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BUSINESS AND ADVOCACY

Achieving Quality in Cardiovascular Imaging II

Proceedings From the Second American College of Cardiology–Duke University Medical Center Think Tank on Quality in Cardiovascular Imaging

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Despite rapid technologic advances and sustained growth, less attention has been focused on quality in imaging than in other areas of cardiovascular medicine. To address this deficit, representatives from cardiovascular imaging societies, private payers, government agencies, the medical imaging industry, and experts in quality measurement met in the second Quality in Cardiovascular Imaging Think Tank. The participants endorsed the previous consensus definition of quality in imaging and proposed quality measures. Additional areas of needed effort included data standardization and structured reporting, appropriateness criteria, imaging registries, laboratory accreditation, partnership development, and imaging research. The second American College of Cardiology–Duke University Think Tank continued the process of the development, dissemination, and adoption of quality improvement initiatives for all cardiovascular imaging modalities.

Technological innovations such as novel contrast agents, molecular radionuclide imaging, computed tomography (CT) angiography of the coronary arteries, and cardiac magnetic resonance (CMR) are transforming cardiovascular imaging and providing enhanced capabilities for diagnosing adverse medical conditions and implementing effective therapy. However, increasing growth in the use and cost of cardiovascular imaging procedures during the past decade has raised concerns within the U.S. government and other health care payers (1), whereas the evidence base for demonstrating how imaging in general, and quality of imaging in particular, contributes to improved patient outcomes for cardiovascular diseases has admittedly lagged behind this growth. Proposals to improve quality standards

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in cardiovascular imaging, similar to those developed in other aspects of healthcare, have been suggested to facilitate the appropriate delivery of these new technologies and ensure that they improve patient outcomes and public health.

In January 2006, the American College of Cardiology (ACC) and Duke University convened a meeting of representatives of cardiovascular imaging societies, private payers, government agencies, industry, and experts in outcomes assessment to define quality in imaging and identify a preliminary list of opportunities for improving quality (i.e., Imaging Quality Think Tank I) (Fig. 1) (2). Major domains for quality assessment and improvement were laboratory structure, patient selection, image acquisition, image interpretation, results communication, and patient outcomes. A convergence of opinion was reached on multiple metrics of quality for each domain and across imaging modalities, enabling subsequent work by individual societies and consortia to develop explicit quality measures.

A second meeting (Imaging Quality Think Tank II) with similarly broad representation was held in October 2007 to build on the first conference, report on the progress of the intervening 18 months, and focus on tools and processes that would further quality measurement and improvement. The deliberations and conclusions of this meeting form the substance of this report. Subsequent meetings are envisioned to advance the field by addressing the implementation of these tools, processes, and standards in quality improvement strategies.

Progress Since Imaging Quality Think Tank I

Much has been accomplished since the development of a cross-modality action plan modeled on domains of imaging care at the conclusion of Think Tank I. Despite payers' pressures to reduce the costs of imaging, there has been sustained cooperation among all imaging provider groups in their commitment to advance the quality agenda across all modalities; at the same time, innovative modality-specific projects also have emerged. A summary of the activities in each domain of quality in imaging is presented in Table 1.

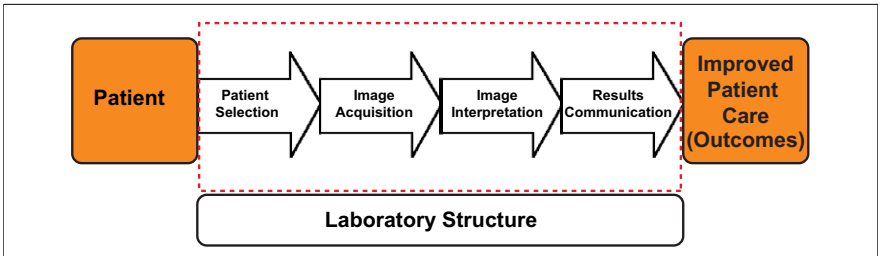

Figure 1. Dimensions of Care Framework for Evaluating Quality of Cardiovascular Imaging

Reproduced from Douglas et al. (2) with permission.

Currently, quality in laboratory structure is assessed primarily by accreditation. Laboratory accreditation can be obtained for CT, MR, nuclear, and ultrasound laboratories through either the American College of Radiology (ACR) or the Intersocietal Accreditation Commission (IAC). Under the umbrella of the IAC, laboratory accreditation is available for noninvasive vascular imaging (ICAVL), echocardiography (ICAEL), nuclear cardiology (ICANL), computed tomography (ICACTL), and magnetic resonance imaging (ICAMRL). A complete list of sponsoring organizations is available at the IAC website (3). Accreditation standards of both organizations emphasize physician and technologist training, equipment performance, imaging protocols, report content, and timeliness. In addition, accreditation bodies mandate periodic submission of sample studies to monitor the quality of imaging acquisition. Ongoing quality improvement initiatives and continuing medical education also are required.

Although accreditation is a voluntary process, in the past 2 years an increasing number of payers have mandated accreditation for reimbursement, a concept endorsed by several medical societies, including ACC, ACR, the American Society of Echocardiography (ASE), and the American Society of Nuclear Cardiology. Societies have created resources for laboratories seeking accreditation—ASE's Echo ToolBox (4) is an example of a quality assurance program that facilitates accreditation, a key element of which is an online structured reporting system. Similarly, the ACR also has developed modules for CT, CMR, ultrasound, and nuclear medicine/positron emission tomography (5–7).

Significant progress also has been made in optimizing patient selection through the development of appropriateness criteria by the ACC Foundation, often in conjunction with imaging societies, the American Heart Association (AHA), and ACR. The ACC Foundation Appropriate Use Criteria for nuclear cardiology (8), cardiac CT and MRI (9), resting transthoracic and transesophageal echocardiography (10), and stress echocardiography (11) have been published. The ACR also has cross-modality appropriateness criteria for cardiac-based clinical variants (12). Projects to implement and evaluate the application of imaging appropriateness criteria in practice are underway. The nuclear cardiology criteria are being updated and a document focusing on cross-modality noninvasive imaging criteria is in progress. Finally, the appropriateness of coronary revascularization, often a goal of diagnostic imaging, will be published in 2008. Additional

Table 1. Steps in Quality of Cardiovascular Imaging by Subspecialty/Society

	ACC	ACR	ASE	ASNC	NASCI	SCCT	SCMR	SVM	SCAI
Laboratory structure									
Accreditation	C	C	C	C	IP	C	C	C	C
Tools for achieving lab accreditation	—	—	C	—	—	—	—	—	—
Technologist credentialing	—	C	C	C	—	—	C	C	C
MD credentialing	C	C	C	C	IP	IP	C	C	C
Patient selection									
Appropriateness criteria (AC)	C	C	C	C	C	C	C	IP	C
Tools for evaluating AC	C	IP	IP	C	IP	—	—	—	—
Tools for implementing AC	IP	IP	IP	IP	—	—	—	—	—
Image acquisition									
Imaging protocols	—	C	C	C	IP	IP	C	C	—
Image interpretation									
Standards for variability	—	C	—	IP	—	—	—	—	—
Standardized image set	—	C	C	IP	IP	—	IP	C	—
Results communication									
Key data elements	C	IP	C	C	IP	IP	IP	—	—
Structured reporting	C	IP	IP	IP	IP	—	IP	—	—
Timeliness guidelines	—	IP	C	C	IP	C	IP	—	IP
Improved outcomes									
Metrics for measuring outcomes	—	IP	—	—	—	—	—	—	IP
Patient satisfaction	—	IP	—	—	—	—	—	—	IP

Assessments of status were provided by each society, and not otherwise verified.
C = complete; ACC = American College of Cardiology; ACR = American College of Radiology; ASNC = American Society of Nuclear Cardiology; ASE = American Society of Echocardiography; IP = in process/planned; NASCI = North American Society for Cardiovascular Imaging; SCAI = Society for Cardiovascular Angiography and Interventions; SCCT = Society of Cardiovascular Computed Tomography; SCMR = Society for Cardiovascular Magnetic Resonance; and SVM = Society for Vascular Medicine.

collaborations between organizations are being investigated.

Improving quality of image acquisition and results communication has been addressed through the development of modality-specific imaging protocols. For example, the Society for Cardiovascular Magnetic Resonance has published specific imaging protocols for each major diagnosis category (13). The American Society of Nuclear Cardiology also has published revised guidelines for image acquisition, processing, display, and reporting (14). Issues of patient safety often reside in the domain of image acquisition (e.g., nephrogenic systemic fibrosis/contrast allergy, CMR safety, diagnostic reference levels in X-ray imaging, echo contrast agents) and have been addressed in modality specific fashion. For example, the ACR has developed specific tools that provide guidance for the safe administration of contrast (15), CMR safety (16), as well as providing relative radiation levels in their appropriateness criteria when applicable.

Tools for improving and measuring quality in image interpretation include online reference image libraries and statements concerning interobserver and intraobserver variability. Criteria for training in the newer imaging modalities of CT and MRI have been developed. Proficiency examinations are well accepted in echocardiography and nuclear cardiology; a board exam for CT has been created, a CMR exam is imminent (17,18), and the American Board of Radiology, since 2004, has had a dedicated cardiac section of their oral board examination. Recognizing the challenge of meeting multimodality training requirements within the constraints of a traditional cardiology fellowship, the ACC has recently updated its adult cardiology fellowship training recommendations with improved training in newer modalities through a multimodality approach (19).

At the same time that modality specific reporting guidelines are being considered, it has been recognized that a major need exists for cross-modality reporting data standards. An ACC-supported, multisociety Quality in Imaging Working Group evolved from Think Tank I and data standards for imaging are in press (20). In addition, potential metrics for quality in results communication in the form of guidelines for timeliness of reporting have also been developed (21).

The final stage of the quality in imaging continuum is patient outcome. Demonstrating improved outcomes attributable to cardiovascular imaging is particularly challenging because of the complex interplay of patient characteristics and treatment strategies, including the substantial variability in therapeutic care patterns after cardiac imaging. Nevertheless, the scientific community rose to the challenge of

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Table 2. Recommendations From Imaging Quality Think Tank II

A. Data Standardization and Structured Reporting
1. Complete and adopt standardized multimodality data definitions and elements.
2. Develop a multi stakeholder policy statement advocating structured reporting implementation using existing consensus data standards.
3. Create Internet- and computer-based structured reporting tools accessible to all laboratories and imaging providers compliant with data standards.
4. Consider requiring structured reporting incorporating standardized data elements for imaging laboratory accreditation and reimbursement.

B. Appropriateness Criteria
1. Complete ongoing appropriateness criteria, refine existing single-modality documents and develop multimodality appropriateness document.
2. Continue research evaluating existing and future appropriateness criteria.
3. Collaborate with providers and payers to implement appropriateness criteria.
4. Develop standardized data elements to evaluate appropriateness of indications for cardiovascular imaging.

C. Imaging Registries
1. Create a multicenter imaging registry(s).
2. Explore development of a national imaging registry that allows for multimodality and multispecialty participation.
3. Investigate incentives to maximize participation in cardiovascular imaging registry(s).

D. Accreditation
1. Continue to improve accreditation processes and standards.
2. Investigate the feasibility of incorporating additional quality metrics, such as structured reporting.
3. Initiate studies evaluating the effect of laboratory accreditation on patient outcomes.

E. Partnership Development
1. Continue communication and collaboration between stakeholders to develop and implement imaging quality tools and processes.

F. Research
1. Define meaningful outcome measures for clinical trials evaluating cardiovascular imaging.
2. Promote the implementation of data standards to facilitate large-scale, high-impact imaging research.
3. Continue multistakeholder investment in imaging research, including creating an infrastructure for a national imaging registry and developing a network of sites capable of performing multimodality imaging.
4. Develop new and existing funding sources.

evaluating cardiac imaging and patient outcomes through a National Heart Lung Blood Institute-sponsored workshop on "Outcomes Research in Cardiovascular Imaging," held in the summer of 2008.

Since Think Tank I, there have been other initiatives that potentially involve all elements of the quality in imaging continuum. They include the creation of data registries such as the Society of Cardiovascular Computed Tomography/Blue Cross Blue Shield collaboration on coronary CT angiography; educational activities by multiple participants, including the ACR Education Center; the development of radiation safety resources (Society for Cardiovascular Angiography and Interventions, ACR); provision of grant support for research in quality (ACR, ASE), and a planned request for recognition of Vascular Medicine as an American Board of Medical Specialists subspecialty (Society for Vascular Medicine). The list presented here is not intended to be exhaustive but rather to recognize the breadth of new and ongoing imaging quality activities.

Findings From Imaging Quality Think Tank II

Building on the "dimensions of care framework" from Think Tank I, Imaging Quality Think Tank II turned its attention to cross-modality issues that transcend the domain paradigm. This section describes the challenges in and potential solutions for developing systems to evaluate and improve quality in cardiovascular imaging (Table 2).

Data standardization and structured reporting. Communication of the results of a cardiovascular imaging study is perhaps the most critical step of an imaging procedure. An ideal report is clear, uses consistent terminology and provides referring physicians with data that are complete and clinically relevant. In the past, societies have attempted to provide guidance for reporting (22,23), and educational efforts have focused on creating a common parlance. However, substantial variation remains, leading to confusion when one reviews imaging reports and potential errors when one incorporates the data from imaging into clinical decision-making. The Think Tank II participants reached an overwhelming consensus in support of the importance of structured reporting in imaging by using common data elements as a solution that would improve both clinical care and research.

Several organizations have developed a dictionary or lexicon of key terms, but these have been done in relative isolation (24,25). Since Think Tank I, an ACC/AHA Writing Group for Data Standards in Cardiac Imaging, overseen by the ACC/AHA Task Force on Data Standards and comprising representatives from all cardiovascular imaging societies, has written a document defining key terminology essential for cardiac imaging procedures, including angiography, cardiovascular CT/CMR, echocardiography, and nuclear cardiology (20). This statement provides uniform language across imaging modalities and delineates key data fields used

for reporting and that might be incorporated into databases/registries. Efforts were made to use established terms and definitions from groups such as the Radiological Society of North America with RadLEx (25) and the AHA/ACC Data Standards Committee, who have previously developed common definitions for heart failure (26), atrial fibrillation (27), and cardiac catheterization data (28).

After creating common data elements, structured reporting can be implemented. In contrast to free text reporting, the combination of data standardization and structured reporting would promote consistency of report language and complete data presentation. The vision of a uniform output from structured reporting includes the ability to compare clinical data from multiple modalities and health care providers. Automatic reporting systems also could encourage rapid dissemination of study results via autofaxing or electronic communication. Quality assessment and improvement activities can include analysis of patterns of utilization, appropriateness, and outcomes, potentially through incorporation into electronic health records or an imaging registry. As proof of concept, Italian investigators have created a large regional database of echocardiographic data for quality improvement and epidemiologic studies (29,30).

The ACC in conjunction with representatives from all cardiovascular imaging societies, AHA and ACR, also has recently published a policy statement advocating the use of structured reporting and data formatting/archiving in imaging (31). This statement recommends working closely with umbrella groups such as Digital Imaging and Communications in Medicine (DICOM) and Integrating the Healthcare Enterprise. For example, the expertise and previous work of the DICOM Standards Committee of the Medical Imaging and Technology Alliance, and their Workgroup 01 on Cardiac and Vascular Information could be leveraged to address some of the operational barriers to structured reporting. Industry will play a critical role in creating tools; standards should allow for creativity and differentiation of individual vendors' products but should require sufficient uniformity to facilitate integration across the spectrum of end-users. A follow-up activity of this meeting is to begin a dialog in earnest with Integrating the Healthcare Enterprise and DICOM, along with key industry groups such as the Medical Imaging Technology Alliance, to determinate how best to move towards a universally accepted structured reporting standard.

The development of report templates will also help to drive the structured reporting initiative and to that end the ACR and NASCI have developed a paper entitled: "Structured reporting: Coronary CT Angiography—A White Paper from the ACR and NASCI" that includes such templates (30).

Although Think Tank II participants were strongly supportive of efforts to define and promote data standards and structured reporting, this effort can only be successful with backing of all imaging stakeholders, institution of accreditation and regulatory requirements, broad availability of compliant computerized reporting systems, as well as substantial provider education. Think Tank II members active in each of these areas were committed to moving forward to provide the tools, knowledge base, and business case for implementation.

The participants of Imaging Quality Think Tank II made the following recommendations:

1. Complete and adopt standardized multimodality data definitions and elements.
2. Develop a multistakeholder policy statement advocating structured reporting implementation using existing consensus data standards.
3. Create Internet- and computer-based structured reporting tools that are compliant with data standards and accessible to all laboratories and imaging providers.
4. Consider requiring structured reporting incorporating standardized data elements for imaging laboratory accreditation and reimbursement.

Appropriateness criteria. Appropriateness criteria for imaging were identified in Think Tank I as an important initial step towards reducing unwarranted testing and variation in cardiovascular imaging. By the time Think Tank II was convened, appropriateness criteria for single-photon emission computed tomography (8), transthoracic and transesophageal echocardiography (10), and cardiac CT/CMR (9) were published or in press. These criteria were the culmination of 2 years of intense multispecialty, multisociety work aimed at producing guidance for practicing clinicians. As such, the development and implementation of the criteria were believed to represent noteworthy solutions for improving patient selection for imaging studies, including a future structure for evaluating national patterns of care once data standards and structured reporting were established. Additional work is required to complete a full set of appropriateness criteria documents, to revise existing documents, and to create the first multimodality appropriateness criteria for ACC. As with other documents, ACC and ACR will work collaboratively on development of these multimodality appropriateness criteria.

Think Tank II participants also recognized the importance of developing tools to evaluate appropriateness criteria and assist providers and payers in their implementation. Key areas of need include appropriateness assessment tools implemented either at point-of-service (imaging laboratory) or point-of-order (referring clinician) for one or multiple modalities; transparency in the classification of indications for imaging studies; mechanisms to enhance communication between ordering provider and image inter-

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preter; and data-driven solutions such as universal patient indexing and automated strategies to collect indications and outcomes. Many of the stakeholders recommended developing these types of solutions as potential, quality enhancing alternatives to the use of radiology benefit managers.

Pilot studies evaluating appropriateness tools across geographic regions and practice types would also add valuable experience. Together, ACC and United Healthcare are conducting a pilot program to evaluate the implementation of appropriateness criteria for myocardial perfusion imaging using an internet-based tool (32), whereas several investigators have reviewed the applicability of the criteria to patients in their laboratories (33). Additional programs are needed to develop strategies to reduce unnecessary testing and duplication.

The participants of Imaging Quality Think Tank II made the following recommendations:

1. Complete on-going appropriateness criteria, refine existing single-modality documents and develop multi-modality appropriateness document.
2. Continue research evaluating appropriateness criteria.
3. Collaborate with providers and payers to implement appropriateness criteria.
4. Develop standardized data elements to evaluate appropriateness of indications for cardiovascular imaging.

Imaging registries. Multicenter registries have proved instrumental for evaluating and improving quality of care for acute coronary syndromes (34–36) and cardiovascular procedures such as cardiac surgery and cardiac catheterization (37,38). An analogous approach using registries for cardiovascular imaging holds great promise for improving safety and quality. Such registries would allow us to better understand the patterns of use in community practice as well as evaluating diagnostic and prognostic value. Although exciting, the feasibility of establishing large imaging registries is challenging on several fronts: technical (few data standards or integrated electronic data collection tools), operational (limited clinician time for data collection and obstacles to longitudinal evaluation), and financial (providing the business case for payer, provider, and manufacturer engagement).

An ideal imaging registry would accurately capture information on who ordered a study, the indications for imaging, patient demographic and clinical information, image acquisition parameters, study findings, and workflow metrics. A registry's value would be further enhanced if these data were linkable, within and among data sources, to create a longitudinal record of a patient's subsequent care and outcomes. Once created, an ideal registry should provide feedback to clinicians through benchmarked data on their care to stimulate quality improvement. The Agency for Healthcare Research and Quality has recently summarized further important functionalities for ideal registries (39).

Unfortunately, currently there are few registries for noninvasive imaging. Those that do exist fall into 1 of 3 categories: "institutional case series" that are small in size, often nonrepresentative or of limited generalizability, and lacking downstream outcomes information; registries based on administrative data from large health insurers; or those from integrated healthcare providers (e.g., Veterans Administration hospitals or health maintenance organizations). Although administrative databases are good sources for studying patterns of cardiovascular imaging utilization, they commonly lack the clinical detail necessary to address why tests were ordered or the accuracy of interpretation. However, ACR and ACC are working collaboratively to establish a registry for cardiac computed tomography angiography based on existing models from ACR in non-cardiac areas of imaging and from the ACC National Cardiovascular Data Registry's (NCDR) registries.

In contemplating a future imaging registry, it is necessary to define the business case to support cardiovascular imaging registries. One mechanism could be linking registry participation with reimbursement. In 2006, the Centers for Medicare and Medicaid Services (CMS) released a guidance document (40) that describes the circumstances under which CMS would issue a national coverage determination that requires collection of additional patient data to supplement standard claims data. Since then, CMS has used this mechanism to prompt the development of several national registries, including the ACC-NCDR implantable cardiac defibrillator registry (41).

Large private insurers could be an alternative force to motivate a broad-based imaging registry as rising costs in cardiovascular imaging are a major concern. Yet, their current means of controlling this growth, such as time-consuming pre-approval processes, have been generally ineffective over the long term and are viewed as intrusive by both patients and their physicians. As an alternative, payers could provide incentives to caregivers for participation in a multimodality clinical data registry including waiver of the pre-approval process, preferred provider status (based on participation), pay for participation, or pay for (appropriate) imaging performance.

A third potential supporter of imaging registries could be the manufacturers of imaging equipment or materials (contrast agents, isotopes, and so on). A large high-quality imaging registry could facilitate the evidence development process both before and after approval. To date, however, neither the Food and Drug Administration nor clinicians in practice have required such evidence, so industry engagement has been somewhat limited.

A fourth potential supporter is the American College of Radiology Imag-

ing Network (42), which has raised funds to launch a cardiovascular imaging research effort. Recently established, its cardiovascular research priorities are still in development. Future study designs could include registries, randomized clinical trials or other efforts.

Once the resources and incentives for an imaging registry are manifest, the challenge will be to reduce barriers to provider participation. Data regarding the patient's clinical characteristics as well as the reasons for the test should ideally be collected from the physician ordering the study. The evolution of electronic healthcare record systems with computer order entry at many centers may streamline such data collection in the future using standardized nomenclature and formats as noted previously. These combined data then could be aggregated into a multivendor, multicenter clinical data warehouse such as currently is done by the registries managed by ACC-NCDR and ACR-NRDR. Finally, appropriate analytic methodology should be applied to these data to allow for meaningful research and provider feedback systems.

The participants of Imaging Quality Think Tank II made the following recommendations:

1. Create a multicenter imaging registry(s).
2. Explore development of a national imaging registry that allows for multimodality and multispecialty participation.
3. Investigate incentives to maximize participation in cardiovascular imaging registry(s).

Accreditation. Accreditation of imaging laboratories ensures the presence of basic structural elements of a quality imaging study process and is increasingly being tied to reimbursement. Think Tank II participants believed that the accreditation process represents an important resource for both quality improvement and research, and as a platform for measuring quality in cardiovascular imaging.

It was felt that several features of the current accreditation process could be improved and warrant study. First, the process is based on a one-time submission of applicant-selected cases and documents. Although the options of site visits and random post-accreditation audits exist, these are rarely performed. Review of unselected studies from laboratories would better establish "real-world" quality and remove the opportunity for bias by "cherry picking" only the best studies for review. However, this will need to be approached carefully since there are other factors that are considered as part of the image quality evaluation. All applicant images must be measured against the same standard. Other factors can affect the images available for submission on any given day such as low patient volume, patient body habitus, comorbidities, and patient cooperation. Moreover, although the requirements for accreditation have been carefully selected with the input of subspecialty societies and experts in the modality, there may be opportunities for adding quality measures such as presence of structured reporting and time for report generation. Furthermore, the rates of success on initial and subsequent applications have not been reported, and the reasons for which laboratories fail to become accredited are not well understood. Such analyses should be possible using data available through the IAC and the ACR. Finally, assessment of the impact of accreditation on patient outcomes could provide a powerful endorsement of the value of quality improvement efforts in imaging.

The participants of Imaging Quality Think Tank II made the following recommendations:

1. Continue to improve accreditation processes and standards.
2. Investigate the feasibility of incorporating additional quality metrics, such as structured reporting.
3. Initiate studies evaluating the effect of laboratory accreditation on patient outcomes.

Partnership development. Development and implementation of the aforementioned tools and processes will require the coordinated efforts of a variety of stakeholders, including quality and modality experts who must define standards and subspecialty societies who must provide clear policy mandates that will drive adoption of quality principles by their members. Laboratory accreditation and personnel certifying entities should consider adopting these standards as requirements. Accreditation bodies should adjust their workflow and feedback mechanisms to ensure continuous and meaningful attention to quality as well as the development of robust data sources to evaluate the impact of quality improvement processes. The industry should recognize that taking a proactive role in driving quality will contribute to their products' commercial value and should work to enhance this value through modifications in the design and distribution of their products. Payers must encourage and reward providers who implement quality standards and measures as a preferred avenue to improving imaging value for patients. The natural alignments between the goals of practitioners, societies, imaging quality researchers, industry, and payers of healthcare services must be leveraged. All stakeholders should participate actively in efforts to determine the "value" of cardiovascular imaging to hasten a paradigm shift in how cardiovascular diagnostic imaging is used and judged.

The participants of Imaging Quality Think Tank II made the following recommendation:

1. Continue communication and collaboration between stakeholders to develop and implement imaging quality tools and processes.

Research. Part of the "value" of cardiovascular imaging is derived from the

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results of clinical research in imaging. Traditionally, imaging research has focused on establishing a clinical role for an existing or emerging modality based upon its diagnostic test performance (i.e., its sensitivity and specificity), rather than its impact on therapy or prognosis. These studies have typically been small and cross-sectional with limited follow-up time as the result of constraints of data collection and cost. The current culture of accepting short-term studies as sufficient for the introduction of new modalities fundamentally undermines the feasibility of performing the longer-term studies necessary to establish the impact of imaging on meaningful outcomes. Moreover, many short-term studies do not adhere to the principles of design appropriate for diagnostic testing, introducing potential bias (43).

Most importantly, however, to date the results of many well-designed studies provide limited insight into central questions of imaging quality. For example, although a study in which the authors compare a new modality for the assessment of the anatomic severity of coronary artery disease (e.g., cardiac CT angiography) with a current standard (e.g., invasive angiography) may be adequate from a regulatory perspective to introduce this new modality into practice, it leaves important quality questions unanswered, such as optimal patient selection, performance and interpretation of the new test, as well as the impact on outcomes including downstream diagnostic testing, resulting implementation of evidence-based therapy, and cost (44). Thus, research evaluating new versus standard diagnostic strategies and measuring clinical and cost outcomes are needed in addition to those evaluating test performance.

Although research addressing the outcomes of imaging is rare, recent studies can serve as examples of possible strategies (45,46). For example, a study by Heidenreich et al. (47) demonstrated significantly greater rates of appropriate beta blocker use following attachment of a clinical reminder to echocardiogram reports of patients with left ventricular systolic dysfunction. Thus, novel studies focusing on imaging quality and its improvement are beginning to emerge. In addition, the feasibility of clinical trials of imaging was discussed, with the ACR Imaging Network identified as an example of a successful national trials network (42).

Several barriers have slowed progress in developing the evidence base for imaging quality. First, the urgent need for more informative studies is underappreciated. A broad range of constituencies including payers, manufacturers, clinicians, research funding entities, and academics need to endorse the importance of research that speaks to critical questions of patient selection, image interpretation, reporting, and the impact of imaging on care and outcomes. Another obstacle is the lack of adequate data sources. Registries, as discussed previously, represent an important opportunity to provide standardized data sources comprised of adequate sample sizes from diverse real-world practice settings, including detailed clinical data with longitudinal follow-up. Research networks that use standardized data are another potential resource.

Closely related to this is the likely need for very large sample sizes to demonstrate that imaging might improve outcomes. Assuming a trial takes 10,000 subjects to prove drug A improves mortality compared to placebo, a trial of an imaging test X, which leads to more appropriate use of drug A by 10%, would require roughly 100,000 subjects to prove a mortality benefit compared to no imaging.

Limited research funding is also a critical impediment. In part this is attributable to different standards for approving imaging equipment compared to pharmaceuticals, which do not create a business case for extensive preapproval research. Furthermore, as reimbursement for imaging continues to decrease, imaging providers and professional societies will have limited capacity to fund implementation of quality improvement tools or research. As research often requires a concerted effort among many stakeholders, it would be unreasonable for the imaging provider to bear the sole responsibility for quality initiatives.

The lack of existing data, inadequate financial resources, limited methodological expertise, and poor alignment of stakeholders are further important barriers to investigative progress. For example, health plans may have databases including detailed characteristics of patients who undergo imaging and the providers who refer for or perform the imaging. However, they may not possess the methodological expertise necessary to take full advantage of these data. The exploration and development of approaches to align existing resources and to increase them is an important strategy to advancing the imaging quality research agenda.

The participants of Imaging Quality Think Tank II made the following recommendations:

1. Define meaningful outcome measures for clinical trials evaluating cardiovascular imaging.
2. Promote the implementation of data standards to facilitate large-scale, high-impact imaging research.
3. Continue multistakeholder investment in imaging research, including creating an infrastructure for a national imaging registry and developing a network of sites capable of performing multimodality imaging.
4. Develop new and existing funding sources.

Conclusions

The first ACC-Duke Imaging Quality Think Tank meeting created a conceptual framework for quality in cardiovascular imaging and outlined steps needed to improve it. The second

Think Tank reinforced the themes and conclusions of the prior meeting and outlined specific new areas of focus. These included structured reporting using standardized data elements across cardiovascular imaging, ongoing work in appropriateness criteria development and implementation, exploration of imaging registries, strengthening laboratory accreditation, ongoing partnership development, and more robust imaging research, especially related to outcomes. We hope that, in addition to providing forums for subspecialty societies and stakeholders for continued discussion of past accomplishments and future challenges, the legacy of these two Imaging Quality Think Tanks in the broader cardiovascular imaging community is an acceleration of the adoption of continuous quality improvement for the optimal treatment of our patients.

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Key Words: cardiovascular imaging ■ quality ■ appropriateness ■ health outcomes.

▶APPENDIX

For a complete list of participants and organizations of the ACC-Duke Think Tank II on Quality in Cardiovascular Imaging, please see the online version of this article.