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Journal

Journal of Thoracic Imaging, 32(5)

ISSN

0883-5993

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Publication Date

2017-09-01

DOI

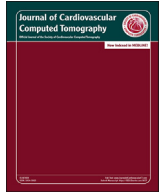
10.1097/rti.0000000000000287

Peer reviewed



Contents lists available at ScienceDirect

Journal of Cardiovascular Computed Tomography

journal homepage: www.JournalofCardiovascularCT.com

Guidelines

2016 SCCT/STR guidelines for coronary artery calcium scoring of noncontrast noncardiac chest CT scans: A report of the Society of Cardiovascular Computed Tomography and Society of Thoracic Radiology

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ARTICLE INFO

Article history:

Received 26 October 2016

Accepted 9 November 2016

Available online xxx

Keywords:

Coronary artery disease

Coronary artery calcium

Computed tomography

ABSTRACT

The Society of Cardiovascular Computed Tomography (SCCT) and the Society of Thoracic Radiology (STR) have jointly produced this document. Experts in this subject have been selected from both organizations to examine subject-specific data and write this guideline in partnership. A formal literature review, weighing the strength of evidence has been performed. When available, information from studies on cost was considered. Computed tomography (CT) acquisition, CAC scoring methodologies and clinical outcomes are the primary basis for the recommendations in this guideline. This guideline is intended to assist healthcare providers in clinical decision making. The recommendations reflect a consensus after a thorough review of the best available current scientific evidence and practice patterns of experts in the field and are intended to improve patient care while acknowledging that situations arise where additional information may be needed to better inform patient care.

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1. Preamble

It is essential for the medical profession to play a central role in the critical evaluation and appraisal of the best available evidence for disease diagnosis. Appropriately applied, thorough expert analysis of available data on diagnostic testing can inform physician decision making, improve patient outcomes and reduce costs. Such a data review can be used to produce clinical practice recommendations which can then guide clinical practice.

According to World Health Organization statistics cardiovascular disease is the most frequent cause of death globally, with an estimated 17.5 million people dying from cardiovascular disease in 2012, representing 31% of all global deaths. Of these deaths, an

estimated 7.4 million were due to coronary heart disease. The prevalence of coronary artery disease and lung cancer have both seen dramatic increases, partly attributable to changing dietary patterns, obesity, tobacco use and aging of the population.¹ This has occurred in the developed world and is occurring in the developing world where there are limited resources for healthcare. Coronary artery calcium (CAC), quantified on ECG-gated CT examinations without using intravenous contrast material, is the most robust predictor of CAD events in the asymptomatic primary prevention population, particularly in those with an intermediate-risk.² The predictive value of CAC is superior to the exclusive use of the Framingham Risk Score³ and the 2013 ACC/AHA Pooled Cohort Equations.⁴ The algorithms proposed in the 2016 European Society of Cardiology Guidelines on Cardiovascular Disease Prevention in Clinical Practice⁵ have not yet been evaluated in comparison to CAC.

Traditionally, ECG-gated CT non-contrast CT has been used for

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Abbreviations

ACC/AHA	American College of Cardiology/American Heart Association
CAC	Coronary artery calcium
CAD	Coronary artery disease
CT	Computed tomography
ECG	Electrocardiograph
FRS	Framingham risk score
LDCT	Low dose CT
MESA	Multi-Ethnic Study of Atherosclerosis
MDCT	Multidetector CT
NCCT	Noncontrast CT
NLST	National Lung Screening Trial
SCCT	Society of Cardiovascular Computed Tomography
SDM	Shared decision making
STR	Society of Thoracic Radiology.

the assessment of coronary calcium, CAC can also be detected and quantified on nongated chest CT examinations, including low radiation dose CT examinations acquired for lung cancer screening. Several analytic approaches have been employed for measurement and reporting. CAC scoring of non-gated examinations has been shown to correlate well with scores obtained from traditional ECG-gated scans. Ordinal scoring based on a semi-quantitative analysis has correlated well with CAD outcomes. A CAC score can potentially be reported from the approximately 7.1 million annual diagnostic noncontrast CT (NCCT) examinations performed annually in the United States.⁶ There will potentially be another 7–10 million low dose screening chest CT examinations per year if lung cancer screening reaches the individuals at risk for lung cancer, as defined by the 2014 U.S. Preventive Services Task Force statement⁷ which mandates coverage by third party payors under the terms of the Affordable Care Act, and the subsequent 2015 Center for Medicare & Medicaid Services coverage decision for this service.⁸ Using standard risk factor based paradigms, the majority of the high risk, older, current and former heavy smokers for whom lung cancer CT screening is recommended have an intermediate to high risk for coronary artery disease (Fig. 1).⁹

The purpose of this joint guideline from the Society of Cardiovascular Computed Tomography and the Society of Thoracic Radiology is to endorse the reporting of CAC on all NCCT examinations as the appropriate standard of care, to increase awareness of the prognostic importance of CAC among physicians ordering CT irrespective of the physician's specialty, and to develop risk classifications that may be included in the CT report. Formal recommendations for management, similar to the lung cancer CT screening abnormalities using Lung-RADS^{TM10} will be part of forthcoming SCCT Expert Consensus and CAC-RADS documents.

The Society of Cardiovascular Computed Tomography (SCCT) and the Society of Thoracic Radiology (STR) have jointly produced this document. Experts in this subject have been selected from both organizations to examine subject-specific data and write this guideline in partnership. A formal literature review, weighing the strength of evidence has been performed. When available, information from studies on cost was considered. Computed tomography (CT) acquisition, CAC scoring methodologies and clinical outcomes are the primary basis for the recommendations in this guideline.

This guideline is intended to assist healthcare providers in clinical decision making. The recommendations reflect a consensus after a thorough review of the best available current scientific

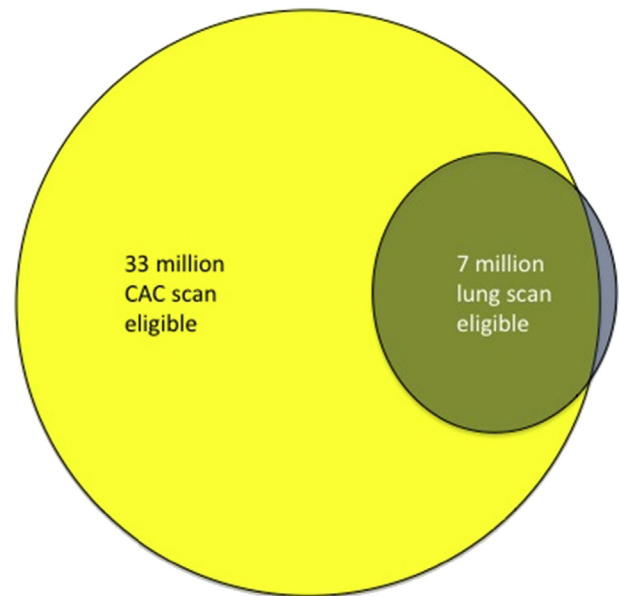


Fig. 1. United States estimates, and overlap, of CAC and lung scan eligible patients. The number of eligible patients in the United States is estimated at 33 million for CAC scanning (orange)⁶ and 7 million for lung scanning (yellow).²⁷ Excluding lung scan eligible patients who have established coronary disease (5.3%, unpublished data from the I-ELCAP database) yields an overlap of 6.6 million lung scan patients who would be expected to benefit from CAC scanning. Reprinted with permission of Oxford University Press from Hecht HS, Henschke CI, Yankelevitz D, Fuster V, Narula J. Combined Detection of Coronary Artery Disease and Lung Cancer. *Eur Heart J* 2014; 35:2792–6.

evidence and practice patterns of experts in the field and are intended to improve patient care while acknowledging that situations arise where additional information may be needed to better inform patient care.

The SCCT and STR have made every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the authors. Authors were asked to disclose all current and prior relationships that may be perceived as relevant prior to initiation of the review and its resulting manuscript. Relationships with industry (RWI) and potential conflicts of interest (COI) pertinent to this guideline for authors are disclosed in Appendixes 1.

1.1. Evidence supporting CAC for risk assessment

Multiple algorithms have been proposed to help clinicians identify who is, and who is not, at high risk for CAD. Framingham risk scores (FRS), Pooled Cohort Equations, Reynolds risk score, highly sensitive C-reactive protein (hs-CRP), carotid intima media thickness (CIMT) and CAC are among the various measures that can be used for risk stratification of cardiovascular disease among asymptomatic population.^{3,11} Of all the proposed tests, the CAC score has emerged as the strongest risk prediction tool.² It represents calcific atherosclerosis in the coronary arteries and correlates well with the overall burden of coronary atherosclerosis.

The FRS was the most commonly used cardiovascular risk stratification tool in the general population due to its ease of use, but has been replaced by the 2013 ACC/AHA Cholesterol Guidelines Pooled Cohort Equations.⁴ However, both are probabilistic equations derived from populations, and, therefore, have limited accuracy for risk assessment in the individual. Because CAC can be considered a measure of the disease, it presents the opportunity to intervene with lifestyle changes, statins, and aspirin.

The prognostic value of CAC testing been well validated in

multiple studies, including Dallas Heart¹² Rotterdam,¹³ St Francis,¹⁴ Multi-Ethnic Study of Atherosclerosis (MESA)¹⁵ and the Heinz-Nixdorf Recall¹⁶ among others. CAC has been shown to be the best predictor of future events in the general population,^{13–15} the elderly,^{13,17} and in persons with diabetes.¹⁸ It provides more robust risk prediction than carotid IMT, C-reactive protein, ankle-brachial index, and family history of premature heart disease.¹⁹ Incorporating CAC into the Multi-Ethnic Study of Atherosclerosis (MESA) clearly improves risk stratification and discrimination over scores based on chronologic age.²⁰

CAC has been shown to better identify those asymptomatic individuals who would benefit from statins,²¹ aspirin,²² ACE inhibitors²³ or the polypill²⁴ than risk calculators or other biomarkers. Recently, a study demonstrated that a CAC score of 0 confers a low risk of mortality over a period of 15 years in individuals estimated to be at low to intermediate FRS risk and over a 5-year low risk period in individuals at high FRS risk, unaffected by age or sex.²⁵ Two prominent studies have shown that using CAC testing is more cost effective than the current widespread statin use that is advocated by the ACC/AHA pooled cohort equations or “treat all” strategies.²⁶ It has outperformed risk factor based paradigms such as the Framingham Risk Score (FRS),³ the European Society of Cardiology Score⁴ and the 2013 AHA/ACC Pooled Cohort Equations,⁵ and, in 3 prospective, population-based outcome trials demonstrated an extremely high net reclassification index (NRI) of the FRS, ranging from 52% to 66% in the intermediate risk group.^{16,27,28}

The inclusion of CAC in guidelines is summarized in Table 2. Formal recognition of the power of CAC occurred in 2010,¹⁰ with its inclusion in the ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults with a strong class IIa (reasonable to perform) status for intermediate risk patients. CAC measurement was categorized as reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate Framingham risk, and all diabetic patients 40 years or older.¹¹ The 2010 Appropriate Use Criteria deemed CAC appropriate for intermediate risk patients and for low risk individuals with a family history of premature disease.³⁰ Subsequently, the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults assigned a class IIb (may be considered) recommendation to CAC, and recommended its use in patients in

whom the Pooled Cohort Equation risk decision was unclear.⁴ The 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk stated that CAC was “likely to be the most useful of the current approaches to improving risk assessment among individuals found to be at intermediate risk after formal risk assessment.”³¹ The 2016 European Society of Cardiology Guidelines on Cardiovascular Disease Prevention in Clinical Practice also issued a class IIb recommendation for CAC to risk stratify asymptomatic individuals.⁵

In addition to early detection, patient viewing of the CAC scan has been shown to increase adherence to statin and ASA treatment, to diet and exercise^{32–34} and to improve lipids, BP and weight.³⁵ Since treatment of high risk patients with statins improves their outcomes,³⁶ and CAC accurately detects high risk patients, one could project that the reduction in events could be expected to be as high as 30% based on primary prevention trials.³⁶ A randomized controlled outcome trial of CAC in 39,000 asymptomatic patients, the ROBINS (Risk Or Benefit In Screening for Cardiovascular Disease Risk)³⁷ trial, has recently been implemented in Holland, and may address lingering questions.

1.2. Rationale for CAC scoring of NCCT

The American College of Radiology indications for lung CT scanning are numerous and span the entire gamut of pathology within the thorax (Table 1).³⁸ The work of the International Early Lung Cancer Action Program (IELCAP)³⁹ combined with the only large scale randomized trial of sufficient size to demonstrate a mortality benefit from CT, the National Lung Screening Trial (NLST),⁴⁰ and demonstration of cost effectiveness comparable to other screening tests⁴¹ led to the recognition of low dose CT scanning as an appropriate screening test by the US Preventative Services Task Force in 2014. The Grade B recommendation, that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial, was designated for annual low dose chest CT in individuals at high risk for lung cancer based on age and smoking history, defined as a 30 pack-year or more history of smoking in subjects age 55–79 years who are either current smokers, or former smokers who quit within the past 15 years.⁶ Similar but not identical endorsements had been provided earlier by the National Comprehensive Cancer Network,⁴² the American College of Chest Physicians and the American Society for Clinical

Table 1
American college of radiology indications and performance guidelines.

A. Indications for Lung CT Scans

- 1 Evaluation of abnormalities discovered on chest images.
- 2 Evaluation of clinically suspected cardiothoracic pathology.
- 3 Staging and follow-up of lung cancer and other primary thoracic malignancies, and detection and evaluation of metastatic disease.
- 4 Evaluation of cardiothoracic manifestations of known extrathoracic diseases.
- 5 Evaluation of known or suspected thoracic cardiovascular abnormalities (congenital or acquired), including aortic stenosis, aortic aneurysms, and dissection.
- 6 Evaluation of suspected acute or chronic pulmonary emboli.
- 7 Evaluation of suspected pulmonary arterial hypertension.
- 8 Evaluation of known or suspected congenital cardiothoracic anomalies.
- 9 Evaluation and follow-up of pulmonary parenchymal and airway disease.
- 10 Evaluation of blunt and penetrating trauma.
- 11 Evaluation of postoperative patients and surgical complications.
- 12 Performance of CT-guided interventional procedures.
- 13 Evaluation of the chest wall.
- 14 Evaluation of pleural disease.
- 15 Treatment planning for radiation therapy.
- 16 Evaluation of medical complications in the intensive care unit or other settings.

B. Performance Guidelines for Lung CT Scans

- 1 Multirow detector acquisition.
- 2 Scan rotation time: ≤ 1 sec.
- 3 Acquired slice thickness: ≤ 2 mm.
- 4 Limiting spatial resolution: ≥ 8 lp/cm for ≥ 32 -cm display field of view (DFOV) and ≥ 10 lp/cm for < 24 cm DFOV.

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Oncology,⁴³ the American Cancer Society,⁴⁴ the American Association for Thoracic Surgery and the Society of Thoracic Surgeons⁴⁵ and the American Lung Association⁴⁶ (Table 2). The NLST, with 53,454 high-risk participants who received three rounds of either CT or chest radiography screening with 5–7 years of follow-up, was terminated after the CT arm reduced mortality by 20% compared to the radiographic group. Confirmation of the NLST findings is underway in 7 individually smaller European randomized trials which collectively are expected to encompass 37,000 patients.

While NCCT examinations are performed in patients of all ages and CAD risk categories, lung cancer screening patients are almost all at intermediate to high risk for CAD by virtue of their age and smoking history, in addition to the increasing prevalence of risk factors with increasing age, and are an especially fertile cohort for CAD assessment (Fig. 1). However, since the CAC information is always in the field of view and analysis is simple and quick, reporting CAC on every NCCT examination is appropriate. Due to inconsistent insurance coverage for CAC scanning, some patients at risk for CAD are not able to benefit from dedicated ECG-gated CAC evaluation outside of the lung cancer screening CT.

Until recently, there was no specific recommendation for the reporting of CAC on NCCT examinations or for the preferred methods of analysis, and there are very few studies evaluating the extent of the underreporting. CAC was present in 58% of the non-gated noncontrast CT examinations in 355 patients with known or suspected CAD. Of these, 44% were not reported. Only 1 of 139 patients with left main CAC and 6 of 188 patients with left anterior descending CAC were mentioned.⁴⁷ In a second study, the presence of any CAC was noted by expert reader interpretation in 108 of 201 (53%) NCCT examinations in patients without suspected CAD. However, only 69% of the 108 positive scans were described in the CT report.⁴⁸

In 2016, the American College of Radiology National Radiology Data Registry's Lung Cancer Screening Registry (ACR NRDR LCSR) was approved by the Centers for Medicare and Medicaid Services (CMS) to enable providers to meet quality reporting requirements to receive Medicare CT lung cancer screening payment and will monitor physician and facility performance quality and provide

comparisons and develop benchmarks.⁴⁹ It remains the only CMS approved registry. A required field of the registry form is the reporting of "coronary artery calcification, moderate or severe" (Fig. 2). One of the goals of the current guideline is to extend this to all NCCT examinations and to provide more specific recommendations.

2. Site requirements

The universal requirement for performing NCCT is to use the least amount of radiation needed to reasonably obtain the diagnostic information needed. Hence, there are many different non-gated, non-contrast CT protocols available that address different clinical scenarios ranging from interstitial and obstructive lung disease and lung nodule evaluation to cancer follow up and NCCT examinations to evaluate a variety of thoracic symptoms and even aortic size in patients who have contraindications to iodinated contrast material. The requirements for these can vary greatly, depending on the indication and the specific make and model of the respective CT scanner. Each facility should acquire at least 360 CT examinations in the past 36 months by a board certified radiologist.

2.1. Equipment

NCCT can be performed to modern standards on a vast variety of CT scanners. In the United States today the great majority of these will be multidetector CT (MDCT) scanners with at least 8 detector rows. For non-gated NCCT examinations there is no requirement for an intravenous contrast power injector, ECG leads, cardiac monitoring equipment or cardiac gating software and hardware. All equipment must meet state and federal requirements and ACR or equivalent technical standards and practice guidelines.⁵⁰

2.2. Acquisition and reconstruction

The American Association of Physicists in Medicine (AAPM) created a Working Group on Standardization of CT Nomenclature

Table 2
Guidelines and appropriateness criteria.

A. Low Dose Lung Scan			
	Age	Pack Years	Within past
National Comprehensive Cancer Network (39)	50–74	≥30	15 years
		≥20 with additional risk factor	15 years
American College of Chest Physicians and American Society for Clinical Oncology (43)	55–74	≥30	15 years
American Cancer Society (44)	55–74	≥30	15 years
American Association for Thoracic Surgery (45)	55–79	≥30	15 years
	50–79	≥20 with 5% 5 year risk	15 years
American Lung Association (46)	55–74	≥30	15 years
United States Preventive Services Task Force (7)	55–79	≥30	15 years
B. Coronary Artery Calcium			
	Population		Recommendation
2009 USPSTF (29)	NA		c
2010 ACC/AHA Risk Guidelines (11)	10–20% intermediate risk		Ila
	Diabetics >40 yo		Ila
	6–10% low to intermediate risk		Ilb
2010 Appropriate Use Criteria (30)	10–20% intermediate risk		Appropriate
	Low risk with family history of premature coronary disease		Appropriate
	High risk		Uncertain
	Low risk		Inappropriate
2013 ACC/AHA Cholesterol and Risk Guidelines (4, 31)	Uncertain risk after Pooled Cohort Equations		Ilb
2016 ESC Cardiovascular (4) Disease Prevention Guideline	Around the 5% or 10% SCORE threshold		m

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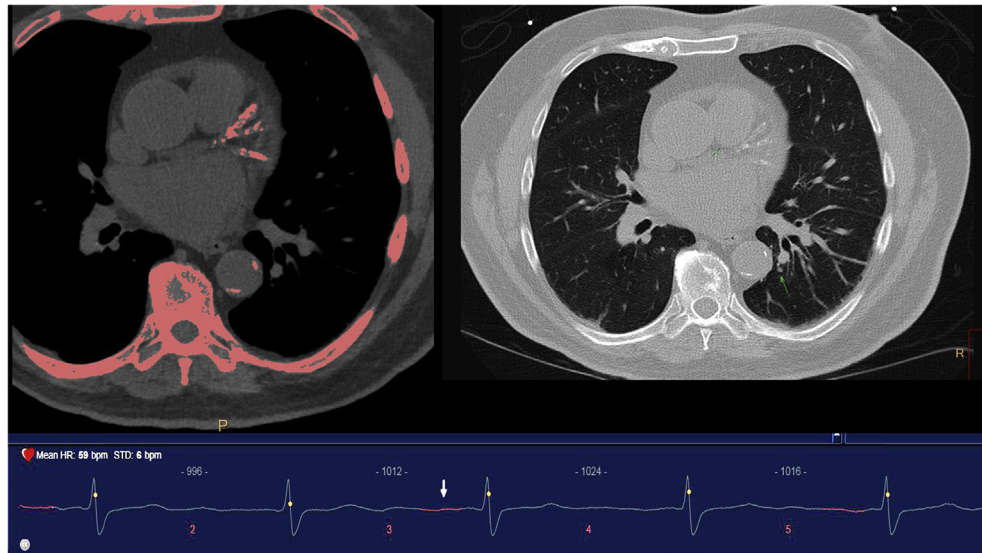


Fig. 2. American College of Radiology National Radiology Data Registry- Lung Cancer Screening Registry (ACR NRDR-LCSR).

and Protocols in 2010, which later was renamed “Alliance for Quality Computed Tomography Working Group”. The task for this group was to develop a set of consensus reference CT protocols for common CT indications for each of the CT manufacturer’s models to aid sites performing CT in creating and maintaining reasonable and appropriate CT protocols for specified indications.⁵¹ The acquisition parameters for these various combinations of scans and make/models are detailed on the AAPM Alliance for Quality Computed Tomography Working Group web page and are updated periodically and hence are not repeated here.⁵¹ Nonetheless, the following require emphasis:

2.2.1. Scanner, slice thickness, mAs and kVp

CAC has always been analyzed with 2.5 or 3 mm slice thickness, 120 kVp, and mAs varying with patient body habitus. NCCT is routinely performed with ≤ 2 mm slice thickness with similar kVp and mAs as CAC scanning. For CAC analysis the studies must be reconstructed to either 2.5 or 3 mm slice thickness to provide scores comparable to the CAC database. Gated and nongated acquisitions are illustrated in Figs. 3 and 4.

2.2.2. Reconstruction algorithms

The standard of care for both CAC and lung nodule evaluation remains filtered back projection. It is reasonable to continue to employ filtered back projection except in centers that have validated iterative or model based reconstruction algorithms, as is the case for iterative reconstruction of CAC studies acquired at lower radiation doses.⁵²

2.3. Staff

All technologists, physicists and supervising and interpreting physicians involved in the operation of a CT practice must meet minimum requirements for accreditation. The physician interpreting NCCT examinations should be certified by the American Board of Radiology, and must have document interpretation and reporting of 300 CT examinations in the past 3 years.⁵³ Alternatively, the physician must have completed a certified residency program and have interpreted 500 CT examinations in three years. For low dose CT (LDCT) screening examinations the interpreting radiologist should have supervised and interpreted at least 300

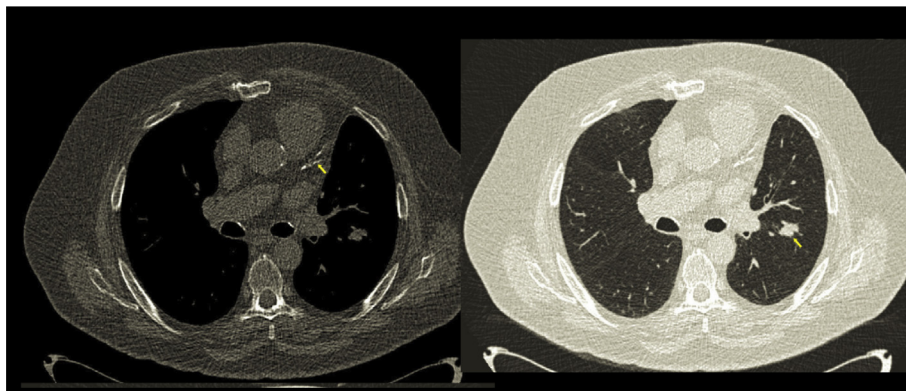


Fig. 3. Combined gated heart and lung scan. A 65 year old asymptomatic male smoker with 40 pack year history and hyperlipidemia underwent combined scanning. Images were prospectively acquired in a step and shoot mode on a 256 slice scanner at 120kV and 25 mAs, with 3 mm slice thickness and radiation exposure of 0.95 mSv. Left: Calcium scan demonstrating extensive calcified coronary plaque in the left coronary artery (pink). The total Agatston calcium score was 1467. Right: Lung window reconstruction reveals a 3mm left lower lobe nodule (green arrow) Bottom: EKG gating signal (yellow dot on R wave). Reprinted with permission of Oxford University Press from Hecht HS, Henschke CI, Yankelevitz D, Fuster V, Narula J. Combined Detection of Coronary Artery Disease and Lung Cancer. Eur Heart J 2014; 35:2792–6.

7A15. *Other clinically significant or potentially significant abnormalities – CT exam result modifier S:	☐ No If yes, what were the other findings? (Select all that apply.)	☐ Yes	
	☐ Aortic aneurysm	☐ Coronary arterial calcification, moderate or severe	☐ Pulmonary fibrosis
	☐ Mass, please specify, e.g., neck, mediastinum, liver, kidneys: _____		
	☐ Other interstitial lung disease, select type if known:		
	☐ UIP/IPF		
	☐ ILD, other, please specify: _____		
☐ ILD, unknown			

Fig. 4. Combined nongated heart and lung scan. A 60 year old asymptomatic male smoker with 35 year pack history underwent combined scanning. Images were acquired at 120 kVp, 25 mAs with a radiation exposure of 0.8 mSv. Left: Nongated calcium scan demonstrating extensive calcified coronary plaque (arrow). The total Agatston score was 823. Right: Lung window reconstruction reveals a left lower lobe mass (arrow) subsequently diagnosed as adenocarcinoma. Reprinted with permission of Oxford University Press from Hecht HS., Henschke CI, Yankelevitz D, Fuster V, Narula J. Combined Detection of Coronary Artery Disease and Lung Cancer. *Eur Heart J* 2014; 35:2792–6.

chest CT examinations in the past 36 months. Additionally, the physician must meet continuing experience and continuing education criteria set forth by the ACR or equivalent society. These requirements include among others Maintenance of Certification (MOC) and continuing medical education (CME) requirements.

The radiologic technologist must be state licensed and registered with The American Registry of Radiologic Technologists (ARRT) and be CT certified or equivalent, and have documented experience in CT. CT certification via ARRT is a *post primary* certification that follows a primary certification in Radiography, Nuclear Medicine, or Radiation Therapy.⁵³ Alternatively or additionally, the technologist may be certified by the Nuclear Medicine Technology Certification Board (NMTCB)⁵⁴ and have documented training and experience in operating CT equipment and radiation physics and protection. It is recommended that the technologists have passed an advanced examination for CT certification.

The physicist should be certified in Diagnostic Radiological/Imaging Physics or Radiological Physics by the ABR or the American Board of Medical Physics the Canadian College of Physicists in Medicine. Alternatively, the physicist may have documented coursework in the biological sciences including courses in biology or radiation biology, and anatomy, physiology, or similar topics related to the practice of medical physics, and have at least 3 years of documented experience in a clinical CT environment, or have conducted surveys of at least 3 CT units between January 1, 2007 and January 1, 2010. The physicist must meet continuing experience and continuing education criteria as stipulated by the ACR and others for site accreditation.

2.4. Quality assurance

Quality control (QC) includes a number of measures that are designed to ensure that optimal imaging parameters are consistently utilized, and that protocols are not corrupted over time and keep up with the latest guidelines and recommendations. Tools for quality control and quality assurance are described by several professional societies and institutions, including, but not limited to the ACR, the IAC CT (formerly ICACTL), and the AAPM.^{50,51,53} These methods include phantom scanning, dose measurements, protocol review, and submission of imaging data to accrediting organizations. QC has to be performed continuously under supervision of a qualified physicist and mandates annual CT performance evaluation. The continuous QC includes daily water CT number and standard deviation measurements and Artifact Evaluation, monthly visual checklists and display monitor quality control. The annual survey includes review of clinical protocols, scout prescription, image thickness and radiation beam width measurements, accuracy of table travel, alignment light, and CT numbers, low-contrast performance and dosimetry, and other tests as mandated by state or other regulations.⁵⁵

Local policies and procedures have to be in place for *Quality assurance* (QA) and quality outcomes improvement. QA typically involves systematic physician peer review. This process involves double reading of a randomly selected set of cases, which includes an assessment of level of agreement and quality concerns. Summary statistics for the institution and for each physician are to be obtained and reviewed. Policies and procedures should be in place defining the actions to be taken in the case of significant discrepancies in the peer review findings.⁵⁰

3. Patient selection

Is it necessary to report CAC on all patients undergoing a NCCT examination or should it be restricted to those who would be candidates for CAC screening by guidelines? The inclusion criteria for CAC scanning of asymptomatic patients referred for risk assessment are based upon risk-status and have focused on intermediate and low-intermediate cardiac risk assessment categories as well as persons with diabetes. Those at very low risk and those at very high risk have not been considered ideal candidates, since the results of the calcium scan will change their risk status less often (12–16% for low risk, and 34% for high risk) than for intermediate risk patients (56%).^{16,27,28} However, since the information is in every scan irrespective of the indication for the NCCT examination, it appears prudent to report it irrespective of the scan indication. The usual concepts of inclusion and exclusion criteria do not apply since cardiac risk assessment is never the primary indication for a NCCT examination.

4. Patient preparation

Non gated non-contrast CT acquisitions do not require much patient preparation compared to most other CT indications. Unless performed in conjunction with a contrast enhanced CT, no intravenous access is required. Rarely is a combined non-contrast and contrast enhanced thoracic CT examination indicated.⁵⁶ Oral contrast is usually not required, but may be used in cases where the abdomen and pelvis is also interrogated. Unlike ECG-gated CT angiography, no premedication is required and no ECG leads need to be placed on the patient's chest. All unnecessary radiopaque material is usually removed from the thorax and the patient is positioned supine on the table. Bismuth breast shields are not recommended, following the 2012 AAPM Position Statement on the Use of Bismuth Shielding for the Purpose of Dose Reduction in CT scanning, which recommends other methods for breast dose reduction instead.⁵⁷ The arms are extended above the head to avoid higher radiation doses required to penetrate the extremities and to decrease beam hardening artifacts. A critical step is practicing the breath hold instructions with the patients. The importance of this step is often but often under recognized. The patient's anticipation

of the often automated breath hold instructions and the knowledge of the need to hold still during that breath hold will reduce the prevalence of avoidable respiratory and gross body motion artifact.

5. Patient education-shared decision making

Shared decision making (SDM) is a broad mandate of the Affordable Care Act⁵⁸ that establishes a collaborative process between patients and health care professionals to incorporate the best available scientific evidence and the patient's values and preferences into medical decisions. With respect to lung cancer screening, Medicare has mandated a shared decision making discussion between the patient and a health professional, including the use of one or more decision aids, to include the benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure.⁸ With respect to the initiation of statin therapy, the 2013 ACC/AHA Cholesterol guidelines have mandated SDM to discuss patient preferences, adverse effects, and the potential for ASCVD risk reduction benefits.⁴ The extension of the Medicare lung cancer screening shared decision making mandate to include a discussion of the benefits and harms of CAC, as well as offering to the patient the option of declining CAC analysis and reporting, requires consideration. Interestingly, the new SCCT CAC guidelines have recommended the inclusion of CAC in the statin SDM to ensure patients awareness of the potential effect it may have on the initiation of statin treatment.⁵⁹

Since CAC is not the primary indication for the screening CT examination, it has not been specifically mandated for SDM inclusion and may further complicate an already complicated discussion, it appears reasonable to treat it like any "other clinically significant or potentially significant abnormalities" to be recorded in the ACR NRDR-LCSR, rather than to include it in the SDM. This recommendation may be revisited as CAC reporting of NCCT examinations becomes routine and widely accepted as the standard of care, particularly if requested by Medicare.

6. CAC scoring methodologies (Table 3)

6.1. Gated CT examinations

Ideally, NCCT examinations would be EKG gated to minimize motion artifact and provide the most accurate, reproducible CAC scoring when reconstructed to the appropriate slice thickness, facilitating the use of the very large EKG gated CAC database. While this may provide better quality NCCT for noncardiac structures as well, it may be difficult to implement on a broad scale, since it involves additional hardware and ECG electrodes, scanner software, and may increase radiation exposure.

6.2. Nongated CT examinations

6.2.1. Agatston scoring

6.2.1.1. Accuracy. Several analytic approaches have been employed for NCCT CAC scoring; most have performed standard Agatston scoring. In 128 patients undergoing both nongated low dose lung cancer screening and gated CAC scanning with 2.5 mm slice thickness, Kim et al. noted 91% sensitivity, 89% specificity, 91% positive predictive value, 93% negative predictive value and 90% accuracy for CAC>0 on the gated CAC scan; the correlation coefficient was 0.892 for agreement of absolute scores.⁶⁰ Wu et al., in 513 nongated low dose lung cancer screening patients undergoing gated CAC scans as well, reported 98% sensitivity, specificity, positive predictive value, negative predictive value, and accuracy.⁶¹ In 50 patients with both nongated and gated 64 slice CT scans, Budoff

et al. reported a correlation coefficient of 0.96, with a median variability of 44% and mean differences of 354. Concordance between the 4 major CAC risk categories was 92%.⁶² In a meta-analysis of 661 patients undergoing both scans in 5 validation studies of nongated versus gated Agatston scoring, the correlation coefficient for agreement of CAC scores was 0.94 (95% CI 0.89, 0.97), and for agreement of the 4 categories of CAC scores in 533 patients was 0.89 (95% CI 0.82, 0.96). There were 8.8% false negative NCCT for CAC noted on the gated scans, and 19.1% underestimation of high CAC scores.⁶³

Most recently, 4544 subjects underwent both 3mm gated CAC scans and 6 mm standard nongated chest CT scans by electron beam computed tomography, with a ≥6 year follow up for all cause mortality.⁶⁴ There were 157 deaths, matched 1:3 to 494 survivor controls. There was excellent correlation between the 2 scans in the 651 subjects ($r = 0.93$, $p < 0.001$); the median CAC scores were lower on the 6 mm scan (22 versus 104 Agatston units, $p < 0.001$), consistent with the decreased sensitivity of thicker slices to detect CAC. The weighted Kappa statistic for agreement between CAC score categories of 0, 1–100, 101–300 and > 300 on the 3mm ECG-gated CT compared to the 6mm standard chest CT was 0.62, and 3mm scores were ~3.2 x greater than the 6mm score.

An automatic technique for analyzing nongated scans has been described.⁶⁵ In 1749 lung cancer screening patients, the correlation between automated and standard Agatston scores was excellent ($r = 0.9$) with a median difference of 2.5 (interquartile range 25%–75% of 0.0–53.2). The agreement between 5 major CAC categories was also excellent ($k = 0.85$), with 80% in exact agreement.

6.2.1.2. Prognostic value. Agatston scoring was performed in 958 lung cancer screening patients who had 127 cardiovascular events over a median of 20.5 months.⁶⁶ Compared with a CAC score of 0, multivariate-adjusted HRs for coronary events were 1.38 (95% CI, 0.39–4.90), 3.04 (95% CI, 0.95–9.73), and 7.77 (95% CI, 2.44–24.75), for scores of 1–100, 101–1000 and > 1000. Automated CAC and aortic calcium analysis of nongated lung scans were incorporated into a risk prediction model in 3648 lung cancer screening patients for respectively cardiovascular outcomes after a 3 year follow up period. The event frequencies were 12.2% and 4.0% for high and low risk groups respectively.⁶⁷ Low dose nongated CT scans were evaluated in 1442 patients in the National Lung Screening Trial.⁶⁸ Compared to Agatston scores of 0, scores of 1–100, 101–1000, and greater than 1000 had HR of 1.27 (95% CI: 0.69, 2.53), 3.57 (95% CI: 2.14, 7.48), and 6.63 (95% CI: 3.57, 14.97), respectively.

In the gated 3mm versus nongated 6mm study discussed above,⁶⁴ each SD higher CAC yielded identically increased OR for all cause mortality of 1.5. Compared to 0 CAC, the OR for the 1–100, 101–300 and > 300 categories were 1.9, 2.3 and 2.6 respectively for the 6mm nongated scans, and 2.1, 2.9 and 3.2 for the 3mm gated scans respectively, in models fully adjusted for risk factors.

6.2.2. Ordinal scoring

6.2.2.1. Prognostic value. Ordinal scoring refers to the assessment of CAC using a simple integer score designed to correlate with the total burden of CAC within the coronary tree. Rather than produce a score along the continuous scale like the Agatston score, ordinal scoring is simpler with fewer possible score values. There are no accuracy studies since nongated semiquantitative ordinal scores cannot be directly compared to gated Agatston scores. However, the prognostic value of ordinal scoring has been evaluated in several studies. In the first, the presence of CAC in the left main, left anterior descending, left circumflex, and right coronary arteries was categorized as absent, mild, moderate, or severe and scored as 0, 1, 2, or 3, respectively.⁶⁹ CAC was classified as mild if less than 1/3 of the length of the entire artery contained calcification (CAC = 1),

moderate if 1/3–2/3 (CAC = 2) and severe if more than 2/3 of the artery showed calcification (CAC = 3). The final score was the sum of the individual artery scores, ranging from 0 to 12, and were divided into 3 categories of increasing severity: 0, 1–3, and 4–12. In 8782 smokers followed for a median of 6 years for cardiovascular deaths, the rates of death were 1.2%, 1.8%, 5.0% and 5.3% for scores of 0, 1–3, 4–6 and 7–12, respectively. The adjusted HR for scores of 4–12 was 2.1 (95% CI: 1.4, 3.1). The 3 ordinal score categories have an excellent agreement ($k = 0.83$, 95% CI: 0.76–0.85) with the 3 nongated Agatston score categories of 0, 1–400 and >400.⁷⁰

A different summed segmented vessel-specific ordinal scale was also utilized in the NLST referred to above, in which 1447 patients were followed for coronary heart disease deaths over ~7 years.⁶⁸ The coronary tree was divided into 10 segments, which were scored 0, 1, 2 and 3 for no, mild, moderate and heavy calcium respectively, for a total score range of 0–30. Compared to 0, scores of 1–5, 6–11, and 12–30 had adjusted HR of 1.72 (95% CI: 1.05, 3.34), 5.11 (95% CI: 2.92, 10.94), and 6.10 (95% CI: 3.19, 14.05).

6.2.3. Visual estimation

The NLST data were also analyzed by visual estimation of the entire coronary tree.⁶⁸ Categories of CAC on visual estimation are none, mild, moderate and severe. Compared to no CAC, the adjusted HR for coronary heart disease deaths were 2.09 (95% CI: 1.3–4.16), 3.86 (95% CI: 2.02, 8.20) and 6.95 (95% CI: 3.73, 15.67) for mild, moderate and heavy calcification, respectively. Good agreement was noted between the visual assessment and Agatston score categories (weighted $k = 0.75$); exact agreement was noted in 73% and to within one category in 99.7%. Interreader category agreements were comparable as well: weighted k of 0.85 for visual assessment and correlation coefficient of 0.92 for Agatston scoring.

The prognostic data and advantages and disadvantages of the scoring methods are summarized in Tables 3 and 4 respectively. Examples of gated and nongated combined low dose lung and CAC scans are displayed in Figs. 2 and 3.

6.3. Scoring recommendations

The recommendations (Table 5) are based upon a combination of available evidence, feasibility of implementation. The decision to report the presence or absence of CAC, rather than the analysis method, is the most critical issue. The NLST data suggest that visual estimation is adequate; it requires the least effort and equipment and will be the easiest to implement. Ordinal scoring offers a semi-quantitative compromise between simple visual estimation and Agatston scoring and requires no added equipment. Agatston scoring is the most quantitative but requires special software and, if the scans are to be ECG gated, will necessitate additional hardware and additional radiation as well. The final decision should be left to the individual centers after balancing the available technology and resources and their clinical and research interests. Since thoracic aortic calcification is almost invariably atherosclerotic, it may be appropriate to report and visually estimate its presence and extent. However there is less evidence on which to make a recommendation at this time.

7. Interpretation and reporting (Table 6)

7.1. Interpretation

For the reporting of CAC on NCCT examinations to improve patient outcomes, CAC scoring results must be linked to risk classification based upon the CAC categories (whether gated or ungated). Using the Agatston score, 0 CAC = no CAC, very low risk, 1–99 = mild CAC, mildly increased risk, 100–299 = moderate CAC, moderately increased risk, ≥ 300 = moderate to severely increased risk. Absolute CAC scores have been shown to be a better predictor of risk than percentile scores⁷¹; however, percentile scores may facilitate communication of relative risk or lifetime risk with patients and providers (i.e. “your CAC score is at the Xth percentile compared to your age, gender, and race matched peers”). Percentile

Table 3
Prognostic value of nongated CAC scoring of noncontrast chest CT examinations.

Study	Duration	Pts/events	Adjusted HR vs 0 CAC	95% CI
A. Nongated Agatston Score				
Jacobs (66)	20.5 months	958/127 CHD events	1–100 101–1000 >1000	1.38 3.04 7.77 0.39, 4.90 0.95, 9.73 2.44, 24.75
Mets (67)	3 years	1834/145 CVD events	100mm ³ 500mm ³ >1500mm ³	1.08 1.48 3.22 1.05, 1.11 1.27, 1.72 2.05, 5.07
Chiles (68)	7 years	1442/210 CHD death	1–100 101–1000 >1000	1.27 3.57 6.63 0.69, 3.57 2.14, 7.48 3.57, 14.97
Hughes-Austin (64)	>6 years	651/157 All cause death	Nongated 6 mm 1–100 101–300 >300 Gated 3mm 1–100 101–300 >300	1.9 2.3 2.6 2.1 2.9 3.2 1.1, 3.1 1.2, 4.3 1.4, 4.9 1.1, 3.8 1.5, 5.7 1.7, 6.0
B. Nongated Ordinal Score				
Shemesh (69)	6 years	8782/193 CHD death	CAC 1–3 CAC 4–12	1.0 2.1 0.7, 1.5 1.4, 3.1
Chiles (68)	7 years	1442/210 CHD death	CAC 1–5 CAC 6–11 CAC 12–30	1.72 5.11 6.11 1.05, 3.34 2.92, 10.94 3.19, 14.05
C. Nongated Visual Score				
Chiles (68)	7 years	1447/210 CHD death	mild moderate heavy	2.09 3.86 6.9 1.3, 4.16 2.02, 8.20 3.73, 15.67

Table 4
Coronary artery calcium scoring techniques.

Technique	Advantages	Disadvantages
ECG gated Agatston scoring	Very large database Standard of care >1250 articles Guidelines Computer analysis Suitable for tracking progression	Software required EKG gating required
Nongated Agatston scoring	No EKG gating required Computer analysis Good correlation with gated	Software required Fewer articles Less reproducible No database
Nongated Ordinal scoring	No software required	No database Few articles Manual analysis
Visual assessment	Quickest analysis No software required	No database 1 article Eyeball analysis

Reprinted with permission of Springer from Hecht HS. Coronary artery calcium analysis and reporting on noncontrast chest CT scans: A paradigm shift in prevention. *Curr Cardiovasc Imaging Rep* 2016; 9:11. doi:10.1007/s12410-016-9372-2.

Table 5
CAC reporting recommendations^a.**Reporting**

Class I. CAC should be evaluated and reported on all noncontrast chest CT examinations

Class IIb. It may be reasonable to evaluate and report thoracic aortic calcification on all noncontrast chest CT examinations

Scoring methodology

Class I. CAC should be estimated as none, mild, moderate or severe

Class IIa. It is reasonable to perform ordinal assessment of CAC on all noncontrast chest CT examinations

Class IIb. It may be reasonable to perform Agatston CAC scoring on all noncontrast chest CT examinations

^a The strength of the recommendations is based upon a combination of available evidence and feasibility of implementation and apply to patients ≥ 40 years of age.

Table 6
Coronary artery calcium score reports for noncontrast CT examinations.

Total:	Percentile:	LM:	LAD:	LCx:	RCA:
A. Coronary Artery Calcium Gated and Nongated Agatston score					
Score	Risk				
0	very low				
1–99	mildly increased				
100–299	moderately increased				
≥ 300	moderate to severely increased				
Total:	LM:	LAD:	LCx:	RCA:	
B. Coronary Artery Calcium Ordinal Score (0–12)					
Score	Risk				
0	very low				
1–3	mild to moderately increased				
4–12	moderate to severely increased				
C. Coronary Artery Calcium Ordinal Score (0–30):					
Score	Risk				
0	very low				
1–5	mildly increased				
6–11	moderately increased				
12–30	moderate to severely increased				
D. Coronary Artery Calcium Visual Score:					
Score	Risk				
None	very low				
Mild	mildly increased				
Moderate	moderately increased				
Severe	moderate to severely increased				

score can be easily calculated from the Multi-Ethnic Study of Atherosclerosis (MESA) website.⁷² In general, >75th percentile for age/gender/race is considered to be a higher relative risk and higher lifetime risk condition, >75th percentile for age, gender and ethnicity = moderate to severely increased relative risk irrespective of the score. When risk factor information is available, the 10-year MESA Coronary Heart Disease Risk Score should be used to quantify

and report absolute 10-year risk.⁷³ The MESA Risk Score is available on the MESA website.⁷⁴

For the first ordinal scoring method described above, 0 = very low risk, 1–3 = mild to moderately increased risk, and 4–12 = moderate to severely increased risk.⁶⁹ For the second ordinal method, 0 = very low risk, 1–5 = mildly increased risk, 6–11 = moderately increased risk, and 12–30 = moderate to severely increased risk.⁶⁸ For visual assessment analysis, none = very low risk, mild = mildly increased risk, moderate = moderately increased risk, and severe = moderately to severely increased risk.⁶⁸

Treatment recommendations should parallel the risk classification and are particularly critical in this context since the referring physicians have not requested the CAC scores and are not likely to be familiar with the therapeutic algorithms for each CAC level. Formal treatment recommendations, however, are beyond the scope of this guideline; they may be part of forthcoming SCCT Expert Consensus and other documents.

7.2. Reporting

The NCCT examination report should include the CAC scores pertaining to the scoring system that has been utilized, as illustrated in Table 4.

8. Referring physician awareness and education

With cardiovascular disease being the leading cause of mortality, it is incumbent on us to both educate physicians interpreting thoracic CT examinations to report the presence and severity of CAC, and, importantly, to educate referring physicians and mid level providers on how to incorporate the information into the management of their patients. While many may be familiar with the

traditional CT examinations performed specifically for CAC and the quantitative Agatston score, most are not likely to be familiar with the reporting of CAC on routine thoracic CT examinations and its equivalence.

Both radiology and cardiovascular medicine specialists and their professional societies play a role in this education. The American College of Radiology (ACR) leads radiology professional organizations in the development of practice standards and guidelines, and has led the development of white papers on incidental abdominal and thyroid findings that have been widely adopted in practice.^{75–79} Several of these recommendations are included as measures adopted by the American College of Radiology, American Medical Association (AMA)-convened Physician Consortium for Performance Improvement[®](PCPI[®]) and National Committee for Quality Assurance program in February 20, 15.⁸⁰ The ACR is currently developing a white paper on incidental thoracic CT findings in which there will be a section on the reporting of coronary arterial calcification on thoracic CT scans. The reporting of CAC on NCCT should be considered as a future quality measure under this program. To reinforce the incorporation of a semiquantitative CAC score on lung cancer screening CTs, it is recommended that materials designed to educate radiologists on the interpretation of lung cancer screening CTs, such as the Lung-RADS[™] interpretation and management scheme,¹⁰ discuss the importance of and how to report CAC in a standardized manner.

Cardiovascular medicine specialists are the experts in patient management and evaluation for coronary artery disease, and play an important role in reinforcing the value of the CAC reported on NCCT examinations with primary care providers and how to incorporate it into their practice. Professional organizations and physicians interpreting thoracic CT examinations should develop materials to facilitate education of referring providers on how to incorporate the CAC information reported on NCCT examinations into routine patient management. Standard reporting language may also be disseminated through or incorporated into physician dictations systems as part of structured reporting tools. The Radiology Reporting Initiative of the Radiological Society of North America provides a library of report templates subspecialty areas including cardiac and chest radiology,⁸⁰ and could be approached to include CAC on NCCT examinations as a reporting template.

Lastly, with the increasing use of the patient portals for access to the electronic medical record on line or using mobile applications, providing content in patient-centric language is also important.

9. Summary

The incorporation of CAC into all noncontrast chest examination reports represents a potential major advance in the early detection and treatment of coronary artery disease. The formal recommendation in this guideline is an extension of the already existing ACR requirement to report moderate/severe CAC on all patients undergoing lung cancer screening recorded in the ACR lung cancer screening registry,⁴⁹ and provides the tools to enable widespread dissemination and application.

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