

ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR APPROPRIATENESS CRITERIA

ACCF/ACR/SCCT/SCMR/ ASNC/NASCI/SCAI/SIR 2006 Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging*

A Report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology

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ABSTRACT

Under the auspices of the American College of Cardiology Foundation (ACCF) together with key specialty and subspecialty societies, appropriateness reviews were conducted for 2 relatively new clinical cardiac imaging modalities, cardiac computed tomography (CCT) and cardiac magnetic resonance (CMR) imaging. The reviews assessed the risks and benefits of the imaging tests for several indications or clinical scenarios and scored them based on a scale of 1 to 9, where the upper range (7 to 9) implies that the test is generally acceptable and is a reasonable approach, and the lower range (1 to 3) implies that the test is generally not acceptable and is not a reasonable approach. The mid-range (4 to 6) indicates an uncertain clinical scenario. The indications for these reviews were drawn from common applications or anticipated uses, as few clinical practice guidelines currently exist for these techniques. These indications were reviewed by an independent group of clinicians and modified by the Working Group, and then panelists rated the indications based on the ACCF Methodology for Evaluating the Appropriateness of Cardiovascular Imaging, which blends scientific evidence and practice experience. A modified Delphi technique was used to obtain first and second round ratings of clinical indications after the panelists were provided with a set of literature reviews, evidence tables, and seminal references. The final ratings were evenly distributed among the 3 categories of appropriateness for both CCT and CMR. Use of tests for structure and function and for diagnosis in symptomatic, intermediate coronary artery disease (CAD) risk patients was deemed appropriate, while repeat testing and general screening uses were viewed less favorably. It is anticipated that these results will have a significant impact on physician decision making and performance, reimbursement policy, and future research directions.

PREFACE

The following paper combines the second and third reports in an ongoing series of technical documents that critically

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and systematically create, review, and categorize appropriateness criteria for cardiovascular diagnostic tests and procedures utilized by physicians caring for patients with cardiovascular diseases. The ACCF believes that a careful blending of a broad range of clinical experience and available evidence-based information can help guide a more efficient and equitable allocation of health care resources in imaging. The ultimate objective of these reviews is to improve patient care and health outcomes in a cost-effective manner based on current understanding of the limits of the imaging modalities examined, without constraining the crucial role of physician judgment in the face of diverse clinical presentations and varying patient characteristics. Although there are a limited number of studies available to evaluate the techniques examined in these reports, the appropriateness criteria hopefully can serve as initial guides for the responsible use of CCT and CMR and related resources. Our approach is not to diminish the acknowledged ambiguity of clinical decision making for certain patients by statistical means or consensus techniques, but to recognize that real differences in clinical opinion can exist for particular patient presentation, especially in an evolving field with limited evidence. Such differences are grounds for more research and for even more careful deliberation on the proper care for each indication and patient. These reports will need to be updated more frequently than most policy statements as further data and information are gained about their use. Not ordering a test when it would be otherwise considered appropriate may be the correct clinical decision, and is a judgment call based on the individual characteristics of patients and their particular clinical scenarios. Likewise, ordering a test for an indication deemed inappropriate may be the correct clinical pathway if supported by mitigating characteristics of the patient that could justify this approach.

This work was not possible without the dedicated work of the Technical Panel, composed of clinician experts, some with special background in cardiac imaging and others with impeccable credentials in general cardiovascular medicine, health services research, and health plan administration. This diversity in backgrounds of the Technical Panel as shown in Appendix C made for a wide range of scoring for many of the indications. It is much easier to "game" or "bias" the scoring process by limiting panel membership solely to specialists of the particular procedure being evaluated for appropriateness. Such specialists would have a natural tendency to rate each indication higher than non-specialists in a given test or procedure. Thus, it is with gratitude that we applaud the Technical Panel, a professional group with a wide range of skills and insights, for a considered and thorough deliberation of the merits of each test for every indication.

Special mention and thanks are due to Elliott Antman, MD, FACC; Ronald Peshock, MD, FACC; Gregory Thomas, MD, FACC; and Samuel Wann, MD, FACC, for reviewing the draft indications; to Joe Allen, who continually drove the process forward; and to ACCF Past President

Pamela Douglas, MD, MACC, for her insight and leadership.

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INTRODUCTION

Rapid technological advances and new clinical applications in cardiovascular imaging technology, coupled with increasing therapeutic options for cardiovascular disease, have led to explosive growth in cardiovascular imaging. In fact, diagnostic imaging services reimbursed under Medicare's physician fee schedule grew more rapidly than any other type of physician service from 1999 to 2003 (1). During this time, the armamentarium of non-invasive diagnostic tools has expanded with innovations in contrast agents; molecular radionuclide imaging; perfusion echocardiography; CT for coronary angiography, cardiac structure and morphology, and calcium scoring and CMR for myocardial structure, function, and viability. These advances present new opportunities for physicians to utilize non-invasive techniques to gain important information about the condition of their patients. However, in the case of CCT and CMR, both tests are relatively expensive technologies, especially with regards to imaging equipment. Additionally, the potential for uncontrolled utilization and stimulation of downstream testing and treatment such as unwarranted coronary revascularization has raised substantial concern from government and private payers as well as clinical thought leaders of evidenced-based cardiovascular medicine. As each of these imaging modalities becomes clinically available, the health care community needs to understand how to incorporate these advances into acceptable clinical care.

Both CCT and CMR have been recognized as having a number of potential uses and advantages over existing technology. Coronary calcium scoring performed with either electron beam CT or multidetector row CT is one application that has gained some acceptance, despite the lack of reimbursement from most payers. Still, there has been, to date, little expert consensus regarding for whom this method is of clinical benefit. Computed tomographic angiography, while very promising with regard to the detection of coronary stenoses, definition of "soft plaque," assessment of left ventricular function and congenital coronary anomalies, and evaluation of cardiac structures, has limited data supporting its use for many clinical applications, especially with regard to its role within patient care algorithms. Cardiac magnetic resonance imaging, although continuing to demonstrate clinical utility, has been used primarily in specialized centers and, until recently, has had its major role in clinical research evaluating myocardial viability and cardiac structure and function. Cardiac magnetic resonance also has been found useful in the evaluation of ischemic heart disease with vasodilator stress perfusion imaging and dobutamine stress function imaging.

In an effort to respond to the need for the rational use of these newer imaging techniques, CCT and CMR, the ACCF, in conjunction with the societies listed on this report, undertook a process to determine the appropriateness of selected indications for these rapidly evolving cardiovascular imaging procedures. The Appropriateness Criteria Project was initiated to support the delivery of quality cardiovascular care and to ensure the effective use of diagnostic imaging tools, and it is an ongoing effort by ACCF to rigorously examine the appropriateness of all established imaging modalities.

METHODS

A detailed description of the methods used for ranking of the clinical indications is outlined in Appendices A and B and also more generally can be found in a previous publication entitled, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (2). Briefly, this process blends scientific evidence and practice experience by engaging a Technical Panel in a modified Delphi exercise. The Technical Panel was purposely balanced with a diverse set of individuals who ranged from imaging specialists within the CCT and CMR community including cardiologists and radiologists to referring physicians, health services researchers, and a medical director from a private payer. The panel members are highlighted in Appendix C.

The 39 CCT and 33 CMR indications that were rated are thought to encompass the majority of cases referred for CCT and CMR, respectively. They were constructed by several experts within the field and were modified slightly based on discussions of the Working Group, indication reviewers, and the panelists who rated the indications. Although not comprehensive, they are characteristic of contemporary practice. They include symptomatic patients stratified by pre-test probability of disease, asymptomatic patients based on Framingham risk, and patient presentation for assessment of structure and function, including coronary artery anomalies (3-7).

A reference list of key publications within the fields of CCT and CMR was provided to the raters. Additionally, evidence tables for various applications, as well as factual summaries of the potential uses of the test were distributed to the raters (online Appendix C and D at www.acc.org). Care was given to provide objective, non-biased information.

The panelists were asked to assess whether the use of CCT and CMR for various indications was appropriate, uncertain, or inappropriate. In rating each indication, the panel was provided the following definition of appropriateness:

An appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.*

**Negative consequences include the risks of the procedure (i.e., radiation or contrast exposure) and the downstream impact of poor test performance such as delay in diagnosis (false negatives) or inappropriate diagnosis (false positives).*

The Technical Panel scored each indication as follows:

Score 7 to 9

Appropriate test for specific indication (test is generally acceptable and is a reasonable approach for the indication).

Score 4 to 6

Uncertain for specific indication (test may be generally acceptable and may be a reasonable approach for the indication). (Uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.)

Score 1 to 3

Inappropriate test for that indication (test is not generally acceptable and is not a reasonable approach for the indication).

RESULTS OF RATINGS

The final ratings for CCT (Tables 1 to 8) and CMR (Tables 12 to 17) are listed by indication sequentially, by purpose and clinical scenario, as obtained from the second round rating sheets submitted by each panelist. In addition, Tables 9 to 11 and 18 to 20 arrange the indications into 3 main scoring categories (appropriate [median score of 7 to 9], uncertain [median score of 4 to 6], and inappropriate [median score of 1 to 3]) for CCT and CMR, respectively. Other tables, including documentation of the mean absolute deviation from the median and level of agreement for each indication, are found in the online Appendices A and B at www.acc.org. Abbreviations used in the tables and the text of this report are listed below.

Abbreviations

ACS = acute coronary syndromes
CABG = coronary artery bypass grafting surgery
CAD = coronary artery disease
CCT = cardiac computed tomography
CHD = coronary heart disease
CMR = cardiac magnetic resonance imaging
CT = computed tomography
EBCT = electron beam computed tomography
ECG = electrocardiogram
HF = heart failure
ICD-9 = International Classification of Diseases-9th Revision
LCD = local coverage determination
METs = estimated metabolic equivalents of exercise
MI = myocardial infarction
MPI = myocardial perfusion imaging
NSTEMI = non-ST-segment elevation myocardial infarction
PCI = percutaneous coronary intervention
SPECT MPI = single-photon emission computed tomography myocardial perfusion imaging
STEMI = ST-segment elevation myocardial infarction
TEE = transesophageal echocardiography

CCT APPROPRIATENESS CRITERIA (BY INDICATION)

Assume the logical operator between each variable listed for an indication is “AND” unless otherwise noted (e.g., Low pre-test probability of CAD AND No ECG changes and serial enzymes negative).

Table 1. Detection of CAD: Symptomatic

Indication		Appropriateness Criteria (Median Score)
Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
1.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise 	U (5)
2.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise 	A (7)
3.	<ul style="list-style-type: none"> • High pre-test probability of CAD 	I (2)
Evaluation of Intra-Cardiac Structures (Use of CT Angiogram)		
4.	<ul style="list-style-type: none"> • Evaluation of suspected coronary anomalies 	A (9)
Acute Chest Pain (Use of CT Angiogram)		
5.	<ul style="list-style-type: none"> • Low pre-test probability of CAD • No ECG changes and serial enzymes negative 	U (5)
6.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • No ECG changes and serial enzymes negative 	A (7)
7.	<ul style="list-style-type: none"> • High pre-test probability of CAD • No ECG changes and serial enzymes negative 	U (6)
8.	<ul style="list-style-type: none"> • High pre-test probability of CAD • ECG—ST-segment elevation and/or positive cardiac enzymes 	I (1)
9.	<ul style="list-style-type: none"> • “Triple rule out”—exclude obstructive CAD, aortic dissection, and pulmonary embolism • Intermediate pre-test probability for one of the above • ECG—no ST-segment elevation and initial enzymes negative 	U (4)

Table 2. Detection of CAD: Asymptomatic (Without Chest Pain Syndrome)

Indication		Appropriateness Criteria (Median Score)
Asymptomatic (Use of CT Angiogram)		
10.	<ul style="list-style-type: none"> • Low CHD risk (Framingham risk criteria) 	I (1)
11.	<ul style="list-style-type: none"> • Moderate CHD risk (Framingham) 	I (2)
12.	<ul style="list-style-type: none"> • High CHD risk (Framingham) 	U (4)

Table 3. Risk Assessment: General Population

Indication		Appropriateness Criteria (Median Score)
Asymptomatic (Calcium Scoring)		
13.	<ul style="list-style-type: none"> • Low CHD risk (Framingham) 	I (1)
14.	<ul style="list-style-type: none"> • Moderate CHD risk (Framingham) 	U (6)
15.	<ul style="list-style-type: none"> • High CHD risk (Framingham) 	U (5)

Table 4. Detection of CAD With Prior Test Results

Indication		Appropriateness Criteria (Median Score)
Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
16.	<ul style="list-style-type: none"> • Uninterpretable or equivocal stress test (exercise, perfusion, or stress echo) 	A (8)
17.	<ul style="list-style-type: none"> • Evidence of moderate to severe ischemia on stress test (exercise, perfusion, or stress echo) 	I (2)

Table 5. Risk Assessment With Prior Test Results

Indication		Appropriateness Criteria (Median Score)
Asymptomatic (Calcium Scoring)		
18.	<ul style="list-style-type: none"> • Prior calcium score within previous 5 years 	I (1)
Asymptomatic (Use of CT Angiogram)		
19.	<ul style="list-style-type: none"> • High CHD risk (Framingham) • Within 2 years prior cardiac CT angiogram or invasive angiogram without significant obstructive disease 	I (2)
20.	<ul style="list-style-type: none"> • High CHD risk (Framingham) • Prior calcium score greater than or equal to 400 	I (3)

Table 6. Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery

Indication		Appropriateness Criteria (Median Score)
Low-Risk Surgery (Use of CT Angiogram)		
21.	<ul style="list-style-type: none"> • Intermediate perioperative risk 	I (1)
Intermediate- or High-Risk Surgery (Use of CT Angiogram)		
22.	<ul style="list-style-type: none"> • Intermediate perioperative risk 	U (4)

Table 7. Detection of CAD: Post-Revascularization (PCI or CABG)

Indication		Appropriateness Criteria (Median Score)
Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
23.	<ul style="list-style-type: none"> • Evaluation of bypass grafts and coronary anatomy 	U (6)
24.	<ul style="list-style-type: none"> • History of percutaneous revascularization with stents 	U (5)
Asymptomatic (Use of CT Angiogram)		
25.	<ul style="list-style-type: none"> • Evaluation of bypass grafts and coronary anatomy • Less than 5 years after CABG 	I (2)
26.	<ul style="list-style-type: none"> • Evaluation of bypass grafts and coronary anatomy • Greater than or equal to 5 years after CABG 	I (3)
27.	<ul style="list-style-type: none"> • Evaluation for in-stent restenosis and coronary anatomy after PCI 	I (2)

Table 8. Structure and Function

Indication		Appropriateness Criteria (Median Score)
Morphology (Use of CT Angiogram)		
28.	<ul style="list-style-type: none"> Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves 	A (7)
29.	<ul style="list-style-type: none"> Evaluation of coronary arteries in patients with new onset heart failure to assess etiology 	A (7)
Evaluation of Ventricular and Valvular Function (Use of CT Angiogram)		
30.	<ul style="list-style-type: none"> Evaluation of LV function following myocardial infarction OR in heart failure patients 	I (3)
31.	<ul style="list-style-type: none"> Evaluation of LV function following myocardial infarction OR in heart failure patients Patients with technically limited images from echocardiogram 	U (5)
32.	<ul style="list-style-type: none"> Characterization of native and prosthetic cardiac valves Patients with technically limited images from echocardiogram, MRI, or TEE 	U (5)
Evaluation of Intra- and Extra-Cardiac Structures (Use of Cardiac CT)		
33.	<ul style="list-style-type: none"> Evaluation of cardiac mass (suspected tumor or thrombus) Patients with technically limited images from echocardiogram, MRI, or TEE 	A (8)
34.	<ul style="list-style-type: none"> Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery) Patients with technically limited images from echocardiogram, MRI, or TEE 	A (8)
35.	<ul style="list-style-type: none"> Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation 	A (8)
36.	<ul style="list-style-type: none"> Noninvasive coronary vein mapping prior to placement of biventricular pacemaker 	A (8)
37.	<ul style="list-style-type: none"> Noninvasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization 	A (8)
Evaluation of Aortic and Pulmonary Disease (Use of CT Angiogram*)		
38.	<ul style="list-style-type: none"> Evaluation of suspected aortic dissection or thoracic aortic aneurysm 	A (9)
39.	<ul style="list-style-type: none"> Evaluation of suspected pulmonary embolism 	A (9)

*Non-gated, CT angiogram which has a sufficiently large field of view for these specific indications.

CCT APPROPRIATENESS CRITERIA (BY APPROPRIATENESS CATEGORY)

Table 9. Inappropriate Indications (Median Score 1–3)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
3.	• High pre-test probability of CAD	I (2)
Detection of CAD: Symptomatic—Acute Chest Pain (Use of CT Angiogram)		
8.	• High pre-test probability of CAD • ECG—ST-segment elevation and/or positive cardiac enzymes	I (1)
Detection of CAD: Asymptomatic (Without Chest Pain Syndrome)—Asymptomatic (Use of CT Angiogram)		
10.	• Low CHD risk (Framingham risk criteria)	I (1)
11.	• Moderate CHD risk (Framingham)	I (2)
Risk Assessment: General Population—Asymptomatic (Calcium Scoring)		
13.	• Low CHD risk (Framingham)	I (1)
Detection of CAD With Prior Test Results—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
17.	• Evidence of moderate to severe ischemia on stress test (exercise, perfusion, or stress echo)	I (2)
Risk Assessment With Prior Test Results—Asymptomatic (Calcium Scoring)		
18.	• Prior calcium score within previous 5 years	I (1)
Risk Assessment With Prior Test Results—Asymptomatic (Use of CT Angiogram)		
19.	• High CHD risk (Framingham) • Within 2 years prior cardiac CT angiogram or invasive angiogram without significant obstructive disease	I (2)
20.	• High CHD risk (Framingham) • Prior calcium score greater than or equal to 400	I (3)
Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery—Low-Risk Surgery (Use of CT Angiogram)		
21.	• Intermediate perioperative risk	I (1)
Detection of CAD: Post-Revascularization (PCI or CABG)—Asymptomatic (Use of CT Angiogram)		
25.	• Evaluation of bypass grafts and coronary anatomy • Less than 5 years after CABG	I (2)
26.	• Evaluation of bypass grafts and coronary anatomy • Greater than or equal to 5 years after CABG	I (3)
27.	• Evaluation for in-stent restenosis and coronary anatomy after PCI	I (2)
Structure and Function—Evaluation of Ventricular and Valvular Function (Use of CT Angiogram)		
30.	• Evaluation of LV function following myocardial infarction OR in heart failure patients	I (3)

Table 10. Appropriate Indications (Median Score 7–9)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
2.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise 	A (7)
Detection of CAD: Symptomatic—Evaluation of Intra-Cardiac Structures (Use of CT Angiogram)		
4.	<ul style="list-style-type: none"> • Evaluation of suspected coronary anomalies 	A (9)
Detection of CAD: Symptomatic—Acute Chest Pain (Use of CT Angiogram)		
6.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • No ECG changes and serial enzymes negative 	A (7)
Detection of CAD With Prior Test Results—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
16.	<ul style="list-style-type: none"> • Uninterpretable or equivocal stress test (exercise, perfusion, or stress echo) 	A (8)
Structure and Function—Morphology (Use of CT Angiogram)		
28.	<ul style="list-style-type: none"> • Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves 	A (7)
29.	<ul style="list-style-type: none"> • Evaluation of coronary arteries in patients with new onset heart failure to assess etiology 	A (7)
Structure and Function—Evaluation of Intra- and Extra-Cardiac Structures (Use of Cardiac CT)		
33.	<ul style="list-style-type: none"> • Evaluation of cardiac mass (suspected tumor or thrombus) • Patients with technically limited images from echocardiogram, MRI, or TEE 	A (8)
34.	<ul style="list-style-type: none"> • Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery) • Patients with technically limited images from echocardiogram, MRI, or TEE 	A (8)
35.	<ul style="list-style-type: none"> • Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation 	A (8)
36.	<ul style="list-style-type: none"> • Noninvasive coronary vein mapping prior to placement of biventricular pacemaker 	A (8)
37.	<ul style="list-style-type: none"> • Noninvasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization 	A (8)
Structure and Function—Evaluation of Aortic and Pulmonary Disease (Use of CT Angiogram*)		
38.	<ul style="list-style-type: none"> • Evaluation of suspected aortic dissection or thoracic aortic aneurysm 	A (9)
39.	<ul style="list-style-type: none"> • Evaluation of suspected pulmonary embolism 	A (9)

*Non-gated, CT angiogram which has a sufficiently large field of view for these specific indications.

Table 11. Uncertain Indications (Median Score 4–6)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
1.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise 	U (5)
Detection of CAD: Symptomatic—Acute Chest Pain (Use of CT Angiogram)		
5.	<ul style="list-style-type: none"> • Low pre-test probability of CAD • No ECG changes and serial enzymes negative 	U (5)
7.	<ul style="list-style-type: none"> • High pre-test probability of CAD • No ECG changes and serial enzymes negative 	U (6)
9.	<ul style="list-style-type: none"> • “Triple rule out”—exclude obstructive CAD, aortic dissection, and pulmonary embolism • Intermediate pre-test probability for one of the above • ECG—no ST-segment elevation and initial enzymes negative 	U (4)
Detection of CAD: Asymptomatic (Without Chest Pain Syndrome)—Asymptomatic (Use of CT Angiogram)		
12.	<ul style="list-style-type: none"> • High CHD risk (Framingham) 	U (4)
Risk Assessment: General Population—Asymptomatic (Calcium Scoring)		
14.	<ul style="list-style-type: none"> • Moderate CHD risk (Framingham) 	U (6)
15.	<ul style="list-style-type: none"> • High CHD risk (Framingham) 	U (5)
Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery—Intermediate or High Risk Surgery (Use of CT Angiogram)		
22.	<ul style="list-style-type: none"> • Intermediate perioperative risk 	U (4)
Detection of CAD: Post-Revascularization (PCI or CABG)—Evaluation of Chest Pain Syndrome (Use of CT Angiogram)		
23.	<ul style="list-style-type: none"> • Evaluation of bypass grafts and coronary anatomy 	U (6)
24.	<ul style="list-style-type: none"> • History of percutaneous revascularization with stents 	U (5)
Structure and Function—Evaluation of Ventricular and Valvular Function (Use of CT Angiogram)		
31.	<ul style="list-style-type: none"> • Evaluation of LV function following myocardial infarction OR in heart failure patients • Patients with technically limited images from echocardiogram 	U (5)
32.	<ul style="list-style-type: none"> • Characterization of native and prosthetic cardiac valves • Patients with technically limited images from echocardiogram, MRI, or TEE 	U (5)

CMR APPROPRIATENESS CRITERIA (BY INDICATION)

Assume the logical operator between each variable listed for an indication is “AND” unless otherwise noted (e.g., Low pre-test probability of CAD AND No ECG changes and serial enzymes negative).

Table 12. Detection of CAD: Symptomatic

Indication		Appropriateness Criteria (Median Score)
Evaluation of Chest Pain Syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
1.	<ul style="list-style-type: none"> • Low pre-test probability of CAD • ECG interpretable AND able to exercise 	I (2)
2.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise 	U (4)
3.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise 	A (7)
4.	<ul style="list-style-type: none"> • High pre-test probability of CAD 	U (5)
Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)		
5.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise 	I (2)
6.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise 	I (2)
7.	<ul style="list-style-type: none"> • High pre-test probability of CAD 	I (1)
Evaluation of Intra-Cardiac Structures (Use of MR Coronary Angiography)		
8.	<ul style="list-style-type: none"> • Evaluation of suspected coronary anomalies 	A (8)
Acute Chest Pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
9.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • No ECG changes and serial cardiac enzymes negative 	U (6)
10.	<ul style="list-style-type: none"> • High pre-test probability of CAD • ECG—ST-segment elevation and/or positive cardiac enzymes 	I (1)

Table 13. Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)

Indication		Appropriateness Criteria (Median Score)
11.	<ul style="list-style-type: none"> • Normal prior stress test (exercise, nuclear, echo, MRI) • High CHD risk (Framingham) • Within 1 year of prior stress test 	I (2)
12.	<ul style="list-style-type: none"> • Equivocal stress test (exercise, stress SPECT, or stress echo) • Intermediate CHD risk (Framingham) 	U (6)
13.	<ul style="list-style-type: none"> • Coronary angiography (catheterization or CT) • Stenosis of unclear significance 	A (7)

Table 14. Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery

Indication		Appropriateness Criteria (Median Score)
Low-Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
14.	• Intermediate perioperative risk predictor	I (2)
Intermediate- or High-Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
15.	• Intermediate perioperative risk predictor	U (6)

Table 15. Detection of CAD: Post-Revascularization (PCI or CABG)

Indication		Appropriateness Criteria (Median Score)
Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)		
16.	• Evaluation of bypass grafts	I (2)
17.	• History of percutaneous revascularization with stents	I (1)

Table 16. Structure and Function

Indication		Appropriateness Criteria (Median Score)
Evaluation of Ventricular and Valvular Function		
Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and delayed contrast enhancement		
18.	<ul style="list-style-type: none"> • Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves • Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and contrast enhancement 	A (9)
19.	• Evaluation of LV function following myocardial infarction OR in heart failure patients	U (6)
20.	<ul style="list-style-type: none"> • Evaluation of LV function following myocardial infarction OR in heart failure patients • Patients with technically limited images from echocardiogram 	A (8)
21.	<ul style="list-style-type: none"> • Quantification of LV function • Discordant information that is clinically significant from prior tests 	A (8)
22.	<ul style="list-style-type: none"> • Evaluation of specific cardiomyopathies (infiltrative [amyloid, sarcoid], HCM, or due to cardiotoxic therapies) • Use of delayed enhancement 	A (8)
23.	<ul style="list-style-type: none"> • Characterization of native and prosthetic cardiac valves—including planimetry of stenotic disease and quantification of regurgitant disease • Patients with technically limited images from echocardiogram or TEE 	A (8)
24.	<ul style="list-style-type: none"> • Evaluation for arrhythmogenic right ventricular cardiomyopathy (ARVC) • Patients presenting with syncope or ventricular arrhythmia 	A (9)
25.	<ul style="list-style-type: none"> • Evaluation of myocarditis or myocardial infarction with normal coronary arteries • Positive cardiac enzymes without obstructive atherosclerosis on angiography 	A (8)
Evaluation of Intra- and Extra-Cardiac Structures		
26.	<ul style="list-style-type: none"> • Evaluation of cardiac mass (suspected tumor or thrombus) • Use of contrast for perfusion and enhancement 	A (9)
27.	• Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis)	A (8)
28.	• Evaluation for aortic dissection	A (8)
29.	<ul style="list-style-type: none"> • Evaluation of pulmonary veins prior to radiofrequency ablation for atrial fibrillation • Left atrial and pulmonary venous anatomy including dimensions of veins for mapping purposes 	A (8)

Table 17. Detection of Myocardial Scar and Viability

Indication		Appropriateness Criteria (Median Score)
Evaluation of Myocardial Scar (Use of Late Gadolinium Enhancement)		
30.	<ul style="list-style-type: none"> To determine the location and extent of myocardial necrosis including ‘no reflow’ regions Post-acute myocardial infarction 	A (7)
31.	<ul style="list-style-type: none"> To detect post PCI myocardial necrosis 	U (4)
32.	<ul style="list-style-type: none"> To determine viability prior to revascularization Establish likelihood of recovery of function with revascularization (PCI or CABG) or medical therapy 	A (9)
33.	<ul style="list-style-type: none"> To determine viability prior to revascularization Viability assessment by SPECT or dobutamine echo has provided “equivocal or indeterminate” results 	A (9)

CMR APPROPRIATENESS CRITERIA (BY APPROPRIATENESS CATEGORY)

Table 18. Inappropriate Indications (Median Score 1–3)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
1.	<ul style="list-style-type: none"> Low pre-test probability of CAD ECG interpretable AND able to exercise 	I (2)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)		
5.	<ul style="list-style-type: none"> Intermediate pre-test probability of CAD ECG interpretable AND able to exercise 	I (2)
6.	<ul style="list-style-type: none"> Intermediate pre-test probability of CAD ECG uninterpretable OR unable to exercise 	I (2)
7.	<ul style="list-style-type: none"> High pre-test probability of CAD 	I (1)
Detection of CAD: Symptomatic—Acute Chest Pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
10.	<ul style="list-style-type: none"> High pre-test probability of CAD ECG—ST-segment elevation and/or positive cardiac enzymes 	I (1)
Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
11.	<ul style="list-style-type: none"> Normal prior stress test (exercise, nuclear, echo, MRI) High CHD risk (Framingham) Within 1 year of prior stress test 	I (2)
Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery—Low Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
14.	<ul style="list-style-type: none"> Intermediate perioperative risk predictor 	I (2)
Detection of CAD: Post-Revascularization (PCI or CABG)—Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)		
16.	<ul style="list-style-type: none"> Evaluation of bypass grafts 	I (2)
17.	<ul style="list-style-type: none"> History of percutaneous revascularization with stents 	I (1)

Table 19. Appropriate Indications (Median Score 7–9)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
3.	<ul style="list-style-type: none"> • Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise 	A (7)
Detection of CAD: Symptomatic—Evaluation of Intra-Cardiac Structures (Use of MR Coronary Angiography)		
8.	<ul style="list-style-type: none"> • Evaluation of suspected coronary anomalies 	A (8)
Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
13.	<ul style="list-style-type: none"> • Coronary angiography (catheterization or CT) • Stenosis of unclear significance 	A (7)
Structure and Function—Evaluation of Ventricular and Valvular Function		
Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and delayed contrast enhancement		
18.	<ul style="list-style-type: none"> • Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves • Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and contrast enhancement 	A (9)
20.	<ul style="list-style-type: none"> • Evaluation of LV function following myocardial infarction OR in heart failure patients • Patients with technically limited images from echocardiogram 	A (8)
21.	<ul style="list-style-type: none"> • Quantification of LV function • Discordant information that is clinically significant from prior tests 	A (8)
22.	<ul style="list-style-type: none"> • Evaluation of specific cardiomyopathies (infiltrative [amyloid, sarcoid], HCM, or due to cardiotoxic therapies) • Use of delayed enhancement 	A (8)
23.	<ul style="list-style-type: none"> • Characterization of native and prosthetic cardiac valves—including planimetry of stenotic disease and quantification of regurgitant disease • Patients with technically limited images from echocardiogram or TEE 	A (8)
24.	<ul style="list-style-type: none"> • Evaluation for arrhythmogenic right ventricular cardiomyopathy (ARVC) • Patients presenting with syncope or ventricular arrhythmia 	A (9)
25.	<ul style="list-style-type: none"> • Evaluation of myocarditis or myocardial infarction with normal coronary arteries • Positive cardiac enzymes without obstructive atherosclerosis on angiography 	A (8)
Structure and Function—Evaluation of Intra- and Extra-Cardiac Structures		
26.	<ul style="list-style-type: none"> • Evaluation of cardiac mass (suspected tumor or thrombus) • Use of contrast for perfusion and enhancement 	A (9)
27.	<ul style="list-style-type: none"> • Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis) 	A (8)
28.	<ul style="list-style-type: none"> • Evaluation for aortic dissection 	A (8)
29.	<ul style="list-style-type: none"> • Evaluation of pulmonary veins prior to radiofrequency ablation for atrial fibrillation • Left atrial and pulmonary venous anatomy including dimensions of veins for mapping purposes 	A (8)
Detection of Myocardial Scar and Viability—Evaluation of Myocardial Scar (Use of Late Gadolinium Enhancement)		
30.	<ul style="list-style-type: none"> • To determine the location, and extent of myocardial necrosis including ‘no reflow’ regions • Post acute myocardial infarction 	A (7)
32.	<ul style="list-style-type: none"> • To determine viability prior to revascularization • Establish likelihood of recovery of function with revascularization (PCI or CABG) or medical therapy 	A (9)
33.	<ul style="list-style-type: none"> • To determine viability prior to revascularization • Viability assessment by SPECT or dobutamine echo has provided “equivocal or indeterminate” results 	A (9)

Table 20. Uncertain Indications (Median Score 4–6)

Indication		Appropriateness Criteria (Median Score)
Detection of CAD: Symptomatic—Evaluation of Chest Pain Syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
2.	<ul style="list-style-type: none"> Intermediate pre-test probability of CAD ECG interpretable AND able to exercise 	U (4)
4.	<ul style="list-style-type: none"> High pre-test probability of CAD 	U (5)
Detection of CAD: Symptomatic—Acute Chest Pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
9.	<ul style="list-style-type: none"> Intermediate pre-test probability of CAD No ECG changes and serial cardiac enzymes negative 	U (6)
Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
12.	<ul style="list-style-type: none"> Equivocal stress test (exercise, stress SPECT, or stress echo) Intermediate CHD risk (Framingham) 	U (6)
Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery—Intermediate or High Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)		
15.	<ul style="list-style-type: none"> Intermediate perioperative risk predictor 	U (6)
Structure and Function—Evaluation of Ventricular and Valvular Function Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and delayed contrast enhancement		
19.	<ul style="list-style-type: none"> Evaluation of LV function following myocardial infarction OR in heart failure patients 	U (6)
Evaluation of Myocardial Scar (Use of Late Gadolinium Enhancement)		
31.	<ul style="list-style-type: none"> To detect post PCI myocardial necrosis 	U (4)

DISCUSSION

The indications contained in this report were selected to cover a wide variety of clinical presentations. They are based on common patient presentations such as symptoms suggestive of ischemia, multiple cardiac risk factors in an asymptomatic individual, and specific scenarios with indices of high clinical suspicion that are further stratified based on factors such as clinical risk, prior test results, and the interval since prior testing. The purpose of this approach is to delineate the possible value of CCT or CMR for a physician faced with everyday patient scenarios. The indications do not correspond directly to International Classification of Diseases-9th Revision (ICD-9) codes, as they convey more information than usually found in the ICD-9 classification system. Some correlation with previous model local coverage determination (LCD) documents is purposeful, but the indications are designed to provide further guidance within the categories outlined in the model LCD for ordering physicians. It is recognized that not all categories within an LCD or for ICD-9 codes are represented.

The appropriateness criteria for CCT and CMR are 2 separate reports and were not developed in a way that can provide comparative information about the utility of one test versus the other. Although the same panel ranked the indications for both CCT and CMR, members of the Technical Panel were asked specifically NOT to comparatively rank each of these imaging procedures, but instead to consider each test on its own merits. As such, the scores and

the conclusions about appropriateness also should not be compared with the prior report for appropriateness for single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI) (8) or to those soon to be written for other imaging procedures, such as echocardiography.

For the 39 indications for CCT, 13 were found to be appropriate, and 12 were uncertain. Fourteen of these indications were felt to be inappropriate reasons for CT test performance. There was great variability in scores for the uncertain category, suggesting markedly differing opinions. However, there was substantial agreement as defined by RAND (9) for a panel this size for the categories labeled as either appropriate or inappropriate, with 77% and 86%, respectively, showing agreement. Cardiac computed tomography was considered reasonable for a number of scenarios beyond assessments of structure and function, but still over 40% of the indications were for this area.

For CMR, 17 of the 33 indications were ranked as appropriate, with another 7 being uncertain. Nine scenarios were considered to be inappropriate reasons for magnetic resonance test performance. Similar to the indications for CCT, uncertain scenarios showed wider dispersion of scores than those for indications at either end of the spectrum. Agreement, as defined for a panel this size by RAND (9), was present for 82% of the appropriate indications and 89% for those felt to be inappropriate. Two-thirds of the appropriate and uncertain indications for CMR were related to

assessment of structure and function. These results support the strengths of CMR as a tool for defining the etiology of complex patient presentations where the clinical suspicion is high. The scores for other uses reflect the evolving nature of the capabilities of the test.

The indications contained in this report are not exhaustive. For example, the use of CCT or CMR for the non-invasive evaluation of coronary arteries before non-coronary cardiac surgery was not listed as an indication, although this may be an evolving application. Additionally, there may be medical reasons that would preclude the application of the appropriateness criteria to a specific patient, and clinician judgment should be used at all times in the application of these criteria. Furthermore, the local availability or quality of equipment or personnel may influence the selection of appropriate imaging procedures. Appropriateness criteria, in other words, are not substitutes for sound clinical judgment and practice experience with each patient and clinical presentation. For example, the rating of an indication as inappropriate should not preclude a provider from performing CCT or CMR procedures when there are patient- and condition-specific data to support that decision. Conversely, not doing a study that is deemed appropriate may be the correct decision in light of unique patient, clinical, and other relevant information.

The category of "uncertain" was discussed at length by the Technical Panel and the Working Group. The consensus of the Panel was that this intermediate level of appropriateness should be labeled "uncertain," as either critical data were lacking or significant differences of opinion exist among Panel members regarding the value of the method for that particular indication. The categorization of a particular indication as uncertain should serve as a nidus for additional information and research so as to formulate a definitive level of appropriateness.

The primary objective of this report is to provide guidance regarding the perceived suitability of CCT and CMR for diverse clinical scenarios. As with the Appropriateness Criteria for SPECT MPI (8), consensus among the raters was desirable, but achievement of complete agreement within this diverse panel would have been artificial and not necessarily of clinical value. Two rounds of rating with intervening discussion did lead to some consensus. However, further attempts to drive consensus might have artificially diluted true differences in opinion among panelists. This is especially true for both CCT and CMR, as these are still emerging clinical imaging modalities with an evolving evidence base.

The appropriateness criteria in these reports are expected to be useful for clinicians, health care facilities, and third-party payers in the delivery of quality cardiovascular imaging. For example, individual clinicians could use the ratings as a supportive decision or educational tool when ordering a test or providing a referral to another qualified physician. The criteria also may be used to respond to a referring physician who has ordered a test for an inappropriate

indication. Facilities and payers can use the criteria either prospectively in the design of protocols and pre-authorization procedures or retrospectively for quality reports. It is hoped that payers will use this document as the basis for their own strategies to ensure that their members receive quality, but cost-effective, cardiovascular care.

When used for accountability, appropriateness criteria should be used in conjunction with systems that support quality improvement. Prospective pre-authorization procedures, for example, may be used most effectively once a retrospective review has identified a pattern of potential inappropriate use. Because the criteria are based on up-to-date scientific evidence and the deliberations of the Technical Panel, they can be used to help resolve future reimbursement cases or appeals but should not be applied to cases completed before issuance of this report.

The linking of indications rated as generally acceptable practice with analysis of related patient outcomes, and a review of what is "necessary" care, will improve understanding of regional variations in imaging and the potential for ensuring the equitable and efficient allocation of resources for diagnostic studies. Further exploration of the indications that are rated as "uncertain" will generate new empirical research and the data required to further define the appropriateness of CCT and CMR. Finally, periodic assessment and updating of the indications and criteria will be required as new data and field experience become available.

APPENDIX A: METHODS

Panel Selection

An initial list of potential Technical Panel members was generated based on a call for nominations issued to all relevant stakeholders. Panel members were selected by the Working Group in a manner that ensured an appropriate balance with respect to expertise in the specific modality, academic versus private practice, health services research, and specialty training.

Development of Indications

The process for creating a robust set of indications involved consulting current literature, previously published statements, and model local coverage determination documents. The indications capture the majority of scenarios faced by cardiologists or referring physicians, but are not meant to be inclusive of all potential indications for which CCT or CMR imaging studies may be performed. Review was done by the Working Group, including additional comments from external reviewers. As a result of the meeting of the Technical Panel before the second round of rating, a few of the indications were clarified and modified. A final set of indications comprised the list of possible clinical scenarios that were rated for appropriateness by the panelists and compiled for this report.

General Assumptions

All indications for CCT and CMR were considered with the following important assumptions:

1. All indications should first be evaluated based on the available medical literature. In many cases, studies are reflections of the capabilities and limitations of the test but provide minimal information about the role of the test in clinical decision making. Appropriateness criteria development requires determination of a reasonable course of action for clinical decision making based on a risk/benefit trade-off as determined by individual patient indications.
2. Cost **SHOULD** be considered **implicitly** in the appropriateness determination.
3. Risks, such as radiation exposure and contrast adverse effects, should be considered.
4. Additional factors may be considered **implicitly** in the appropriateness determination including the impact of the image on clinical decision making when combined with clinical judgment.
5. For each indication, the panelists' ratings should reflect whether the test is reasonable for the patient according to the appropriateness definition, **not whether the test is better or worse than another**. It also should not consider issues of local availability or skill for any modality or variation in equipment. It should be assumed that the imaging procedure will be performed in accordance with best practice, using appropriate equipment and techniques.
6. Specific comparisons with previous sets of appropriateness criteria should **not** be made.
7. **All techniques** are assumed to be performed in an optimal fashion, using appropriate equipment and protocols.
8. The test is assumed to be performed by a qualified individual in a facility that is proficient in the imaging technique.

Assumptions for CCT only:

1. Cardiac computed tomography imaging equipment and personnel are available that have the minimal technical capabilities required for the indication (the number of detector rows, spatial and temporal resolution, and acquisition protocols).
2. Indications for CT angiography assume that calcium scoring also may be obtained for that indication.
3. Calcium scoring is assumed to be performed by EBCT or multislice CT.
4. Unless specifically noted, use of the test to determine non-cardiac etiologies for an indication is not considered.
5. For CT angiography, patients are assumed not to present with any of the following:
 - a. Irregular rhythm (e.g., atrial fibrillation/flutter, frequent irregular premature ventricular contractions or premature atrial contractions, and high grade heart block);

- b. Very obese patients, body mass index greater than 40 kg/m²;
 - c. Renal insufficiency, creatinine greater than 1.8 mg/dL;
 - d. Heart rate greater than 70 beats/min refractory to heart-rate-lowering agents (e.g., a combination of beta-blocker and calcium-channel blocker);
 - e. Metallic interference (e.g., surgical clips, pacemaker, and/or defibrillator wires, or tissue expander).
6. For CT angiography, patients must be able to:
 - a. Hold still;
 - b. Follow breathing instruction;
 - c. Take nitroglycerin (for performing coronary CT angiography only);
 - d. Take iodine in spite of steroid prep for contrast allergy;
 - e. Lift both arms above the shoulders.

Note: Any patient presenting with the characteristics listed in 5 and 6 above is assumed to be excluded from the indications for scoring purposes.

Assumptions for CMR only:

1. Cardiac magnetic resonance imaging equipment and personnel are available that have the minimal technical capabilities required for the indication.
2. Images are obtained with at least a 1.5-T magnet using standard sequences provided by the current vendors.
3. Use of gadolinium contrast is assumed for studies involving perfusion, angiograms, and contrast enhancement.
4. Patients are assumed not to present with general CMR imaging contraindications examples of which include:
 - a. severe claustrophobia;
 - b. specific metallic contraindications such as pacemakers, defibrillators, and certain aneurysm clips.

Note: Studies are ongoing with regards to pacemakers and implantable defibrillators. In April 2005, the Food and Drug Administration approved magnetic resonance imaging studies immediately after implantation of sirolimus- and paclitaxel-eluting stents, which is now reflected in the respective package instructions for use.

Rating Process

The Technical Panel was instructed to follow the process outlined in the article previously published by the College entitled, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (2). The appropriateness method combines expert clinical judgment with the scientific literature in evaluating the benefits and risks of medical procedures. Ratings of the net benefits and risks of performing medical procedures for a comprehensive array of potential patient indications or scenarios are obtained from a multidisciplinary panel of expert clinicians. Each panel member has equal weight in producing the final result, and the method does not force consensus.

The rating process includes a modified Delphi process involving 2 rounds of ratings and an intervening face-to-face meeting. The first round of ratings was completed individually with no interaction among panel members. The panel was then convened for a face-to-face meeting that was facilitated by a moderator. The goal of the meeting was to focus discussion on indications for which the first round scores of the panel were widely divergent. The objective of the meeting was to allow all views to be heard. The second round ratings were conducted individually subsequent to the face-to-face meeting. The second round ratings were used to determine the final appropriateness score based on the median score for each indication.

At the face-to-face meeting, each panelist received a personalized rating form that indicated his/her rating for each indication and the distribution of ratings of other members of the panel, but without personal identification. In addition, the moderator received a summary rating form with similar information (including panelist identification), along with other statistics that measured the level of agreement among panel members. A measure of the level of disagreement was applied to each score after both the first and second round scoring was completed. This project employed the BIOMED Concerted Action on Appropriateness definition for a panel size of 14 to 16. As defined in the RAND/UCLA manual (9) upon which the ACCF ratings method is based, the BIOMED rule for agreement (+) is that no more than 4 panelists rate the indication outside the 3-point region containing the median; for disagreement (-), at least 5 panelists rate in each extreme rating region (i.e., 1 to 3 and 7 to 9). Measures of agreement and the dispersion of ratings (mean absolute deviation from the median) may highlight areas where definitions are not clear or ratings are inconsistent, where panelist perceptions of the "average" patient may differ, or where various specialty groups or individual panelists may have differences of clinical opinion. In cases of obvious disagreement or outlier scores, the indication was highlighted in a summary table and identification of the outlier raters brought to the attention of the moderator. This information was used by the moderator to guide the panel's discussion.

Relationships With Industry

The College and its partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the Technical Panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the Appropriateness Criteria Working Group, discussed with all members of the Technical Panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by each Technical Panel and Oversight Working Group member can be found in Appendix D.

Literature Review

The Technical Panel members were asked to refer to the literature summary, evidence tables, and reference list provided for each modality when completing their ratings (online Appendix C and D at www.acc.org). A paper recently published on clinical indications for CMR (10) also was provided. Lastly, they were given the previously published materials pertaining to the appropriateness criteria work (2,8).

APPENDIX B: DEFINITIONS AND PROCESSES FOR DETERMINING LIKELIHOOD OF DISEASE AND RISK

Determining Pre-Test Probability of CAD

Chest Pain Syndrome: Any constellation of symptoms that the physician feels may represent a complaint consistent with obstructive CAD. Examples of such symptoms include, but are not exclusive to: chest pain, chest tightness, burning, dyspnea, shoulder pain, and jaw pain.

Pre-Test Probability of CAD: Once the physician determines the presence of symptoms that may represent obstructive CAD (chest pain syndrome present), then the pre-test probability of CAD should be determined.

Although there are several methods for determining pre-test probability of CAD (3,4), the method assumed for this report is a modification of a literature review (5) recommended by the American College of Cardiology/American Heart Association (ACC/AHA) 2002 Guideline Update for Exercise Testing (11) and ACC/AHA 2002 Guideline Update for Management of Patients with Chronic Stable Angina (12). The reader should refer to the definitions of angina and Table B1.

Angina: As defined by the ACC/AHA 2002 Guideline Update on Exercise Testing (11):

- **Typical Angina (Definite):** 1) Substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin (6).
- **Atypical Angina (Probable):** Chest pain or discomfort that lacks one of the characteristics of definite or typical angina (6).
- **Non-Anginal Chest Pain:** Chest pain or discomfort that meets one or none of the typical angina characteristics.

Determining Pre-Test Risk

Assessment for Risk Stratification

Risk Assessment The rating sheets on risk assessment include indications in patients with suspected CAD. This assessment is particularly valuable in the setting of asymptomatic individuals.

It is assumed that clinicians will use imaging studies in addition to standard methods of risk assessment as presented in the ACC/AHA Scientific Statement: Assessment of Cardiovascular Risk by Use of Multiple-Risk-Factor Assessment Equations (7), see Tables B2 and B3. Numerous discussions of the Framingham Risk Score calculation can be found online

Table B1. Pre-Test Probability of CAD by Age, Gender, and Symptoms*

Age (yrs)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
30-39	Men	Intermediate	Intermediate	Low	Very low
	Women	Intermediate	Very low	Very low	Very low
40-49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very low	Very low
50-59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very low
60-69	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low

High: Greater than 90% pre-test probability; Intermediate: Between 10% and 90% pre-test probability; Low: Between 5% and 10% pre-test probability; Very Low: Less than 5% pre-test probability. *No data exist for patients less than 30 years or greater than 69 years, but it can be assumed that prevalence of CAD increases with age. In a few cases, patients with ages at the extremes of the decades listed may have probabilities slightly outside the high or low range.

Reproduced with permission from ACC/AHA 2002 Guideline Update for Exercise Testing (11).

including at the National Heart, Lung, and Blood Institute Web site: <http://www.nhlbi.nih.gov/about/framingham/riskabs.htm>).

Coronary Heart Disease (CHD) Risk

• **CHD Risk—Low**

Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CHD risk less than 10%.

• **CHD Risk—Moderate**

Defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CHD risk between 10% and 20%.

• **CHD Risk—High**

Defined as the presence of diabetes mellitus or the 10-year absolute CHD risk of greater than 20%.

Evaluating Perioperative Risk for Non-Cardiac Surgery

Method for Determining Perioperative Risk Perioperative risk was determined for this report using a “Stepwise Approach to Preoperative Cardiac Assessment,” found in the ACC/AHA 2002 Guideline Update for Perioperative Cardiovascular Evaluation for Noncardiac Surgery (13). Based on that algorithm, once it is determined that the patient does not require urgent surgery, and that there has not been revascularization within the last 5 years, the clinician should determine the patient’s perioperative risk predictors (see definitions in the following text). If major

Table B2. Men: 10-Year CHD Risk According to Framingham Risk Score

Age	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	Absolute Risk	Absolute Risk§
(Low-risk level)*	(2%)	(3%)	(3%)	(4%)	(5%)	(7%)	(8%)	(10%)	(13%)	Total CHD‡	Hard CHD§
Points†											
0	1.0									2%	2%
1	1.5	1.0	1.0							3%	2%
2	2.0	1.3	1.3	1.0						4%	3%
3	2.5	1.7	1.7	1.3	1.0					5%	4%
4	3.5	2.3	2.3	1.8	1.4	1.0				7%	5%
5	4.0	2.6	2.6	2.0	1.6	1.1	1.0			8%	6%
6	5.0	3.3	3.3	2.5	2.0	1.4	1.3	1.0		10%	7%
7	6.5	4.3	4.3	3.3	2.6	1.9	1.6	1.3	1.0	13%	9%
8	8.0	5.3	5.3	4.0	3.2	2.3	2.0	1.6	1.2	16%	13%
9	10.0	6.7	6.7	5.0	4.0	2.9	2.5	2.0	1.5	20%	16%
10	12.5	8.3	8.3	6.3	5.0	3.6	3.1	2.5	1.9	25%	20%
11	15.5	10.3	10.3	7.8	6.1	4.4	3.9	3.1	2.3	31%	25%
12	18.5	12.3	12.3	9.3	7.4	5.2	4.6	3.7	2.8	37%	30%
13	22.5	15.0	15.0	11.3	9.0	6.4	5.6	4.5	3.5	45%	35%
>14	26.5	>17.7	>17.7	>13.3	>10.6	>7.6	>6.6	>5.3	>4.1	>53%	>45%

*Low-risk level is defined in the Framingham Report as the risk of coronary heart disease (CHD) at any age for a non-smoker, non-diabetic, with blood pressure less than 120/80 mmHg, total cholesterol of 160-199 mg/dL, LDL-C 100 to 129 mg/dL, and HDL-C greater than or equal to 45 mg/dL in men and greater than or equal to 55 mg/dL in women. †Points = number of points estimated from ACC/AHA Scientific Statement: Assessment of Cardiovascular Risk by Use of Multiple-Risk-Factor Assessment Equations, Table 4 (7). ‡Total Coronary Heart Disease (Total CHD) includes angina pectoris, recognized and unrecognized myocardial infarction, unstable angina, and CHD deaths. §Hard CHD includes all of the total CHD events except for angina pectoris. Reprinted with permission from Grundy SM, Pasternak R, Greenland P, et al. ACC/AHA scientific statement: assessment of cardiovascular risk by use of multiple-risk-factor assessment equations: a statement for healthcare professionals from the American Heart Association and the American College of Cardiology. J Am Coll Cardiol 1999;34:1348-59 (7).

Table B3. Women: 10-Year CHD Risk According to Framingham Risk Score

Age	40-44	45-49	50-54	55-59	60-64	65-69	70-74		
(Low-risk level)*	(2%)	(3%)	(5%)	(7%)	(8%)	(8%)	(8%)	Absolute Risk	Absolute Risk
Points†								Total CHD‡	Hard CHD§
0	1.0							2%	1%
1	1.0							2%	1%
2	1.5	1.0						3%	2%
3	1.5	1.0						3%	2%
4	2.0	1.3						4%	2%
5	2.0	1.3						4%	2%
6	2.5	1.7	1.0					5%	2%
7	3.0	2.0	1.2					6%	3%
8	3.5	2.3	1.4	1.0				7%	3%
9	4.0	2.7	1.6	1.1	1.0	1.0	1.0	8%	3%
10	5.0	3.3	2.0	1.4	1.3	1.3	1.3	10%	4%
11	5.5	3.7	2.2	1.6	1.4	1.4	1.4	11%	7%
12	6.5	4.3	2.6	1.9	1.6	1.6	1.6	13%	8%
13	7.5	5.0	3.0	2.1	1.9	1.9	1.9	15%	11%
14	9.0	6.0	3.6	2.6	2.3	2.3	2.3	18%	13%
15	10.0	6.7	4.0	2.9	2.5	2.5	2.5	20%	15%
16	12.0	8.0	4.8	3.4	3.0	3.0	3.0	24%	18%
≥ 17	>13.5	>9.0	>5.4	>3.9	5.4	5.4	5.4	>27%	>20%

*Low-risk level is defined in the Framingham Report as the risk of coronary heart disease (CHD) at any age for a non-smoker, non-diabetic, with blood pressure less than 120/80 mmHg, total cholesterol of 160-199 mg/dL, LDL-C 100 to 129 mg/dL, and HDL-C greater than or equal to 45 mg/dL in men and greater than or equal to 55 mg/dL in women. †Points = number of points estimated from ACC/AHA Scientific Statement: Assessment of Cardiovascular Risk by Use of Multiple-Risk-Factor Assessment Equations, Table 4 (7). ‡Total Coronary Heart Disease (Total CHD) includes angina pectoris, recognized and unrecognized myocardial infarction, unstable angina, and CHD deaths. §Hard CHD includes all of the total CHD events except for angina pectoris. Reprinted with permission from Grundy SM, Pasternak R, Greenland P, et al. ACC/AHA scientific statement: assessment of cardiovascular risk by use of multiple-risk-factor assessment equations: a statement for healthcare professionals from the American Heart Association and the American College of Cardiology. J Am Coll Cardiol 1999;34:1348-59 (7).

risk predictors are present, coronary angiography and the postponement or cancellation of non-cardiac surgery should be considered. Once perioperative risk predictors are assessed based on the algorithm, then the surgical risk and patient's functional status should be used to establish the need for non-invasive testing.

Perioperative Risk Predictors*

- **Major risk predictors**
 Unstable coronary syndromes, decompensated heart failure (HF), significant arrhythmias, and severe valve disease.
- **Intermediate risk predictors**
 Mild angina, prior myocardial infarction (MI), compensated or prior HF, diabetes, or renal insufficiency.
- **Minor risk predictors**
 Advanced age, abnormal electrocardiogram (ECG), rhythm other than sinus, low functional capacity, history of cerebrovascular accident, and uncontrolled hypertension.

Surgical Risk Categories*

- **High-Risk Surgery—cardiac death or MI greater than 5%**
 Emergent major operations (particularly in the elderly), aortic and peripheral vascular surgery, prolonged surgical procedures associated with large fluid shifts and/or blood loss.

- **Intermediate-Risk Surgery—cardiac death or MI = 1% to 5%**
 Carotid endarterectomy, head and neck surgery, surgery of the chest or abdomen, orthopedic surgery, prostate surgery.
- **Low-Risk Surgery—cardiac death or MI less than 1%**
 Endoscopic procedures, superficial procedures, cataract surgery, breast surgery.

*As defined by the ACC/AHA Guideline Update for Perioperative Cardiovascular Evaluation of Non-Cardiac Surgery (13).

ECG—Uninterpretable

Refers to ECGs with resting ST-segment depression (greater than or equal to 0.10 mV), complete left bundle-branch block, pre-excitation (Wolf-Parkinson-White syndrome), or paced rhythm.

APPENDIX C: ACCF APPROPRIATENESS CRITERIA WORKING GROUP AND TECHNICAL PANEL

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APPENDIX D: RELATIONSHIPS WITH INDUSTRY

Table D1. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR Appropriateness Criteria Writing Group, Technical Panel, Working Group, and Indication Reviewers (In Alphabetical Order)

Committee Member	Research Grant	Speakers Bureau/Honoraries/ Expert Witness	Stock Ownership	Board of Directors	Consultant/Advisory Board/ Steering Committee
CCT/CMR Appropriateness Criteria Writing Group					
Dr. Robert C. Hendel	<ul style="list-style-type: none"> • Astellas Healthcare • GE Healthcare • Cornatus Genetics 	<ul style="list-style-type: none"> • Bristol-Myers Squibb 			<ul style="list-style-type: none"> • GE Healthcare • CV Therapeutics
Dr. Christopher Kramer	<ul style="list-style-type: none"> • Siemens Medical Solutions • Novartis Healthcare • Astellas Healthcare 	<ul style="list-style-type: none"> • GE Healthcare 			<ul style="list-style-type: none"> • GE Healthcare
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Dr. Michael Poon	<ul style="list-style-type: none"> • Siemens Medical Solutions 	None	None	None	<ul style="list-style-type: none"> • Siemens Medical Solutions
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