Complete Summary

GUIDELINE TITLE

ACCF/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment and in evaluation of patients with chest pain. A report of the American College of Cardiology Foundation Clinical Expert Consensus Task Force (ACCF/AHA Writing Committee to Update the 2000 Expert Consensus Document on Electron Beam Computed Tomography) developed in collaboration with the Society of Atherosclerosis Imaging and Prevention and the Society of Cardiovascular Computed Tomography.

BIBLIOGRAPHIC SOURCE(S)

Greenland P, Bonow RO, Brundage BH, Budoff MJ, Eisenberg MJ, Grundy SM, Lauer MS, Post WS, Raggi P, Redberg RF, Rodgers GP, Shaw LJ, Taylor AJ, Weintraub WS, American College of Cardiology Foundation Clinical Expert Consensus Task, Society of Atherosclerosis Imaging and Prevention, Society of Cardiovascular Computed Tomography. ACCF/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment and in evaluation of patients with chest pain. J Am Coll Cardiol 2007 Jan 23;49(3):378-402. [115 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: O'Rourke RA, Brundage BH, Froelicher VF, et al. American College of Cardiology/American Heart Association expert consensus document on electron-beam computed tomography for the diagnosis and prognosis of coronary artery disease. J Am Coll Cardiol 2000;36:326–40.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Coronary heart disease (CHD)
- Chest pain

GUIDELINE CATEGORY

Diagnosis
Evaluation
Risk Assessment

CLINICAL SPECIALTY

Cardiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide a perspective on the current state of the role of coronary artery calcium scoring by fast computed tomography in clinical practice

TARGET POPULATION

Patients with chest pain or those with or at risk for coronary heart disease

INTERVENTIONS AND PRACTICES CONSIDERED

Coronary arterial calcium measurement by computed tomography (CT) scanning

MAJOR OUTCOMES CONSIDERED

- Accuracy of coronary artery calcium scoring for estimating coronary heart disease death or myocardial infarction
- Risk of coronary heart disease death or myocardial infarction
- Coronary heart disease events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A complete literature review from the Griffith Resource Library at the American College of Cardiology concerning coronary artery calcification measurement by fast computed tomography methods from 1998 through early 2005 (National Library of Medicine's Elhill System) was performed. Additional relevant prior or subsequently published references have also been identified by personal contacts of the Writing Committee members, and substantial efforts were made to identify all relevant manuscripts that were currently in press.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

At the first meeting, members of the Writing Committee were given assignments to provide descriptions and analyses of coronary artery calcium (CAC) measurement for identifying and modifying coronary event risk in the asymptomatic patient, for modifying the clinical care and outcomes of symptomatic patients suspected of having coronary artery disease (CAD), and for understanding the role of CAC measurement in selected patient subgroups.

Considerable discussion among the group focused on the best and most proper way to assess clinical appropriateness of tests such as CAC measurement since there have been no clinical trials to evaluate the impact of CAC testing on clinical outcomes in either symptomatic or asymptomatic patients. The Writing Committee agreed uniformly that the ideal assessment of cardiac tests would require clinical trials that utilize important patient outcomes such as improving the quality or quantity of a patient's life. However, recognizing that this standard is not available for CAC measurement, the Committee considered other standards of evidence in reaching a consensus opinion.

Two committee members evaluated the quality of each included report with the results of this analysis being included in Table 2 in the original guideline document. The quality assessment criteria included: 1) documentation of prospective data collection; 2) inclusion of self-referred patient series or from a

population sample; 3) reporting of coronary heart disease (CHD) events; 4) reporting of outcome data by gender and ethnicity; 5) sample size greater than 1000 individuals; 6) avoiding potential for limited challenge (i.e., an inclusion of very low to very high-risk patients resulting in a wide spread in the outcome results) by not reporting data within strata of clinical risk; 7) reporting measured versus historical or self-reported risk factor data; and 8) reporting univariable and multivariable prognostic models (i.e., ascertaining the incremental value of CAC scores). A review of the highlighted reports reveals that all studies identified for inclusion were of at least moderate-high quality.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Writing Committee consisted of acknowledged experts in the field of coronary artery disease. In addition to members of the American College of Cardiology Foundation (ACCF) and American Heart Association (AHA), the Writing Committee included representatives from the Society of Atherosclerosis Imaging and Prevention (SAIP) and Society of Cardiovascular Computed Tomography (SCCT).

This statement builds on a previous ACC/AHA Expert Consensus Document published in 2000 that focused on electron beam computed tomography for diagnosis and prognosis of coronary artery disease. In preparing the present document, the Writing Committee began with the previous report as a basis for its deliberations and subsequent literature review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-Effectiveness of Coronary Calcium Scoring for Risk Assessment of Cardiac Death or Myocardial Infarction (MI)

Establishing the cost-effectiveness of testing, especially screening tests, is quite challenging. To establish effectiveness, coronary artery calcium (CAC) measurement would have to be shown to enhance life, prolong life, or both. This task can be relatively straightforward with therapies for which there are randomized controlled clinical trials establishing efficacy in terms of quality of life, events, or mortality. These types of studies do not exist for CAC measurement, and in general do not exist for any cardiovascular test. Standards for cost-effectiveness analysis call for evaluating effects on survival, quality of life and cost using a lifetime time horizon. Even for therapies which have major clinical impact, such as lowering of low-density lipoprotein (LDL) cholesterol, and where the clinical trial data are consistent and convincing, this is challenging to accomplish. For a single test, which might be expected to have a smaller impact than a major

therapeutic strategy, establishing cost-effectiveness can be a difficult, if not unrealistic goal.

In the absence of clinical trial data, cost-effectiveness is generally approached with simulations in which decisions, test results, and outcomes are estimated, with as much information coming from the medical literature as possible. For tests, such as CAC measurement, simulations can be especially difficult because the test results can lead to many different possible decisions and thus many different potential outcomes. Furthermore, for evaluating any test or therapy, it is essential to understand the nature of the intervention and the comparators. In the case of CAC measurement, there are several possible ways to view how the test would affect care and outcome, and the comparators may not be clear.

Despite these challenges, there have been several attempts to assess the cost-effectiveness of CAC scoring. One set of researchers constructed a decision analytic model of the addition of CAC score to the Framingham Risk Score (FRS). The base case assumed that any CAC greater than 0 would increase the relative risk 4-fold. Multiple additional assumptions were made, some of which the Writing Committee members considered difficult to justify. The base case offered an incremental cost-effectiveness ratio (ICER) of $86,752 for a 42-year-old subject. The ICER was sensitive to the gain in life expectancy for early intervention, the utility of being at risk, and the added prognostic value of CAC. This study offers good insight into some of the problems in assessing the cost-effectiveness of CAC, but it is the judgment of the Writing Committee that it is not sufficiently grounded in data to be useful for medical decision making. The authors updated this analysis using the hazard ratio from the Prospective Army Coronary Calcium project, finding an ICER of $31,500. This conclusion was sensitive to variation in the extent to which CAC actually predicts events (sensitivity analysis) and to assumed degree of the efficacy of primary prevention strategies (in sensitivity analysis). Furthermore, there were only 9 coronary events used to establish the hazard ratios. The analysis is also limited by the assumptions in the model. Another set of researchers developed a similar decision-analytic model, finding that in individuals with estimated risk of coronary events below 0.6% per year, the ICER approached $500,000, but was $42,339 if the estimated event rate was 1% per year, and $30,742 if the event rate was 2% per year. This model was also highly dependent on the underlying assumptions, as is always the case for any cost-effectiveness model.

Summary and Conclusion

While several serious efforts to understand the cost-effectiveness of CAC measurement have been made, the Committee felt that models were not, and could not be, sufficiently well grounded in data to offer results that could be used for medical decision making or establishing policy at this time.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The document was reviewed by four official representatives from the American College of Cardiology Foundation (ACCF), and American Heart Association (AHA); organizational review by the Society of Atherosclerosis Imaging and Prevention (SAIP) and Society of Cardiovascular Computed Tomography (SCCT), as well as 14 content reviewers.

This document was approved for publication by the governing bodies of ACCF and AHA in September 2006. In addition, the governing boards of the SAIP and SCCT reviewed and formally endorsed this document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This document has updated information on coronary artery calcification (CAC) measurement with particular emphasis on data that have appeared since 2000 when the previous American College of Cardiology /American Heart Association Expert Consensus Document was published. In considering the data presented here, the Expert Consensus Committee felt that specific clinical examples should be highlighted and clinical recommendations linked to these examples for use by clinicians.

The following clinical scenarios were noted to be relevant to CAC measurement, and the Committee's consensus on these questions is noted.

1. **What is the role of coronary calcium measurement by coronary computed tomography (CT) scanning in asymptomatic patients with intermediate coronary heart disease (CHD) risk (between 10% and 20% 10-year risk of estimated coronary events)?**

   The Committee judged that it may be reasonable to consider use of CAC measurement in such patients based on available evidence that demonstrates incremental risk prediction information in this selected (intermediate risk) patient group. This conclusion is based on the possibility that such patients might be reclassified to a higher risk status based on high CAC score, and subsequent patient management may be modified.

2. **What is the role of coronary calcium measurement by CT scan in patients with low CHD risk (below 10% 10-year risk of estimated CHD events)?**

   The Committee does not recommend use of CAC measurement in this selected patient group. This patient group is similar to the "population screening" scenario, and the Committee does not recommend screening of the general population using CAC measurement.

3. **What is the role of coronary calcium measurement by fast CT scan in asymptomatic patients with high CHD risk (greater than 20% estimated 10-year risk of estimated CHD events, or established coronary disease, or other high-risk diagnoses)?**

The Committee does not advise CAC measurement in this selected patient stratum as they are already judged to be candidates for intensive risk reducing therapies based on current National Cholesterol Education Program guidelines.

4. **Is the evidence strong enough to reduce the treatment intensity in patients with calcium score = 0 in patients who are considered intermediate risk before coronary calcium score?**

   No evidence is available that allows the Committee to make a consensus judgment on this question. Accordingly, the Committee felt that current standard recommendations for treatment of intermediate risk patients should apply in this setting.

5. **Is there evidence that coronary calcium measurement is better than other potentially competing tests in intermediate risk patients for modifying cardiovascular disease risk estimate?**

   In general, CAC measurement has not been compared to alternative approaches to risk assessment in head-to-head studies. This question cannot be adequately answered from available data.

6. **Should there be additional cardiac testing when a patient is found to have high coronary calcium score (e.g., CAC greater than 400)?**

   Current clinical practice guidelines indicate that patients classified as high risk based on high risk factor burden or existence of known high-risk disease states (e.g., diabetes) are regarded as candidates for intensive preventive therapies (medical treatments). There is no clear evidence that additional non-invasive testing in this patient population will result in more appropriate selection of treatments.

7. **Is there a role of CAC testing in patients with atypical cardiac symptoms?**

   Evidence indicates that patients considered to be at low risk of coronary disease by virtue of atypical cardiac symptoms may benefit from CAC testing to help in ruling out the presence of obstructive coronary disease. Other competing approaches are available, and most of these competing modalities have not been compared head-to-head with CAC.

8. **Can coronary calcium data collected to date be generalized to specific patient populations (women, African American men)?**

   CAC data are strongest for Caucasian, non-Hispanic men. The Committee recommends caution in extrapolating CAC data derived from studies in white men to women and to ethnic minorities.

9. **What is the appropriate follow-up when an incidental finding in the lungs or other non-cardiac tissues is found on a fast coronary CT study?**

Current radiology guidelines should be considered when determining need for follow-up of incidental findings on a fast CT study, such as that which was recently published to guide follow-up of small pulmonary nodules (MacMahon et al., 2005).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of coronary artery calcium (CAC) scoring by computed tomography for global cardiovascular risk assessment and evaluation of patients with chest pain

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document has been developed as a Clinical Expert Consensus Document (CECD), by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) in collaboration with the Society of Atherosclerosis Imaging and Prevention (SAIP) and Society of Cardiovascular Computed Tomography (SCCT). It is intended to provide a perspective on the current state of the role of coronary artery calcium (CAC) scoring by fast computed tomography in clinical practice. Clinical Expert Consensus Documents are intended to inform practitioners, payers, and other interested parties of the opinion of the ACCF and AHA concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Topics chosen for coverage by expert consensus documents are so designed because the evidence base, the experience with technology, and/or the clinical practice are not considered sufficiently well developed to be evaluated by the formal American

College of Cardiology/American Heart Association (ACC/AHA) Practice Guidelines process. Often the topic is the subject of considerable ongoing investigation. Thus, the reader should view the CECD as the best attempt of the ACC and AHA to inform and guide clinical practice in areas where rigorous evidence may not yet be available or the evidence to date is not widely accepted.

Data Quality Issues

A lack of rigor in study methodology was a focus of the 2000 American College of Cardiology document. Evaluation of more recent publications indicates that some of the important methodological limitations of earlier reports have been addressed. Notably, more recent publications report the independent prognostic value of CAC in multivariable models including measured risk factor data. Larger sample sizes have also resulted in improved precision in risk prediction models. However, issues of selection or referral bias when using patient cohorts remain pertinent and are likely to have resulted in an overestimation of risk when based on clinical cohorts as compared with population samples. It is important to recognize that relative risk ratios from patient cohorts have generally been higher than from studies conducted in population samples even when the overall direction of the prognostic findings has been concordant.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Greenland P, Bonow RO, Brundage BH, Budoff MJ, Eisenberg MJ, Grundy SM, Lauer MS, Post WS, Raggi P, Redberg RF, Rodgers GP, Shaw LJ, Taylor AJ, Weintraub WS, American College of Cardiology Foundation Clinical Expert Consensus Task, Society of Atherosclerosis Imaging and Prevention, Society of Cardiovascular Computed Tomography. ACCF/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global

cardiovascular risk assessment and in evaluation of patients with chest pain. J Am Coll Cardiol 2007 Jan 23;49(3):378-402. [115 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2007 Jan 23)

GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association

SOURCE(S) OF FUNDING

The American College of Cardiology Foundation and the American Heart Association

GUIDELINE COMMITTEE

Writing Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Writing Committee Members: Philip Greenland, MD, FACC, FAHA (Chair); Robert O. Bonow, MD, FACC, FAHA; Bruce H. Brundage, MD, MACC, FAHA; Matthew J. Budoff, MD, FACC, FAHA; Mark J. Eisenberg, MD, MPH, FACC; Scott M. Grundy, MD, PHD; Michael S. Lauer, MD, FACC, FAHA; Wendy S. Post, MD, MS, FACC; Paolo Raggi, MD, FACC; Rita F. Redberg, MD, MSC, FACC, FAHA; George P. Rodgers, MD, FACC; Leslee J. Shaw, PHD; Allen J. Taylor, MD, FACC, FAHA; William S. Weintraub, MD, FACC

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American Heart Association and American College of Cardiology make every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task

force, reported orally to all members of the writing panel at the first meeting, and updated as changes occur.

Table: Writing Group Disclosures

Name	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder	Other
Dr. Philip Greenland (Chair)	None	None	None	None	None	None	
Dr. Robert O. Bonow	None	None	None	None	None	None	
Dr. Bruce H. Brundage	None	None	None	None	None	None	
Dr. Matthew J. Budoff	None	None	None	General Electric	None	None	
Dr. Mark J. Eisenberg	None	None	None	None	None	None	
Dr. Scott M. Grundy	None	None	None	None	None	None	
Dr. Michael S. Lauer	None	None	None	None	None	None	
Dr. Wendy S. Post	None	• Novartis • Pfizer • Merck	None	None	None	None	Honoraria: Merck; Pfizer; Wyeth
Dr. Paolo Raggi	None	None	None	None	None	None	
Dr. Rita F. Redberg	None	None	None	None	None	None	
Dr. George P. Rodgers	Biophysical	None	Scientific Advisory Council	None	None	Biophysical	
Dr. Leslee J. Shaw	None	General Electric/ Amersham	None	None	None	None	
Dr. Allen J. Taylor	None	None	None	None	None	None	
Dr. William S. Weintraub	None	None	None	None	None	None	

Note: This table represents the relationships of committee members with industry that were reported orally at the initial writing committee meeting and updated in conjunction with all meetings and

conference calls of the writing committee during the document development process. It does not necessarily reflect relationships with industry at the time of publication.

Table: Peer Reviewers' Disclosures

Name	Representation	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau
Dr. John R. Crouse, III	Official Reviewer— AHA	None	None	None	None
Dr. Kim A. Eagle	Official Reviewer— ACCF Board of Trustees	• Robert Wood Johnson Foundation • Sanofi-Aventis • NHBLI	• Pfizer • NIH • Bristol-Myers Squibb • Biosite • Cardiac Sciences • Blue Cross Blue Shield of Michigan	None	None
Dr. Kendrick Shunk	Official Reviewer— AHA	None	None	None	None
Dr. Richard F. Wright	Official Reviewer— ACCF Board of Governors	None	None	None	None
Dr. Daniel S. Berman	Content Reviewer— Individual Reviewer	Tyco-Mallinckroot	• Bristol-Myers Squibb • Astellas • General Electric	Spectrum Dynamics	None
Dr. John J. Carr	Content Reviewer— Individual Reviewer	None	None	None	None
Dr. Daniel Edmundowicz	Content Reviewer— Individual Reviewer	None	None	None	None
Dr. Robert Detrano	Content Reviewer— Individual Reviewer	None	None	None	None
Dr. Victor A. Ferrari	Content Reviewer— Individual Reviewer	None	• GlaxoSmithKline • Novartis	None	None
Dr. Thomas C. Gerber	Content Reviewer—AHA Cardiac Imaging Committee	None	None	None	None
Dr. Maleah	Content	None	None	None	None

Name	Representation	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau
Grover McKay	Reviewer—ACCF Imaging Committee				
Dr. George T. Kondos	Content Reviewer—Individual Reviewer	None	None	None	None
Dr. Joao A. Lima	Content Reviewer—Individual Reviewer	None	• Toshiba • General Electric/ Amersham	None	• Toshiba • General Electric/ Amersha
Dr. Christopher M. Kramer	Content Reviewer—ACCF Imaging Committee	GE Healthcare	• Astellas • Novartis	None	GE Healthcare
Dr. Chris O'Donnell	Content Reviewer—Individual Reviewer	None	None	None	None
Dr. Kim Allan Williams	Content Reviewer—ACCF Imaging Committee	GE Healthcare	• Bristol-Myers Squibb • CV Therapeutics	GE Healthcare	• GE Healthca • Astellas

Note: This table represents the relationships of committee members with industry that were reported by the authors as relevant to this topic. It does not necessarily reflect relationships with industry at the time of publication. Participation in the peer review process does not imply endorsement of the document. Names are listed in alphabetical order within each category of review.

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This guideline updates a previous version: O'Rourke RA, Brundage BH, Froelicher VF, et al. American College of Cardiology/American Heart Association expert consensus document on electron-beam computed tomography for the diagnosis and prognosis of coronary artery disease. J Am Coll Cardiol 2000;36:326–40.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology (ACC) Web site, and from the American Heart Association (AHA) Web site.

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 8, 2007. The information was verified by the guideline developer on July 11, 2007.

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