Vascular* • Boston Scientific* • Cerenis Therapeutics* • Cordis* • IDEV Technology* • Lutonix* • The Medicines Company† • Meditrial for SICI-GISE† • Medtronic* • Micell* • Micro Innovations* • NIH-CCTRN* • OrbusNeich† • Sistemu Inovacijas* • SCAI† • St. Jude*	None
Vasken Dilsizian	Official Reviewer—Society of Nuclear Medicine	University of Maryland Medical Center—Professor of Radiology; Director, Nuclear Cardiology	• Astellas • Lantheus Medical Imaging* • Trovis*	None	None	• GE*	• GE	None
Anton Fuiz	Official Reviewer—Society for Cardiovascular Magnetic Resonance	Washington Hospital Center—Cardiovascular Disease Physician	None	None	None	None	None	None

Peer Reviewer	Representation	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Thomas C. Gerber	Official Reviewer—North American Society for Cardiovascular Imaging	Mayo Clinic—Professor of Medicine, Radiology	None	None	None	• RESCUE (NIH/ ACRIN)†	• *American Journal of Radiology*† • *Mayo Clinic Proceedings*† • NASCI† • SAIP†	None
Smadar Kort	Official Reviewer—American Society of Echocardiography	Stony Brook University Medical Center—Clinical Professor of Medicine	• Premier	None	None	None	• Boston Scientific	None
Steven J. Lester	Official Reviewer—American Society of Echocardiography	Mayo Clinic Arizona—Consultant Cardiologist; Department of Medicine (Innovation)—Associate Chair; Mayo College of Medicine—Associate Professor; Echocardiography Laboratory Program—Director; Echocardiography Fellowship—Director	None	None	None	None	None	None
G. B. John Mancini	Official Reviewer—ACC Board of Governors	Vancouver Hospital Research Pavilion—Professor of Medicine	• Merck	None	None	• Merck*	• Miraculins*	None
Jennifer H. Mieres	Official Reviewer—American Heart Association	Hofstra North Shore-LIJ School of Medicine—Associate Professor of Medicine	None	None	None	None	• ASNC† • AstraZeneca†	None
Kenneth Nichols	Official Reviewer—American Society of Nuclear Cardiology	North Shore-LIJ Health System—Associate Professor of Radiology	None	None	• Syntermed*	None	None	None
Rajan Patel	Official Reviewer—Society for Cardiovascular Angiography and Interventions	Ochsner Medical Center—Faculty Physician	None	None	None	• Renew Chronic Angina Multi-center study†	• ACC† • AHA† • SCAI†	None
Athena Poppas	Official Reviewer—ACC Board of Trustees	Rhode Island Hospital Division of Cardiology—Associate Professor of Medicine, Brown Medical School	None	None	None	• NIH*	None	None
Geoffrey A. Rose	Official Reviewer—Intersocietal Accreditation Commission	Sanger Heart & Vascular Institute—Director, Cardiac Ultrasound Laboratory; Vice Chief of Cardiology; Vice President	None	None	None	None	• Prevail trial/ Atritech • Realism trial/ Abbott Laboratories	None
David Sahn	Official Reviewer—ACC Clinical Quality Committee	Oregon Health & Science University—Director, Clinical Care Center for Congenital Heart Disease	• GE • Philips • Siemens • TomTec	None	None	• Philips • SonoSite • Toshiba • Ventripoint*	None	None
William H. Sauer	Official Reviewer—Heart Rhythm Society	University of Colorado School of Medicine Associate Professor of Medicine, Director, Cardiac Electrophysiology	• Boston Scientific • Medtronic • St. Jude	None	None	None	None	None
U. Joseph Schoepf	Official Reviewer—Radiological Society of North America	Medical University of South Carolina—Associate Professor of Radiology and Medicine	• Bayer • Bracco • MEDRAD • Siemens	None	None	• Bayer* • Bracco* • GE* • MEDRAD* • Siemens*	None	None
Andrew Van Tosh	Official Reviewer—American Society of Nuclear Cardiology	St. Francis Hospital—Clinical Director of Nuclear Cardiology	• Bracco • Cardinal Health	• Astellas	None	• Pfizer (DSMB)	• St. Francis Hospital/BMS-Lantheus	• Third party, general cardiology and stress testing, 2008
L. Samuel Wann	Official Reviewer—Society of Cardiovascular Computed Tomography	University of Wisconsin, Madison and Medical College of Wisconsin, Milwaukee—Clinical Professor of Medicine	None	None	None	None	• United Healthcare	• Defendant, sudden death after ER visit, 2009 • Defendant, patient died of aortic dissection, 2009 • Defendant, ER patient died after discharge, 2009

Peer Reviewer	Representation	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Fredonia B. Williams	Official Reviewer—Mended Hearts	Retired High School Principal	None	None	None	None	None	None
Deepak Bhatt	Content Reviewer—ACC Clinical Quality Committee	VA Boston Healthcare System—Chief, Division of Cardiology	• Duke Clinical Research Institute/ BMS/Pfizer • Duke Clinical Research Institute/ Novartis*	None	None	• Amarin* • AstraZeneca* • Bristol* • Eisai* • FlowCo† • The Medicines Company* • Medtronic* • PLxPharma† • Sanofi-Aventis* • Takeda†	• Boston VA Research Institute/ Novartis† • *Journal of Invasive Cardiology*† • Medscape Cardiology† • Slack Publications/ Cardiology Research Foundation* • Society of Chest Pain Centers† • WebMD*	None
Kathleen Blake	Content Reviewer—ACC Advocacy Committee	Johns Hopkins School of Medicine—Assistant Professor of Medicine; Center for Medical Technology Policy—Senior Research Director	• Reed Smith	None	None	• Radiation Oncology Institute*	• Heart Hospital of New Mexico* • HRS†	None
Pamela Douglas	Content Reviewer—ACC Quality in Technology Work Group	Duke University Medical Center—Ursula Geller Professor of Research in Cardiovascular Diseases	• CardioDX • David H. Murdock Research Institute† • Elsevier • Pappas Ventures • Patient Advocate Foundation† • Universal Oncology† • UpToDate	None	• CardioDX • Universal Oncology, Inc.†	• Atritech† • Department of Defense/ Defense Advanced Research Agency† • Edwards Lifesciences† • Food and Drug Administration (FDA)† • The Duke Endowment† • Gates Foundation† • Ikaria† • NIH† • Pfizer† • Translational Research in Oncology (DSMB) • Walter Coulter Foundation†	• Heart.org† • Medscape • Genomic Medicine Institute Advisory Board/ WebMD Advisor†	None
Joseph P. Drozda	Content Reviewer—ACC Clinical Quality Committee	Sisters of Mercy Health System—Associate Director, Clinical Research	None	None	None	None	• Boston Scientific Rhythm Management • Physician Consortium for Performance Improvement†	None
Blair D. Erb, Jr.	Content Reviewer—ACC Clinical Quality Committee	Cardiology Consultants	None	None	• Abbott Laboratories • Medtronic • Merck	None	None	None
James Fasules	Content Reviewer—ACC Advocacy Committee Staff	American College of Cardiology—Vice President of Advocacy	None	None	None	None	None	None
Timothy F. Feltes	Content Reviewer—ACC Congenital & Pediatric Cardiology Council	Nationwide Children's Hospital—Chief, Pediatric Cardiology and Co Director of the Heart Center	• Medimmune†	None	None	None	None	None
Victor Ferrari	Content Reviewer—ACC Imaging Council	Hospital of the University of Pennsylvania—Professor of Medicine	None	None	None	• NHLBI/NIH (DSMB)†	• *Journal of Cardiovascular Magnetic Resonance*† • SCMR†	None

Peer Reviewer	Representation	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Robert Hendel	Content Reviewer—ACC Task Force on Appropriate Use Criteria	University of Miami School of Medicine—Director of Cardiac Imaging & Outpatient Services	• Astellas	None	None	None	None	• Defendant, SPECT image interpretation, 2004
Lloyd Klein	Content Reviewer—ACC Interventional Scientific Council	Rush Medical College—Professor of Medicine	None	None	None	None	None	None
Richard Kovacs	Content Reviewer—ACC Clinical Quality Committee	Krannert Institute of Cardiology—Professor of Clinical Medicine	• Biomedical Systems • Essentialis • Theravance • Xenoport	None	None	• Biotie (DSMB)	• Cook Incorporated—Med Institute*	None
Ehtisham Mahmud	Content Reviewer—ACC Interventional Scientific Council	University of California, San Diego—Professor of Medicine/Cardiology; Chief of Cardiovascular Medicine; Sulpizio Cardiovascular Center—Co-Director, Interventional Cardiology and Cardiovascular Catheterization Labs—Director	• Gilead • Medtronic	• Medtronic	None	• Abbott Vascular* • Accumetrics* • Boston Scientific* • Gilead* • The Medicines Company* • Merck/SP • Sanofi-Aventis*	• County of San Diego† • SCAI† • St. Jude	None
Laxmi S. Mehta	Content Reviewer—ACC Patient-Centered Care Committee	Women's Cardiovascular Health Program—Clinical Director; OSU's Center for Women's Health—Associate Program Director for Education; The Ohio State University Medical Center—Assistant Professor of Clinical Internal Medicine	None	None	None	None	• AHA†	None
Michael Reardon	Content Reviewer—ACC Clinical Quality Committee	The Methodist DeBakey Heart Center—Professor of Cardiothoracic Surgery	• Medtronic	None	None	None	None	None
Dipan J. Shah	Content Reviewer—ACC Imaging Council	Methodist DeBakey Heart Center—Director	None	• AstraZeneca* • Lantheus Medical Imaging	None	• Astellas* • Siemens*	None	None
Karen D. Walker	Content Reviewer—ACC Council on Clinical Practice	Mercy Hospital and Medical Center—Director Cardiovascular Labs	None	None	None	None	None	None
Brian Whitman	Content Reviewer—ACC Advocacy Committee Staff	American College of Cardiology—Associate Director, Regulatory Affairs	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed at the time of peer review. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

*Indicates significant relationship. †No financial benefit.

ACC = American College of Cardiology; AHA = American Heart Association; ASNC = American Society of Nuclear Cardiology; BMS = Bristol-Myers Squibb; GE = General Electric; HRS = Heart Rhythm Society; NHLBI = National Heart, Lung, and Blood Institute; NIH = National Institute of Health; NASCI = North American Society of Cardiovascular Imaging; SAIP = Society of Atherosclerosis Imaging and Prevention; SCAI = Society of Angiography and Interventions; SCMR = Society for Cardiovascular Magnetic Resonance; and VA = Veterans Administration.