AHA Scientific Statement

Approaches to Enhancing Radiation Safety in Cardiovascular Imaging

A Scientific Statement From the American Heart Association

Endorsed by the American Association of Physicists in Medicine, American College of Cardiology, American Society of Nuclear Cardiology, North American Society for Cardiovascular Imaging, Society of Cardiovascular Computed Tomography, and Society for Coronary Angiography and Interventions

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Cardiac imaging is an invaluable tool in the diagnosis and management of heart disease. As a consequence of new capabilities and widespread availability, the use of medical imaging has increased dramatically in the United States, as has radiation exposure related to imaging. The National Council on Radiation Protection & Measurements reports that the total radiation exposure to the US population from medical imaging has increased 6-fold since 1980, even though the radiation doses from individual examinations have stayed approximately constant or decreased. Nearly 40% of this medical radiation exposure to the US population (excluding radiotherapy) is related to cardiovascular imaging and intervention.[1]

A recent American Heart Association Science Advisory outlined a conceptual framework for understanding radiation exposure from cardiac imaging, including the risks related to exposure to ionizing radiation, and provided general recommendations for the safe use of cardiac imaging that relies on ionizing radiation.[2] We refer readers to this document for an introduction to the basic concepts related to radiation safety. The key approaches to enhancing radiation safety in medical imaging are as follows: (1) Education, that is, ensuring that patients and clinicians understand the potential benefits and risks of medical imaging studies; (2) justification, that is, ensuring that the imaging procedure is clinically necessary and appropriate; and (3) optimization, that is, ensuring that radiation exposure from imaging is kept as low as reasonably achievable. The purpose of the present scientific statement is to outline practical and specific strategies for applying these principles to cardiovascular imaging. Its primary intended audience includes clinicians who refer patients for cardiovascular imaging procedures, for whom the sections on education and justification are most relevant, and clinicians who perform imaging procedures, for whom the section on optimization is also relevant. The statement also addresses existing barriers to implementing radiation dose–reduction strategies (including the challenges of estimating radiation dose), suggestions on how to overcome these barriers, the use and limitations of longitudinal tracking of medical radiation exposures, and future priorities for research. Recommendations included in the present statement were written in accordance with the American Heart Association's guidelines on applying classification of recommendations and level of evidence (Table 1).

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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Table 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT: CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/Test: COR III: No benefit — Not Helpful; COR III: Harm — Excess Cost w/o Benefit or Harmful Treatment: No Proven Benefit; Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Education

Education is a necessary foundation for any efforts to enhance the radiation safety of medical imaging. Clinicians should have an understanding of the potential benefits and risks of imaging studies that use ionizing radiation and of the strengths and weaknesses of the specific type of study under consideration, relative to other imaging modalities, to request and use cardiac imaging optimally. Patients undergoing these procedures, as well as the public at large, should also have a general understanding of these issues to allow them to participate in decisions related to their health care. In the following sections, strategies to effectively educate each of these groups are discussed.

Clinicians

Studies have consistently shown a lack of adequate awareness among physicians of basic concepts related to radiation exposure from medical imaging.[3–6] For example, in one study of clinicians in the United States caring for patients undergoing computed tomography (CT) scans for abdominal and flank pain, fewer than half of the radiologists and only 9% of the emergency department physicians reported being aware that CT scans may be associated with an increased lifetime risk of cancer.[4] This knowledge gap reflects the lack of adequate integration of this topic in current medical school and postgraduate training curricula. Sufficient time should be dedicated to this material, because radiation exposure should be taken into

consideration in the decision to perform medical imaging and the selection of the most appropriate test. Adequate knowledge of the risks attributable to imaging examinations, including risks other than those related to radiation, is required for informed choices in the use of imaging. Furthermore, clinicians can only properly inform their patients of the benefits and risks of an imaging test if they possess the pertinent knowledge themselves.

Any discussion of the risks of an imaging study should be put into perspective by weighing them against the expected benefits. As such, it is important that education focus on the key issues of appropriate selection of patients and imaging tests, including the risks of not performing an imaging study in a specific clinical scenario.

Trainees

Medical school and residency and fellowship training provide crucial opportunities to communicate knowledge of benefits and risks related to imaging with ionizing radiation. This education should begin during medical school, with subsequent reinforcements during postgraduate training. The curricula of training tracks in various medical specialties should be tailored to optimize the knowledge and competence of practitioners who will request, and those who will perform, imaging procedures.

Training of future referring physicians should address the following areas:

1. Basic understanding of available cardiac imaging modalities and relative accuracy in specific clinical situations
2. Cost-efficient, evidence-based use of cardiac imaging, with emphasis on pertinent guidelines and appropriate use criteria
3. Basic concepts related to radiation exposure, such as the biological effects of radiation exposure and the concepts of absorbed and effective dose
4. Radiation dose estimates for commonly used imaging procedures and the risk estimates corresponding to these doses, along with the assumptions and limitations of these estimates

In addition, training should develop the trainee's ability to communicate these complex scientific issues in a manner that patients can understand. The American College of Radiology (ACR) Blue Ribbon Panel on Radiation Dose in Medicine recommended that the ACR approach the Liaison Committee on Medical Education, the accrediting body for medical schools, and the Association of American Medical Colleges with a proposal to incorporate such a requirement into the accreditation standards for medical schools.[7] The American Heart Association, American College of Cardiology, and national cardiac imaging societies including the American Society of Nuclear Cardiology, the Society of Cardiovascular Computed Tomography, and the North American Society for Cardiovascular Imaging should support this effort or develop similar initiatives.

For those physicians who will be performing cardiac imaging, more extensive training (compared with referring physicians) should be required. The expectations for knowledge and competence in radiation safety and management during and at the end of training, as well as their formal assessment by testing, are currently not adequately defined but should be. For clinicians who will be performing cardiac imaging, these competencies should include detailed knowledge of how the imaging equipment they use functions; dose-optimization techniques for the types of studies they perform and interpret; and dose-minimization techniques for operators and staff. Developing the curricula necessary to achieve such training requires collaboration between relevant stakeholders in graduate and postgraduate education, including the American College of Cardiology Foundation, the American Board of Internal Medicine, the American Board of Radiology, and the American Council for Graduate Medical Education.[8] Because most institutions tailor their training curricula to the blueprints of board examination content, questions on these topics should be included consistently on board certification and recertification examinations to promote attention to these topics in training curricula.

One must also recognize and account for the effects of physician training on the patient's radiation dose. For example, the participation of fellows potentially increases the radiation exposure received from invasive diagnostic procedures.[9] Appropriate supervision, training, and documentation to limit such increases and lessen them over the time of training by improving procedural competence should be required.[10] All fellows and other physicians performing fluoroscopically guided cardiovascular procedures should receive training in radiation protection and radiation management and should be provided feedback on patient radiation dose on a regular basis (eg, at the end of each month spent in the cardiac catheterization laboratory) to enhance their awareness and improve their performance in regard to radiation safety.[11,12]

Recommendations

1. **All healthcare providers who can request cardiac imaging procedures should be required to know (a) which cardiac imaging tests use ionizing radiation; (b) basic concepts related to medical radiation exposure, including the concepts of absorbed dose and effective dose; and (c) typical dose estimates for the most commonly used cardiac imaging procedures *(Class I; Level of Evidence C)*.**
2. **All healthcare providers who will perform cardiac imaging with ionizing radiation, including interventional cardiologists and electrophysiologists, should be required to demonstrate adequate knowledge of contemporary dose-optimization techniques for patients and dose-minimization techniques for operators and staff (*Class I; Level of Evidence C*).**

Practicing Clinicians

For practicing physicians, the above-mentioned competencies should be required for board certification, as well as maintenance of certification or recertification. The competencies required for referring clinicians should be evaluated as a routine part of the maintenance of certification board examination. Laboratory accreditation requirements, including those mandated by the Medicare Improvements for Patients and Providers Act,[13] should be used as an opportunity to evaluate

and enforce the higher-level competencies expected of clinicians who perform cardiac imaging.

Other educational resources for practicing clinicians include the published literature and the material presented at national scientific meetings. Many publications on the biological effects of ionizing radiation from governmental agencies and professional medical and technical societies are available publicly. Lists of these resources, such as Table 2, should be identified by professional societies and made available not only to their respective membership but also to practicing physicians and patients. National cardiology and radiology scientific meetings can also serve as venues for education of practicing physicians. There has been increasing attention given to radiation safety of cardiac imaging at meetings of large, national cardiology and radiology, specialty, and subspecialty societies,[32] which is a positive step toward promoting awareness of this topic among physicians. The present writing group recommends that attendance at training sessions, either at national scientific meetings or at the institutional level, and credentialing in radiation safety procedures for those clinicians who perform imaging studies with ionizing radiation be required to help ensure a basic level of radiation safety knowledge among these clinicians.

It must also be acknowledged that in many clinical practice environments, nurse practitioners and physician assistants may request cardiac imaging studies either directly or at the request of a supervising physician. Such nonphysician clinicians should have a basic understanding of radiation safety principles on par with that recommended above for referring physicians.

Technologists/Staff

There are currently no national standards for education or certification of radiological or nuclear medicine technologists, and only 37 states mandate certification and minimum

Table 2. Publicly Available Sources of Information Regarding Radiation Exposure From Medical/Cardiac Imaging

Online resources with information on radiation dose and dose optimization
- http://www.imagewisely.org: Focused on getting practitioners to avoid unnecessary ionizing radiation studies and to use the lowest optimal radiation dose for necessary studies
- http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx
- http://www.pedrad.org: Focused on lowering radiation dose in the imaging of children (includes links to the Image Gently and Step Lightly campaigns)
- http://www.radiologyinfo.org/
- http://www.doseinfo-radar.com/RADARHome.html
- http://www.hps.org/: Health Physics Society, with links to information for public (http://www.radiationanswers.org) and clinicians (http://hps.org/physicians)
- http://www.aapm.org: American Association of Physicists in Medicine

Regulatory and related agencies
- http://www.nrc.gov/about-nrc/radiation.html
- https://rpop.iaea.org/RPOP/RPoP/Content/About.htm: From the International Atomic Energy Agency's Radiation Protection of Patients, which includes a link to a site dedicated to cardiac imaging
- http://www.ncrponline.org/
- http://www.fda.gov/Radiation-EmittingProducts/default.htm
- http://www.hpa.org.uk/Topics/Radiation/
- www.cvexcel.org/Documents/CathPCIProcess.aspx (ACE standards for catheterization laboratory accreditation)

Appropriate use criteria
- ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization[14]
- ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging[15]
- ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization (Focused Update)[16]
- ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac Computed Tomography[17]
- ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy[18]

Statements and reports from national scientific organizations
- SCCT Guidelines on Radiation Dose and Dose-Optimization Strategies in Cardiovascular CT[19]
- SCAI Clinical Expert Consensus Statement on Best Practices in the Cardiac Catheterization Laboratory[20]
- ASNC Information Statement: Recommendations for reducing radiation exposure in myocardial perfusion imaging[21]
- ASNC Information Statement: Strategies for defining an optimal risk-benefit ratio for stress myocardial perfusion SPECT[22]
- ACCF 2012 Health Policy Statement on Patient-Centered Care in Cardiovascular Medicine[23]
- ACC Conference Report (2012): Developing an Action Plan for Patient Radiation Safety in Adult Cardiovascular Medicine[24]
- ASNC Preferred Practice Statement (2012): Patient-Centered Imaging[25]
- NCRP Report No. 168 (2010): Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures[26]
- Health Physics Society Position Statement (2010): Radiation risk in perspective[27]
- Health Physics Society Fact Sheet: Radiation exposure from medical diagnostic imaging procedures[28]
- AAPM Position Statement (2011) on Radiation Risks from Medical Imaging Procedures[29]
- ICRP publication 120: Radiological protection in cardiology[30]
- Patient-centered imaging: shared decision making for cardiac imaging procedures with exposure to ionizing radiation[31]
- SCAI consensus document (2011) on occupational radiation exposure to the pregnant cardiologist and technical personnel[31a]

AAPM indicates American Association of Physicists in Medicine; AATS, American Association for Thoracic Surgery; ACC, American College of Cardiology; ACCF, American College of Cardiology; ACE, Accreditation for Cardiovascular Excellence; ACR, American College of Radiology; AHA, American Heart Association; ASE, American Society of Echocardiography; ASNC, American Society of Nuclear Cardiology; HFSA, Heart Failure Society of America; HRS, Heart Rhythm Society; ICRP, International Commission on Radiological Protection; NASCI, North American Society for Cardiovascular Imaging; NCRP, National Council on Radiation Protection & Measurements; SCAI, Society for Cardiovascular Angiography and Interventions; SCCM, Society of Critical Care Medicine; SCCT, Society of Cardiovascular Computed Tomography; SCMR, Society for Cardiovascular Magnetic Resonance; SNM, Society of Nuclear Medicine; STS, Society of Thoracic Surgeons.

education standards for radiological technologists. The writing group agrees with the position of the American Society of Radiologic Technologists, the American Association of Physicists in Medicine, and the ACR that the standards for the education and credentialing of all fluoroscopic users should be consistent in all states.[33] These standards should be at a level high enough to ensure both patient and worker safety and, at the minimum, equivalent to those applied for certification by the American Registry of Radiologic Technologists.

Until such standards are implemented in all states, radiological technologists who have not passed the registry examination should receive training through Internet-based (eg, Image Wisely [http://www.imagewisely.org/]) or institutional education modules. Topics to be addressed include radiation sources, patient doses, biological effects of ionizing radiation, radiation protection, dose-optimization techniques, and radiation regulations (at both the state and national level).

It is essential that all technologists know whom they should call on locally when patients have questions about radiation dose or the risk of medical imaging studies. In general, these questions can be discussed by either a senior technologist, a physician adequately trained in medical imaging, or a qualified medical physicist.

Patients/Public

Need for Publicly Available Resources to Educate and Inform Public (and Media) in a Balanced Manner

A patient scheduled to undergo an imaging study with ionizing radiation might ask, "What are the best estimates of benefits, total risk, and radiological risk to me of the proposed procedure, and what alternatives are available?" As discussed above, the first task is to educate clinicians so that they, in turn, can provide accurate information about the benefits and risks of cardiac imaging in general and the use of ionizing radiation specifically in a manner their patients can understand.

Public information sources should accurately reflect the scientific literature and conversations with experts and clinicians to improve public and patient understanding. Balanced, responsible reporting on issues related to medical radiation exposure can be an invaluable tool for educating the public. Providing information through Internet-based access is the fastest and least expensive method but may not be accessible to everyone, and alternative methods such as pamphlets, mailings, and public service messages on radio and television should be considered.

Strategies for Effective Communication of Benefits and Risks

Effective communication with patients to convey the benefits and risks of medical management decisions is a prerequisite for shared decision making. Given the technical nature of this information in cardiac imaging with modalities that use ionizing radiation, effective communication can be challenging. For all staff and physicians in an imaging laboratory, some understanding of patient health literacy is necessary to facilitate patients' understanding of the testing process and to allow patients to be fully engaged in clinical decision making.

The concept of computational literacy, which refers to the ability to reason numerically, is important for the appraisal of benefits and risks in cardiac imaging.[34] Computational and health literacy is low in large segments of the adult population, and patients with low health literacy may have increased anxiety about their medical care, including erroneous, exaggerated perceptions of their projected cancer risk after exposure to ionizing radiation.[35,36] Thus, it is important for laboratory staff and physicians to be able to identify patients with critical deficiencies in health and computational literacy. If informed consent is obtained, it should use language targeted for patients who have low literacy, with limited use of medical jargon.

A number of strategies for effective communication of risk and benefits of procedures have been detailed in the literature.[2,37–39] Examples of effective communication techniques include the following:

1. Providing the patient with key facts regarding the procedure using simple language that highlights the benefits of an accurate diagnosis and the importance of early detection and therapeutic intervention
2. Affirmation that their imaging study is appropriate (or uncertain/may be appropriate) based on the American College of Cardiology Foundation's appropriate use criteria (AUC) or American College of Cardiology Foundation/ACR appropriate use of imaging criteria, highlighting the fact that an appropriate indication implies a favorable benefit-risk ratio for the typical patient as judged by an expert panel of physicians
3. Creating a dialogue and allowing the patient to ask questions
4. Directly addressing patient and family concerns regarding risks of the procedure, including those related to ionizing radiation, contrast media and anesthesia, if relevant
5. Comparing risk estimates as a result of exposure to ionizing radiation to commonly performed tasks, such as driving a car

Shared Decision Making and Informed Consent

There are conflicting opinions on whether informed consent should be required for imaging with ionizing radiation.[40,41] Certainly, there are currently no standards for informed consent for noninvasive cardiac imaging procedures that use ionizing radiation, and informed consent for these procedures is not obtained routinely. Furthermore, the legal standards for informed consent and how it is documented vary by US state.[42,43]

Whether or not it is performed within the legal framework of formal written informed consent, nonemergent, advanced cardiac imaging (ie, cardiac CT, nuclear cardiac imaging, and fluoroscopically guided procedures) should be performed on the basis of shared decision making, which is a basic tenet of patient-centered care.[31] Shared decision making is a process in which the physician shares all benefit and risk information on all management alternatives with the patient, and the patient shares all personal information that might make one management alternative more or less acceptable to the patient than others. Then both parties use this information to come to a mutual decision.[44] When a referring physician or patient is uncertain which is the best option, consultation with an imaging specialist should be considered.

Shared decision making for cardiac imaging with ionizing radiation entails that the ordering physician ensure that the patient is aware of and understands the use of ionizing radiation,

the expected radiation dose, the potential risks related to the radiation exposure, and the alternatives to imaging with ionizing radiation. Ideally, the imaging physician and facility should also be engaged in this process and share the responsibility for informing the patient.[30] This information should be put in context by clearly explaining the expected benefit from the test and how the information gathered would be used in the patient's clinical management. It is also important to discuss risks that may be incurred by not performing the imaging study, including the potential consequences of missed or delayed diagnoses, and the risks of alternate procedures, such as those related to conscious sedation or the use of gadolinium-based contrast agents. This counseling should be noted in the patients' records.

The radiogenic risk of most diagnostic imaging procedures is limited to possible increased cancer risk.[45,46] Estimates of the average lifetime attributable risk of cancer for various cardiac imaging procedures are shown in Figure 1, which reflects the higher risk of cancer from a given exposure thought to exist in women and younger individuals. It is important to understand that these risk estimates are based on population averages and rely heavily on data from survivors of the atomic bomb, who were exposed to dose rates and types of radiation different from those incurred by medical imaging, have different background cancer rates, and were under much higher emotional, physical, and nutritional stresses than most recipients of medical imaging.[50,51] The risk for an individual patient will also vary from these population risk estimates on the basis of body habitus and genetic factors. Furthermore, these estimates are based on the assumption of a normal life expectancy; hence, they would overestimate radiogenic risk in individuals with decreased life expectancy.[52]

For fluoroscopically guided cardiac procedures such as percutaneous coronary, structural heart, and electrophysiology procedures, obtaining written informed consent is the standard of care because of the invasive nature of these procedures. In addition to the above-mentioned potential radiogenic cancer risk, discussion of the potential for exceeding the thresholds for deterministic effects of radiation exposure with these procedures, including hair loss and skin injury, should be part of the informed consent for these procedures. In a recent survey of US practice, ≈7% to 10% of patients undergoing percutaneous coronary intervention or combined diagnostic and percutaneous coronary intervention procedures met the criteria for postprocedure radiation follow-up.[53] Such patients should be offered postprocedure education regarding their radiation exposure and be provided with appropriate follow-up.

Recommendation

1. **Nonemergent cardiac imaging using CT, radiopharmaceuticals, or fluoroscopy should be performed on the basis of shared decision making, through which the patient is made aware of the clinical justification and expected benefit of the test, its potential risks, including radiation-related risk, and the risks and benefits of the alternatives, including not having the test performed. The decision to proceed with imaging should be consistent with both current medical evidence and patient values and preferences (*Class I; Level of Evidence C*).**

Justification

Appropriate selection of patients for cardiac imaging is the first step toward enhancing radiation safety. When cardiac imaging is used appropriately, its clinical benefits almost always outweigh any potential risks related to radiation exposure given the risks of most cardiovascular diseases. Hence, limiting cardiac imaging to appropriate indications typically ensures a favorable benefit to risk ratio for these procedures. Yet even when a cardiac imaging study is appropriate, if a comparable test that does not use ionizing radiation (eg, echocardiography or cardiac magnetic resonance imaging) is able to provide the clinical information needed with comparable accuracy, cost, and convenience but lower overall risk (taking into consideration other potential risks, such as those related to use of gadolinium contrast agents or anesthesia), then it may be the preferred approach.

In the following sections, we outline key approaches to implementing the principle of justification, including patient-centered imaging and adherence to pertinent AUC and scientific guidelines to guide decisions on the use of cardiac imaging.

Patient-Centered Imaging

A key objective of patient-centered imaging is to individualize the decision to use imaging and the choice of imaging type such that for every patient, it provides incremental information that, when added to clinical judgment, results in improved outcomes. This concept represents the core principle of patient-centered imaging, which takes into account patient values and preferences, as well as specifics of the patient's epidemiological characteristics and clinical scenario. This approach expresses partnership with the patient, strengthens the patient-physician relationship, provides an excellent platform to obtain informed consent, and reduces the risk for medicolegal liability.

The implementation of patient-centered imaging in clinical practice requires attention to several key principles. First, patient age, sex, presence or absence of symptoms, and presence or absence of known coronary artery disease should be taken into account in the decision to use imaging, as well as the choice of imaging modality. Second, patient preferences should be elicited and considered in the decision to use cardiac imaging. Third, once the decision to use cardiac imaging is made, the imaging protocol should be tailored to the patient, as detailed below. Finally, every effort should be made to avoid unnecessary serial imaging. A conscientious effort to obtain and review patient records, including those from other medical institutions, should be made before an imaging study is requested to ensure that such procedures are not repeated needlessly. Repeat studies, including duplicate imaging and "layered" testing, should only be requested for appropriate indications with clear documentation and communication of the indication and reason for repeating the test.

There are significant challenges to the implementation of patient-centered imaging. First, because neither the benefits nor the risks of a cardiac imaging study for an individual patient in a given clinical scenario can be quantified with any precision, quantitative benefit-risk comparison is generally not feasible. However, because the potential risks related to any cardiac imaging study are very small in general, the limitation of studies to appropriate clinical indications ensures that the

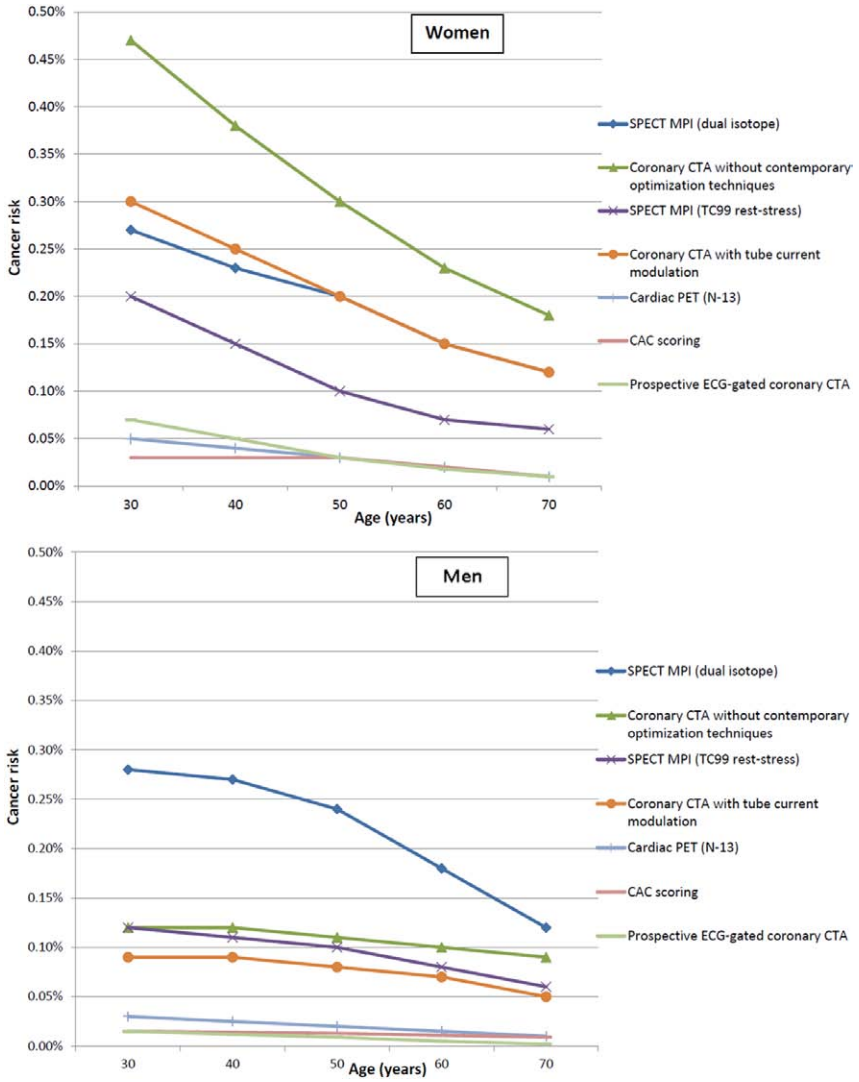

Figure 1. Estimates of average lifetime attributable risk of cancer for various cardiac imaging procedures by age and sex.* Modified from Einstein et al[47] with permission of the publisher. Copyright © 2007, American Medical Association. All rights reserved. Modified from Berrington de González et al[48] with permission of the publisher. Copyright © 2009, American Medical Association. All rights reserved. Modified from Huang et al[49] with permission of the publisher. Copyright © 2010, The British Institute of Radiology. Permission conveyed through Copyright Clearance Center, Inc. SPECT MPI indicates single-photon emission computed tomography myocardial perfusion imaging; and TC-99m, technetium-99m.

benefits of the study far outweigh any potential risks. Second, as detailed in "Strategies for Effective Communication of Benefits and Risks," effective communication of benefits and risks of an imaging procedure in a manner that patients fully comprehend can be challenging. Although it is important to make patients aware of risks related to radiation exposure from imaging procedures, this information must be conveyed in a balanced manner to prevent patients from refusing necessary procedures because of overstated fears. Finally, time constraints in a busy clinical practice can create a substantial barrier to a thorough and balanced discussion of the benefits and risks of imaging with patients. The development of strategies to streamline the process of informing patients in these settings, such as training staff for this purpose or developing educational material for patients (eg, videos, interactive Web sites, brochures), is essential.

Role of AUC

The AUC represent an effort to improve the use of imaging studies in cardiology by promoting the principle of justification. AUC for cardiac radionuclide imaging (2009), cardiac CT (2010), coronary revascularization (including percutaneous coronary intervention; 2009), invasive coronary angiography (2012), and implantable cardioverter-defibrillators and cardiac resynchronization therapy (2013) are among those published to date. The process for developing AUC allows for a summary measure that incorporates test diagnostic performance characteristics, how test findings may influence patterns of clinical care, economic considerations, and the potential adverse effects of testing.[54]

Current AUC do not specifically address the topic of exposure to ionizing radiation, nor do they address the comparative effectiveness of different imaging modalities in specific clinical scenarios or the appropriateness of serial imaging with specific modalities. The largest potential impact of the AUC to reduce radiation exposure from cardiac imaging is to decrease the use

*Risk estimates for various coronary computed tomography angiography (CTA) protocols are modeled on the basis of the use of a 64-slice scanner with the following scan parameters: (1) Coronary CTA without contemporary optimization techniques: retrospective ECG gating, tube voltage of 120 kVp, tube current time product of 170 mAs, gantry rotation time of 0.33 second, slice thickness of 0.6 mm, slice increment per rotation of 3.8 mm, pitch of 0.2, and scan range of 15 cm. (2) Coronary CTA with tube current modulation: same as above except for electrocardiographically controlled tube current modulation with reduction in tube current by 35%. (3) Prospective ECG-gated coronary CTA: tube voltage of 120 kV; 450 mA; gantry rotation time of 0.35 second; cardiac large filter; slice thickness of 0.625 mm; and scan range of 12 cm.

of inappropriate tests. For an appropriate imaging study, the benefits incurred by the incremental information for diagnosis, prognosis, and management exceed the potential negative consequences attributable to the procedure. Procedural risk may be attributed to radiation, contrast media, anesthesia, or other factors, as well as downstream factors related to poor test performance. When cardiac imaging is inappropriate, however, any exposure to radiation is unacceptable. Importantly, clinical scenarios designated as "may be appropriate" (or "uncertain") do not necessarily discourage imaging, but imaging for these indications with modalities that incur radiation (or other) risks should be reserved for at-risk patients who are likely to experience an overall benefit from testing.

Of course, there are inherent limitations to the use of AUC. Because of practical limits in length and detail, they cannot address every clinical scenario. Furthermore, evidence to guide the use of imaging in many clinical scenarios is lacking, and as such, some indications are based solely on expert opinion. Finally, and importantly, there are limited data to inform how these AUC can be implemented in their intended fashion in real-world clinical practice or continually updated with new information.

Current evidence suggests that AUC are not used in clinical practice in many settings,[55] and promoting their use has proven challenging.[56] AUC can only serve as a tool for promoting appropriate use and limiting inappropriate use of procedures if they are meaningfully integrated into clinical decision making. Use of decision support tools for requesting imaging procedures has been shown to facilitate implementation of AUC in practice,[57–59] which is encouraging given the expanding use of electronic medical records systems. In order for AUC to affect a positive change in the use of procedures, further research into methods of promoting their use in clinical practice is essential.

Optimization

The principle of optimization implies that once a cardiac imaging study is deemed appropriate and clinically necessary, the study should be performed in a manner that minimizes radiation exposure while maintaining high diagnostic accuracy. In other words, patients should be exposed to the amount of radiation necessary to produce images adequate for the clinical purpose, not substantially more or less. Achievement of this goal requires conscientious management of radiation exposure with various approaches. In this section, we first discuss the challenges of measuring radiation exposure and dose and then outline key optimization strategies for each cardiac imaging modality. In addition, we address the need to develop quality assessment tools and diagnostic reference levels for cardiac imaging procedures.

Figure 2 outlines the overall approach to justification and optimization of cardiac imaging with ionizing radiation for the diagnosis and evaluation of coronary artery disease. A determination of the appropriateness of imaging is the first, cardinal step. Even if cardiac imaging with ionizing radiation is appropriate, there may be comparable diagnostic tests without radiation, and in some patients, this may be the preferred approach, especially in younger patients in whom the projected lifetime attributable risk of radiogenic cancer is higher.

Challenges of Measuring Absorbed Dose to a Patient and Limitations of Current Methods

Determining patient dose from medical imaging examinations is challenging. Although the amount of radiation delivered by the imaging device or radionuclide (ie, radiation exposure, the amount of radiation that the patient is exposed to) can be quantified relatively easily by standardized methods and test objects, the amount of radiation that is absorbed in a particular patient is dependent on many factors, including the size, shape, and tissue composition of the patient. Thus, discussions regarding "dose" need to differentiate between the radiation output by the imaging equipment or radionuclide and the radiation absorbed by the patient; they are not the same thing.[60]

Cardiac CT

In CT, the radiation output of the scanner is measured by use of standard cylindrical phantoms. These standard phantoms are made of polymethyl methacrylate (eg, acrylic or Plexiglas) and contain 1 central and several peripheral holes into which a radiation-measuring device called an ionization chamber can be inserted.[61,62] From such phantom measurements, the scanner output, typically expressed as the volume CT dose index, can be determined (Table 3).[63–66]

A patient size-specific dose estimate can be provided from the volume CT dose index and the "effective diameter" determined from a patient's cross-sectional body dimensions within the scan region.[62,67] For organs fully contained in the scan range, the size-specific dose estimate provides reasonable estimates of organ doses.

For the thorax, the size-specific dose estimate is within ≈20% of the actual mean dose in the scan region, but the 95% subjective confidence intervals of the risk estimate coefficients span a range of a factor of 10 to 100. Thus, the relatively small difference in estimated dose compared with the actual dose delivered from a CT scan makes practically no difference in the precision of the projected long-term cancer risk related to that dose.[50]

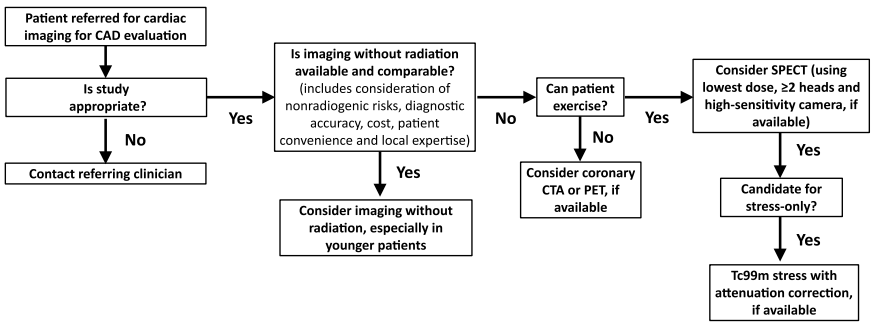

Figure 2. Approach to cardiac imaging for evaluation of coronary artery disease (CAD). CTA indicates computed tomography angiography; PET, positron emission tomography; SPECT, single-photon emission computed tomography myocardial perfusion imaging; and Tc99m, technetium-99m.

Table 3. CT Radiation Dose Metrics

Dose Metric	Definition	Clinical Utility
$CTDI_{vol}$	Standardized measure of the radiation output of a CT system (mGy), measured in a 16- or 32-cm diameter cylindrical phantom[63–66]	Compare radiation output between different protocols or scanners. Only an index of dose; not individual patient dose[60]
DLP	Product of $CTDI_{vol}$ and scan length (mGy·cm)	Compares radiation output between different protocols, scanners. Use to calculate relative stochastic risk; not an absolute risk measure. Higher values of DLP, when $CTDI_{vol}$ is constant, imply that more tissue was irradiated.

CT indicates computed tomography; CTDIvol, volume computed tomography dose index; DLP, dose-length product.

More detailed estimates of organ doses can be simulated by use of Monte Carlo methods and images of either the specific or a similarly sized patient.[68–71] This simulation approach is analogous to the processes used in radiation therapy treatment planning to calculate the dose to target organs and structures. In radiation therapy, in which the dose levels are intentionally set high enough to cause cell death, the accuracy of such dose estimates must be within a few percent or less. By comparison, at the low doses associated with diagnostic imaging, the projected biological effect of radiation is very small, and the quantitative estimates of biological risk are much less certain than the estimates of radiation dose.

Nuclear Cardiology

In nuclear cardiology, the type and activity (millicurie) of the injected radiopharmaceutical are the key determinants of radiation dose. Published estimates of organ doses for various radiopharmaceuticals are for a standard-size person and with standard radiopharmaceutical pharmacokinetics that may not be accurate for an individual patient.[61,72] These generalized methods of estimating organ dose in nuclear cardiology are useful in the comparison of the doses delivered from different radiopharmaceuticals to optimize a given type of study. Compared with CT, the uncertainty in organ doses for individual patients is higher for nuclear cardiology because of the variability of the pharmacokinetics of the radiopharmaceuticals among individual patients.

Fluoroscopy

The key dose metrics in fluoroscopy are total air kerma at the reference point ($K_{a,r}$) and air kerma area product (P_{KA}). $K_{a,r}$ represents the x-ray energy delivered to the air, ie, the air kerma, at a defined distance from the x-ray tube's focal spot, which varies from fluoroscope to fluoroscope and may be inside, at, or outside an individual patient's skin surface. A significant limitation of $K_{a,r}$ is that it does not account for gantry motion during a procedure; instead, it represents the cumulative values, as if all the radiation were directed to a single location. $K_{a,r}$ is used as a predictor of the risk of threshold-dependent deterministic skin effects but is not a direct measure of peak skin dose. There is currently no available method to directly measure peak skin dose, although a qualified physicist can estimate it if air kerma and x-ray geometry details are known. Improved means of estimating actual skin dose distributions are being developed.[70] Air kerma area product is the cumulative sum of the product of instantaneous air kerma and x-ray field area, which reflects the total radiation emitted by the tube. It is used to calculate estimates for patient cancer risk (non-threshold, stochastic effect) and scatter reaching the staff. Similar to dose-length product in CT, it is a measure of the total radiation exposure to the patient. Per FDA regulations, all systems in the United States manufactured since 2006 have the capability to display both $K_{a,r}$ and air kerma area product. Due to its limitations (Table 4), fluoroscopy time alone is not a useful descriptor of radiation dose.

Table 4 summarizes some of the useful dosimetry parameters and their clinical relevance. Patients receiving substantial exposures should be appropriately counseled before discharge. All available exposure data should be recorded in the medical record.[27,71–73] The substantial radiation dose level shown in the table is intended to trigger patient follow-up. The severity of radiation injuries increases with increasing dose.

Table 4. Fluoroscopic Radiation Dose Metrics*

Dose metric	Unit	Clinical utility of the dose metric	Substantial radiation dose level†
Total air kerma at the reference point ($\mathbf{K_{a,r}}$)	Gy	Predictor of the risk of a skin injury; $K_{a,r}$ is not a direct measure of maximum skin dose	5 Gy
Air kerma-area product. ($\mathbf{P_{KA}}$) (also known as dose-area product)	Gy-cm^2	Integrated value of air kerma delivered to the patient, used to calculate relative stochastic risk; not an absolute risk measure. Higher values of P_{KA}, when $K_{a,r}$ is constant, implies that more tissue was irradiated.	500 Gy cm^2 for a 100 cm^2 field at the skin
Fluoroscopy time	minute	Minimal utility because it is not affected by patient size, beam angulation, cine-use, frame rate or other relevant factors.	60 min

*Caution: Different fluoroscopes display data using different units.

†SDRL is defined as the radiation dose level which is intended to trigger follow-up for a radiation level that might produce a clinically relevant injury in an average patient.[27]

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Recommendation

1. **When a patient's radiation exposure related to a fluoroscopic procedure exceeds the institutional trigger level, clinical follow-up for early detection and management of skin injuries should be arranged before discharge. (*Class I; Level of Evidence C*).**

Modality-Specific Optimization Techniques

Cardiac CT

Technological advances in CT scanners and in imaging protocols have made it possible to obtain high-quality images using ever-lower radiation exposures. A number of techniques are available to optimize the radiation exposure used in cardiac CT studies by individualizing the scanning protocols on the basis of patient characteristics and the objective of the examination; these are summarized in Table 5.

In retrospective gating, the original scanning mode in multidetector-row CT for coronary imaging, the x-ray tube emits a stable amount of radiation per unit of time throughout the entire helical (spiral) scan. Projection data are acquired throughout the entire cardiac cycle, but only the data during the period of the least cardiac motion (typically in diastasis) are used for image reconstruction. If the quality of the initial set of images is unsatisfactory, the projection data can be reconstructed to obtain images during other portions of the cardiac cycle. The entire set of projection data can be reconstructed to create moving cine loops of myocardial contraction to examine global and regional left ventricular function. This scanning mode typically uses the highest radiation output, with an effective dose of 15 to 25 mSv.

The Society of Cardiovascular Computed Tomography recently published a comprehensive set of guidelines on radiation dose and dose-optimization strategies in cardiovascular CT.[19] With some reduced radiation exposure protocols, fewer photons reach the detectors for some or all projections; hence, the images may have a grainy, "noisy" appearance when reconstructed with conventional filtered back-projection algorithms.

Iterative reconstruction is a technique that uses mathematical modeling to identify and selectively reduce noise, but it is computationally much more demanding than standard filtered back-projection. Although iterative reconstruction itself does not lower radiation dose, it supports lowering patient dose by creating less noisy images from scans acquired with low x-ray tube output.

Even if image noise is addressed successfully, some reduced radiation exposure scanning protocols do not allow reconstruction of >1 time point during the cardiac cycle, and most are, at the current stage of development, reliable only in patients who have a regular, stable, and slow heart rate and who are not severely overweight.

Nuclear Cardiology

Optimization in nuclear cardiac imaging includes selecting the best protocol, radiotracer, and imaging system, as well as using new technologies.[21,77] A recent statement from the American Society of Nuclear Cardiology details methods of customizing imaging on the basis of a patient's characteristics and reducing the use of "one size fits all" imaging protocols.[25]

Selecting the Best Protocol, Radiotracer, and Imaging System

In single-photon emission CT (SPECT), the use of technetium-99m radiotracers with SPECT is preferred over thallium-201 (because of factors such as greater radiation exposure and poorer spatial resolution with thallium-201), and for both, the injected activity should be based on body weight.[21,25] Use of stress-first protocols may eliminate radiation if the stress portion is normal, in which case the rest portion becomes unnecessary and the study is stress only.[78,79] Attenuation correction or prone imaging for the stress portion may help distinguish soft tissue attenuation from perfusion defects and obviate the need for rest studies.

Although radiation dose is lower with myocardial perfusion positron emission tomography (PET) than with SPECT, largely because of the shorter half-lives of the PET radiotracers, SPECT may be preferred in patients who can exercise.[25] Exercise protocols provide functional information that is unavailable in pharmacological stress protocols, but exercise protocols are not feasible with current US Food and Drug Administration–approved PET tracers.[21,25]

Utilization of New Technologies

Recent hardware and software advances in SPECT and PET allow the maintenance of high image quality and diagnostic accuracy at lower injected activity and radiation dose. Some of these innovations include the use of iterative reconstruction, resolution recovery, multidetector systems, and solid-state detectors.[77,80]

Fluoroscopy

Fluoroscopic systems are designed to meet diverse clinical requirements. User-selectable modes vary considerably in both exposure-rate and image-processing capabilities. The optimum mode needed for a specific patient's procedure should be selected before the patient is placed on the table and verified as part of the time-out process. The actual exposure rates delivered at any moment are determined by a combination of the selected mode, patient characteristics, and operator behavior.

The patient's total radiation exposure is determined by operator behavior. Operators should routinely monitor radiation exposure during fluoroscopic procedures as part of the ongoing evaluation of benefit and risk. Radiation exposure displays are visible to the operator at tableside on most interventional fluoroscopy units. Table 6 reviews some of the actions that an operator can take during a procedure to minimize exposure rate. Exposure rates with cine and digital subtraction angiography are typically much higher than fluoroscopy; hence, as outlined in Table 6, cine and digital subtraction angiography should be used only when necessary.

Need for Evaluation (and Eventual Public Reporting) of Performance of Cardiac Imaging Practices Relative to National Benchmarks

Studies have shown wide variation among and within imaging centers in radiation dose indexes for a given imaging study,[81,82] which for the most part reflects the substantial differences among these centers in adoption of optimization techniques.

Currently, the radiation exposures delivered by specific cardiac imaging procedures are not routinely recorded and archived, although most imaging devices record sufficient technical information to be able to determine the exposure delivered to the patient. In nuclear medicine studies, the amount of radionuclide given to the patient is almost

Table 5. Data Acquisition Modes in Cardiac CT and Strategies for Exposure Reduction

Technique	Data Acquisition Parameter				Prohibits Multiphase Reconstruction	Exposure Reduction*
	Tube Current (mA)	Tube Potential (kV)	Pitch	Scanning Mode		
Prospectively triggered tube current modulation	Varies by ECG signal (automated)	Stable	<1	Helical (spiral)	No	+
Patient-specific tube voltage selection	Stable	Varies by patient	<1	Helical (spiral)	No	++
Prospective axial triggering	On/off by electrocardiographic signal (automated)		N/A ("step-and-shoot" or "volume" mode)	Axial (sequential)	Yes	+++
High-pitch helical scanning	On/off by electrocardiographic signal (automated)		High (>3 vs <1)	Helical (spiral)	Yes	+++

CT indicates computed tomography; N/A, not applicable.

*Symbols denote effectiveness in reducing radiation exposure, ranging from somewhat effective (+) to very effective (+++).

universally recorded. Public availability of radiation exposure data in the form of databases would allow imaging centers or users to compare radiation exposure descriptors from their practices with regional, national, and international values for the purpose of quality control and improvement.[74] The provision of this type of feedback, in conjunction with educational initiatives, has been shown to effectively promote implementation of best practices and safer use of cardiac imaging.[83,84] Additional data reporting regarding exposure levels that put patients at risk for deterministic injuries is also needed.[26,85]

The patient radiation exposure data from medical imaging examinations performed in similar-sized patients and for similar diagnostic tasks can be used to develop benchmarking data and could be examined for trends in exposures over time. Data regarding the measures used to reduce radiation exposure, or the reasons for not using them, and the appropriateness of the procedure according to current AUC should be documented and evaluated over time, when possible.

Development of the mechanisms necessary for patient dose data collection and review at the institutional level is a prerequisite to the creation of national registries that would allow more comprehensive comparison of performance between facilities and development of more reliable, standardized benchmarks.[26,74] Periodic audits and appropriate performance testing by a qualified medical physicist are necessary for optimized clinical functionality of imaging equipment. These evaluations are necessarily more extensive than the minimal testing required for compliance with regulatory safety limits. Archived exposure data should be used to evaluate differences between operators, protocols, and systems, as well as to compare overall performance with published guidance values.[11]

Recommendation

1. **All cardiac imaging facilities should record all relevant radiation-related data in an appropriate database. These exposure reports should be archived and audited regularly for quality assurance and benchmarking (*Class I; Level of Evidence B*).[83,84]**

Need for Diagnostic Reference Levels for Radiation Exposure Related to Cardiac Imaging

Despite their limitations, the dose metrics discussed in "Challenges of Measuring Absorbed Dose to a Patient and Limitations of Current Methods" can serve as useful tools for developing benchmarks and evaluating relative performance across equipment models, procedures, and practices. Such benchmarks for diagnostic imaging should reflect dose metrics that the user can control (either the equipment radiation output or the delivered quantity of radionuclide) rather than patient absorbed dose.

Diagnostic reference levels (DRLs) are radiation exposure levels for a typical-sized patient for a particular high-volume, standardized imaging procedure and represent an established quality control tool to compare radiation dose descriptors within and among imaging centers.[86] DRLs allow imaging users, regulators, professional societies, and accrediting organizations to identify cases, types of studies, or practices that deliver exposures that are higher than usual compared with peer groups. Consistently exceeding DRLs suggests the urgent need to carefully reevaluate and adjust imaging protocols such that the radiation exposure is closer to the normative range.[86–88]

The use of DRLs has been shown to facilitate adoption of optimization techniques that decrease the mean radiation dose

Table 6. Fluoroscopic Exposure Rate Management Techniques

- Position the patient as close as reasonably possible to the image receptor
- Maximize the distance between the patient and the x-ray tube to the extent practicable
- Use collimation to reduce the irradiated area
- Use the lowest acceptable electronic magnification
- Use the lowest clinically acceptable fluoroscopy dose rate and pulse rate at all times
- Use the lowest clinically acceptable cine and DSA dose rate and pulse rate at all times
- Use fluoroscopy only for real-time imaging guidance
- Use image acquisition (cine or DSA) only when higher-quality image review is essential
- Use last-image hold or loop replay in place of live imaging whenever practicable; in some cases, retrospectively stored fluoroscopy may replace image acquisition

DSA indicates digital subtraction angiography.

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and the range of dose distribution of radiological imaging procedures among different facilities.[83,84] The DRL process is inappropriate for the evaluation of interventional procedures and cannot detect those cases with possible skin reactions.[86] DRLs should be established on the basis of large surveys or studies, such as exposure registries, and updated periodically to reflect the effects of protocol optimizations or technological improvements of imaging equipment.

DRLs should be tailored to particular clinical applications of a modality. For some patient populations, procedures, or equipment, it may not always be possible to achieve exposure levels below published DRLs. For example, dose-length product may be appropriately higher in cardiac CT angiography (CTA) procedures performed before transcatheter aortic valve replacement, in which radiation risk is low in this population of elderly patients with critical aortic stenosis and patients may benefit from the assessment of changes in aortic root anatomy over the cardiac cycle, than in cardiac CTA performed in younger emergency department patients with low probability of coronary disease.

In cardiac CT, the measurable radiation exposure descriptors (or dose indexes) useful for establishing DRLs are volume CT dose index, expressed in milligrays, and dose-length product, expressed in milligray-centimeters (Table 3). The corresponding exposure parameter for nuclear cardiology procedures is the activity of the administered radioisotope (typically expressed in units of megabecquerels or millicuries). For fluoroscopy procedures, the main dose indexes are total air kerma at the reference point (in grays; an indicator of skin dose) and air kerma-area product (in gray-centimeters squared; an indicator of total exposure and cancer risk; Table 4).

There are a number of initiatives currently under way to establish DRLs for various imaging procedures. Prominent among them are the National Council on Radiation Protection & Measurements report on DRLs[86] and the ACR Radiation Dose Index Registry.[89,90] At present, available US benchmark data for interventional cardiology procedures are derived from the CathPCI Registry and a Nationwide Evaluation of X-ray Trends (NEXT) survey.[53,91]

Use and Limitations of Tracking Patient Radiation History

Mechanisms for longitudinal tracking of medical radiation exposure over a patient's lifetime have been recommended by several organizations. For example, the International Atomic Energy Agency has proposed a physical or virtual "smart card" that contains a continuously updated record of a patient's radiation exposure data.[92] A Patient Medical Imaging Record card has been developed by the US Food and Drug Administration jointly with the Image Wisely initiative for patients to use to record their imaging procedures; it is available online.[93] The Radiology and Imaging Sciences department at the National Institutes of Health has suggested processes for incorporating radiation exposure reports from medical procedures into the electronic medical record.

Available data suggest that many patients undergo multiple imaging procedures sequentially, which can result in large cumulative exposures.[94–98] Given the rising use of imaging, it is important to gain a clear picture of cumulative exposures within the population to determine the potential public health implications. Tracking radiation exposure of individuals on a broad (national or international) level could provide such information. If used over several decades, it might help to better define the dose-risk relationship at radiation doses relevant to medical imaging, provided that patient dosimetry, outcomes, and risk factors could all be collected comprehensively and accurately.

Although such programs might provide valuable information about patterns and trends of radiation exposure from an epidemiological standpoint, it is important to have a clear understanding of their limitations, particularly because their implementation would require substantial resources. As an important clinical issue, tracking patient radiation dose longitudinally cannot be considered helpful in guiding diagnostic decision making for individual patients in a discrete encounter. *If one assumes a linear relationship between radiation dose and cancer risk, the incremental risk associated with radiation from a given imaging procedure is independent of prior radiation exposures.*[99] *When a physician and patient are weighing the benefits and risks of performing a cardiac imaging study, the benefit-risk balance for that procedure is the same regardless of whether the patient has a high cumulative radiation exposure or not.* For each encounter, the most efficacious (taking into account diagnostic performance, all potential risks, cost, and availability) imaging study should be considered in all patients, not just those with high prior cumulative exposure.[100]

Future Priorities for Research

Continued Technical Advances in Imaging

Computed Tomography

Numerous technical advances in cardiac imaging technologies offer the potential to further reduce radiation exposures, with the goal of achieving comparable diagnostic performance and subjective image quality at lower and lower exposures levels.[101] Current radiation exposure reduction efforts are focused on multiple areas, including new x-ray tube designs, better beam collimation, more efficient solid-state photon-counting detectors, novel photon-counting detectors, and more sophisticated iterative image-reconstruction algorithms.[102,103] It has been estimated that a combination of such methods may lead to a dose reduction of 80% from that possible with current scanners.[102] Optimization and standardization of CT protocols and robust dose index reporting in CT will further enhance the ability to manage radiation exposures in CT.[104]

Nuclear Cardiology

Several clinical and preclinical SPECT cameras that incorporate ≥2 solid-state detectors and are more sensitive to detection of photons have been developed. Although most initial studies and clinical protocols using such cameras have used this advantage to reduce acquisition time, efforts have begun to develop and validate protocols that use lower injected activity.[105,106] Improvements in image reconstruction for nuclear cardiology with improved iterative image-reconstruction methods combined with resolution recovery also offer the potential to reduce dose.[77,80] Development of new PET perfusion tracers will allow

the use of exercise as stress modality and still allow the benefit of the lower radiation exposure in PET compared with SPECT.

Fluoroscopy

In interventional fluoroscopy, x-ray beam management technologies are providing ways to perform imaging and intervention using much lower exposures. CT-like imaging options, such as cone-beam CT or 3-dimensional rotational acquisitions, are providing new options for assessment of the success of interventional procedures in real time, potentially avoiding postprocedural confirmatory imaging examinations.[107–109] Although a single 3-dimensional rotational acquisition or cone-beam CT produces more radiation than a single cine or digital subtraction angiography run, dose savings occur when the single 3-dimensional acquisition replaces multiple cine or digital subtraction angiography runs.[110,111] Essentially, the 3-dimensional data set yields a quick impression of the lesion and its best viewing angle, which allows the operator to eliminate nonproductive diagnostic acquisitions.

Hybrid Imaging

Hybrid scanners that incorporate magnetic resonance imaging, such as PET/magnetic resonance imaging and PET/CT/magnetic resonance imaging, offer the potential for information currently obtained at the cost of ionizing radiation exposure (eg, bolus tracking, attenuation correction, and lesion localization) to be obtained without radiation. Future efforts need to focus on further development and validation of such technology and protocols.

Assessing the Benefit of Imaging in Various Clinical Scenarios Using Clinical Trials and Comparative Effectiveness Studies

In many clinical scenarios, there is little or no evidence to guide the use of imaging and to quantify its potential benefit. Prospective, randomized clinical trials that compare the outcomes of management strategies with and without imaging are difficult to design and hence rare.[112,113] A major component of defining the appropriateness of imaging for a given indication is to examine the comparative effectiveness of multiple imaging modalities for diagnosis and guidance of management. Comparative effectiveness trials and registries form the basis for demonstrating clinical benefit and inform clinical practice guidelines and AUC. There are a number of ongoing randomized clinical trials that may provide critical information about testing strategies, for instance, the National Institutes of Health/National Heart, Lung, and Blood Institute–sponsored Prospective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE),[114] which compares functional imaging with exercise or pharmacological stress with anatomic imaging by coronary CT angiography. Other such trials include the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA),[115] which is comparing conservative and invasive management in patients with stable ischemic heart disease and moderate ischemia based on imaging, and the Randomized Evaluation of Patients With Stable Angina Comparing Utilization of Diagnostic Examination (RESCUE),[116] which is comparing coronary CTA and SPECT myocardial perfusion imaging as initial diagnostic strategies for coronary artery disease in patients with stable angina.

Negative clinical trials, which identify areas with limited or no clinical benefit from imaging, are an important element of developing evidence. Negative clinical trials that result in categorization as inappropriate or in class III clinical recommendations (no benefit) for certain imaging strategies can reduce the use of and decrease population exposure to ionizing radiation. For example, the Detection of Ischemia in Asymptomatic Diabetics (DIAD) trial showed no benefit of screening for ischemia with radionuclide myocardial perfusion imaging in asymptomatic patients with diabetes mellitus compared with no screening.[117] Several other recent negative clinical trials have indicated the use of certain imaging strategies as inappropriate in specific clinical scenarios.[117,118]

Clinical trials and registries of cardiovascular imaging could contribute to radiation safety and reduction of population exposure to ionizing radiation in other ways. For example, routine, mandated collection of available radiation data from clinical studies could result in the development of DRLs for a given patient population.[119] Also, clinical trials or registries should more frequently incorporate assessments of the value of the information obtained by imaging, and assimilation of trial or registry experiences into the crafting of real-world effectiveness and safety strategies should become a more common focus.

Recommendation

1. **In trials, comparative effectiveness studies, and registries that involve diagnostic cardiac imaging with ionizing radiation, all relevant radiation exposure data should be collected and reported (*Class I; Level of Evidence B*).[83,84]**

Continued Refinement of AUC

Indications given an AUC designation of "may be appropriate" (or "uncertain"), such as SPECT and CTA criteria for long-term evaluation after revascularization, should be the focus of future research.[15,17] Studies examining outcomes from cardiac imaging, such as the DIAD trial,[117] should be incorporated into AUC updates. Ongoing clinical trials that compare multiple imaging modalities should form the basis for future multimodality AUC, which may take into consideration the projected risks of radiation exposure as a criterion in the choice of initial testing. As discussed in prior sections, the development of new strategies to promote the routine use of AUC by clinicians is also much needed.

Improving Methods of Effective Communication With Patients

Further research into developing effective communication strategies for conveying information to patients and educating them about the benefits and risks of procedures is necessary to achieve patient-centered imaging.

Epidemiological Studies of the Effects of Radiation Exposure

Population-based assessments examining the relationship between low-dose radiation from medical imaging and risk of malignancy are limited by existing techniques for quantifying in vivo exposure and the large cohort sizes that must be

matched and followed to demonstrate risks in the dose levels associated with medical imaging.[46] For a 10-mSv effective dose (similar to many cardiac imaging procedures), a cohort of >2 million individuals must be studied over their entire lifetime, and other risk- and health-modifying factors controlled or accounted for, to have an 80% chance of detecting a statistically significant increase in cancer risk.[120] Several prospective cohort studies are currently under way to examine the radiation risks related to imaging with CT in children.[121] Support of such epidemiological studies that may better define the dose-risk relationship at radiation doses relevant to medical imaging is essential.

Cellular Biomarkers of Radiosensitivity

Further studies of the molecular and cellular effects of radiation exposure are equally critical to develop an accurate dose-risk model. New methods that are sensitive to DNA repair activity at the doses associated with CT imaging have been developed.[122] Ongoing research to identify genes with differential expression after radiation exposure suggests the potential for the development of biomarkers for sensitivity to the effects of radiation.[122,123] However, much work remains to identify specific sets of genes that alter their expression and to examine their relationship to biological effects in humans. The theoretical future benefits of such work include identification of patient-specific indicators for risk of radiogenic malignancy (other than age and sex) or severe side effects after radiation therapy in individuals who are especially radiosensitive.

Summary

Education, justification, and optimization are the cornerstones to enhancing the radiation safety of medical imaging. Education regarding the benefits and risks of imaging and the principles of radiation safety is required for all clinicians in order for them to be able to use imaging optimally. Empowering patients with knowledge of the benefits and risks of imaging will facilitate their meaningful participation in decisions related to their health care, which is necessary to achieve patient-centered care. Limiting the use of imaging to appropriate clinical indications can ensure that the benefits of imaging outweigh any potential risks. Finally, the continually expanding repertoire of techniques that allow high-quality imaging with lower radiation exposure should be used when available to achieve safer imaging. The implementation of these strategies in practice is necessary to achieve high-quality, patient-centered imaging and will require a shared effort and investment by all stakeholders, including physicians, patients, national scientific and educational organizations, politicians, and industry.

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Cynthia H. McCollough	Mayo Clinic, Rochester	NIH†; Siemens Healthcare†; Thrasher Foundation†	None	None	None	None	None	None
James K. Min	Weill Cornell Medical College/New York Presbyterian Hospital	GE Healthcare*	None	GE Healthcare*	None	None	GE Healthcare*	None
Richard L. Morin	Mayo Clinic	None	None	None	None	None	American Image Management*	None
Brahmajee K. Nallamothu	University of Michigan	None	None	None	None	None	None	None
Khurram Nasir	Baptist Health South Florida	None	None	None	None	None	None	None
Rita F. Redberg	University of California, San Francisco	None	None	None	None	None	None	None
Leslee J. Shaw	Emory University School of Medicine	Bracco*; CV Therapeutics*; GE Healthcare*	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosure Table

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
Stephen Achenbach	University of Erlangen	Siemens†	None	Siemens*	None	None	None	None
Laura Findeiss	University of California, Irvine	None	None	None	None	None	None	None
Donald L. Miller	US Food and Drug Administration	None	None	None	None	None	None	None
Rajan Patel	Ochsner Clinic Foundation	None	None	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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