

Conference Report

Developing an Action Plan for Patient Radiation Safety in Adult Cardiovascular Medicine

Proceedings From the Duke University Clinical Research Institute/American College of Cardiology Foundation/American Heart Association Think Tank Held on February 28, 2011

Participating societies include the American College of Cardiology Foundation, American College of Radiology, American Heart Association, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Nuclear Medicine

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Abstract—Technological advances and increased utilization of medical testing and procedures have prompted greater attention to ensuring the patient safety of radiation use in the practice of adult cardiovascular medicine. In response, representatives from cardiovascular imaging societies, private payers, government and nongovernmental agencies, industry, medical physicists, and patient representatives met to develop goals and strategies toward this end; this report provides an overview of the discussions. This expert “think tank” reached consensus on several broad directions including: the need for broad collaboration across a large number of diverse stakeholders; clarification of the relationship between medical radiation and stochastic events; required education of ordering and providing physicians, and creation of a culture of safety; development of infrastructure to support robust dose assessment and longitudinal tracking; continued close attention to patient selection by balancing the benefit of cardiovascular testing and procedures against carefully minimized radiation exposures; collation, dissemination, and implementation of best practices; and robust education, not only across the healthcare community, but also to patients, the public, and media. Finally, because patient radiation safety in cardiovascular imaging is complex, any proposed actions need to be carefully vetted (and monitored) for possible unintended consequences. (*Circ Cardiovasc Imaging*. 2012;5:400-414.)

Key Words: AHA Scientific Statements ■ appropriate use ■ medical radiation ■ patient safety ■ quality improvement

*See Appendix for Writing Committee disclosure information.

The findings and conclusions in this report are those of the conference participants and do not necessarily reflect the official position of the American College of Cardiology Foundation, the American Heart Association, and the Duke Clinical Research Institute.

This document was endorsed by the American Heart Association, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Nuclear Medicine.

The online-only Appendix, with a complete list of conference participants and organizations and corresponding disclosure information is available with this article at <http://circimaging.ahajournals.org/lookup/suppl/doi:10.1161/HCL.0b013e318252e9d9/-DC1>.

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Introduction

Medical diagnosis and treatment has employed ionizing radiation as an indispensable tool since its introduction by Roentgen in 1895. Advances in medical imaging and procedural technology and utilization growth have resulted in an increase in radiation exposure in cardiovascular patients. This has rekindled the controversy as to whether the low doses of ionizing radiation used in cardiovascular care may lead to an increased lifetime risk of cancer, and whether such risks can be justified in light of the established medical benefits.¹⁻⁹ Recently, the discussion has expanded beyond the medical and physics communities to capture the attention of the media, patients, and lawmakers. In February 2010, the House Committee on Energy and Commerce's Subcommittee on Health held a Hearing on Medical Radiation: An Overview of the Issues,¹⁰ which was followed in March 2010 by a public meeting of the Food and Drug Administration, Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging.^{11,12} Both of these meetings discussed the need to regulate radiation exposure in the clinical setting. Despite these intense efforts by multiple stakeholders, many unanswered questions remain.

Radiation is an unavoidable part of our daily lives, with varying levels of background exposure from natural sources including radionuclides in our bodies, cosmic rays, ground sources, and radon.¹³ Although unnecessary radiation exposure is clearly undesirable, the judicious and appropriate use of low levels of ionizing radiation in medical applications is intrinsic to the current state of the art of cardiovascular care. Its application contributes to many other advances that have remarkably reduced morbidity and mortality from the America's number 1 killer.¹⁴ Thus, the effective diagnosis and treatment of cardiovascular disease (CVD) often requires some exposure to radiation,¹⁵⁻¹⁷ and the goal should be appropriate use rather than the elimination of radiation exposure.¹⁸ The balance between the benefits and risks associated with ionizing radiation must be evaluated in every clinical scenario in order to provide optimal care. For justified procedures, exposure should be optimized to give the lowest possible dose while maintaining image quality to give the highest possible accuracy. For example, in older patients and those with life-threatening CVDs, the benefits of accurate diagnosis and optimal management that are facilitated by imaging are likely to outweigh the minimal or theoretical risks of optimal radiation exposure.

Defining and accomplishing optimal patient radiation safety in adult cardiovascular medicine represents a complex and difficult task. To develop practical approaches to these strategies, in February 2011, the Duke Clinical Research Institute (DCRI), the American College of Cardiology Foundation (ACCF), and the American Heart Association (AHA) convened a meeting of representatives of cardiovascular imaging societies, government agencies, industry, medical physicists, safety experts, and patient representatives. The discussions at the Think Tank, therefore, represent the opinions and recommendations of the participants, and not necessarily the policy of the ACCF or the organizations providing representatives.

This report provides a review of the discussions and strategic recommendations from the Think Tank to enhance patient radiation safety for cardiovascular imaging and procedures. Together, these deliberations provide a robust and feasible road map for optimizing radiation safety, reducing patient dose, and obtaining diagnostic quality images while maintaining optimal cardiovascular care through appropriate and best practice use of imaging for diagnosis and to guide therapeutic procedures.

Contemporary Cardiovascular Therapy and Increasing Radiation Exposure

CVD is responsible for 33.6% or 1 of every 3 deaths in the United States, more than any other cause of death. An estimated 82 600 000 American adults (>1 in 3) have some form of CVD, and the lifetime risk for any CVD is 2 in 3 for men and >1 in 2 for women.¹⁴ Given the high prevalence and mortality associated with CVD, timely diagnosis and treatment are crucial.

The development and clinical application of imaging modalities, such as radionuclide myocardial perfusion imaging, echocardiography, computed tomography (CT), magnetic resonance imaging, fluoroscopy, and angiography have significantly enhanced the diagnostic and therapeutic approach to CVD by improving diagnosis and procedural guidance and enabling less invasive treatments. These advances in early diagnosis and management, coupled with improved treatment of CVD, have contributed to a remarkable reduction in morbidity and mortality; from 1997 to 2007 the death rate from CVD declined 27.8%.¹⁴ Substantial growth in cardiac imaging occurred concurrently with, and may have influenced, the declining cardiovascular morbidity and mortality.^{19,20} However, the increased demand generated in response to the ongoing technological evolution has resulted in a significant increase in the general population's exposure to ionizing radiation for medical purposes. A recent report from the National Council on Radiation Protection and Measurements estimated that the collective dose received from medical uses of radiation in the United States increased by >600% between 1980 and 2006.¹³

Overview of Patient Radiation Protection in Cardiovascular Care

The biological effects of ionizing radiation fall into 2 broad categories. *Deterministic effects* predictably occur above certain thresholds of absorbed dose to a specific tissue and include skin erythema, epilation, and possibly even direct cardiac toxicity. *Stochastic effects* are those in which radiation causes damage that may result in a malignancy, usually at a much later time. The risk and frequency of malignancies caused by the levels of radiation used in medical imaging remains undetermined and controversial. However, given this uncertainty, it is critical to educate providers to minimize dose by performing only diagnostic exams and procedures that are appropriate and necessary, considering the benefits and risks of alternative examinations or procedures without radiation, and by using the best possible combination of equipment, dose, and protocols that will still result in accurate and diagnostic studies. Such practices are aligned

with fundamental principles of radiation protection in medicine;^{21,22,22a} a procedure is *justified* if it is the most appropriate means of accomplishing the clinical goal and is *optimized* by using the smallest necessary amount of radiation that provides diagnostic image quality (ALARA, or using a radiation dose As Low As Reasonable Achievable).^{23,24}

Dosimetry: Measuring Radiation Exposure

Essential to any discussion of radiation safety is the differentiation between exposure and dose. Exposure is the amount of radiation produced by the device and the subsequent ionization of air molecules and is typically and simply measured in air. In comparison, the amount of energy absorbed per unit tissue, referred to as the absorbed dose, is much more relevant to the discussion of radiation risks. Patient absorbed doses vary by organ and body region within a patient. The absorbed dose cannot be measured directly but can only be estimated for a given exam since numerous patient- and exam-specific factors dramatically alter how much radiation is absorbed in different patients for the same imaging protocol from a given device. Thus, even if the scanner-delivered exposure is constant, the number of x-ray photons that reach various tissues and organs varies greatly between individuals. Additional contributors to variability in radiation absorption include machine design and capability, scanning techniques, and other technical parameters. Nevertheless, exposure can be a useful parameter for benchmarking between imaging protocols and institutions.

In addition to the difficulty in measuring the unique dose distribution for each patient for each test, radiation dosimetry metrics differ by imaging modality, making comparisons of exposures from different tests and assessing cumulative dose for a given individual challenging. For radionuclide studies, the administered activity, expressed in standard international (SI) units of Becquerel (Bq), is the standard measurable dosimetry parameter, and internal absorbed doses to the patient may be calculated by standard methods in milligrays per unit administered activity.^{25–27} One millicurie, the traditional unit for activity, corresponds to 37 MBq. For fluoroscopy and cineangiography, the measurable dosimetry parameters include total air kerma at the interventional reference point, measured in Grays (Gy), and the air kerma-area product²⁸ measured in Gy \times cm². For CT, the volume computed tomographic dose index (CTDI_{vol}), expressed in SI units of milligrays (mGy) or dose-length product (DLP) expressed in SI units of mGy/cm are most commonly used.²⁹

The effective dose (E, reported in SI units of millisieverts, mSv) is sometimes used to facilitate comparisons of radiation exposure across modalities and exams. Effective dose is a surrogate for risk used in radiation protection that reflects a whole-body estimate of the dose value that would yield the stochastic risk equivalent to that of a given nonuniform partial-body exposure to ionizing radiation such as occurs in medical imaging.²⁵ Effective dose is a generic estimate of risk with a wide margin of error and cannot be measured directly, but instead is obtained from modeling, simulation, and interpolation. Although effective dose can be used to compare different scan protocols or examinations performed with different imaging modalities that use ionizing radiation, it

cannot express the biological risk specific to individual patients. However, note that effective dose may be useful in comparisons of the stochastic risk of different medical procedures in population groups that receive ionizing radiation, against each other or against background radiation, whereas direct organ dose calculations are better suited to optimize radiological procedures that involve multiple organs. Despite these efforts at standardization, measurement of radiation exposure and risk is controversial, and there is not universal agreement on the appropriate approach.

Modeling the Potential Cancer Risk Associated With Medical Radiation

The risk of malignancy attributable to “low dose” (<100 mSv) levels of ionizing radiation is extrapolated from follow-up of survivors of the atomic bomb explosions in Hiroshima and Nagasaki, Japan, in 1945.³⁰ The appropriateness of this extrapolation is controversial because, in contrast to patients who undergo repeated low-dose medical imaging over decades, these subjects experienced a single episode of whole-body exposure to different types and qualities of radiation (including alpha particles) with higher doses delivered over seconds to days. Nevertheless, the “linear no-threshold” (LNT) model derived from these data is currently used as the standard model of potential radiation risk in radiation protection, including the Biological Effects of Ionizing Radiation (BEIR) VII report.³¹ However, there are some concerns with use of LNT as a standard. The concept of effective dose and the LNT hypothesis were developed for occupational radiation protection and not as predictive biological models for patients exposed to radiation during medical imaging. Further, the assumption inherent in LNT, that cancer risk increases linearly with dose and that there is no dose level below which there is no risk, is challenged by other models that are well covered elsewhere.³² Finally, stochastic risks are random by definition, and therefore should not be linearly related to cumulative exposures.

Based on the LNT model, the average lifetime risk of cancer mortality in the general population attributable to an effective dose of 1000 mSv (an exposure equal to 50 to 500 typical coronary CT angiograms or radionuclide perfusion studies) is estimated at 5% to 7.9%.³¹ However, prospective, long-term observational studies^{33,34} have not unequivocally confirmed an increased risk of solid cancers related to medical or occupational low-dose radiation (<100 mSv) delivered over many years, thereby neither confirming nor refuting the LNT model. This may be because the cancer risk is so small at this dose level that accurate detection of excess risk of over those conveyed by biological factors and other known carcinogens would require tracking >5 000 000 adults over their lifetimes.³² Epidemiological studies of radiation as a carcinogen are further complicated by the long latency period of most radiation-induced cancers. Despite this uncertainty, stochastic radiation risks likely decrease with increasing age and are lower in men than in women; findings that are particularly germane to the population of patients with coronary artery disease.

Approaches to Radiation Safety

Approaches to patient radiation safety must be lifelong and not confined to simply reducing the exposure during a single test or procedure. From a patient standpoint, the American College of Radiology and the National Council on Radiation Protection and Measurements suggest that efforts can be divided into those that occur before the imaging or procedure, during the test or procedure to ensure that exposure is minimized, and then afterwards to ensure lifelong safety.^{35,36} The Joint Commission uses an analogous construct in dividing the requirements for its 2011 Sentinel Event Alert into right test, effective processes, safe technology, and safety culture.^{25,37–41}

Before imaging or procedures: Tests and procedures utilizing radiation should be performed in the right patient, for the right reason, at the right time, and alternatives to radiation should be considered. Thus, the issue of radiation protection is relevant for every clinician making imaging and procedural decisions. The ACCF appropriate use criteria^{16,42–47} offer an important framework to ensure appropriate use, whereas concomitant consideration of relative radiation dose levels may be helpful in balancing efficacy and potential radiation exposure to the patient to determine whether the procedure is justified.³⁵ This step is highly important since the increase in population exposure has occurred in the setting of decreased radiation from each individual test and therefore has resulted entirely from increased use. The International Commission on Radiological Protection^{22,48} and AHA²⁵ have developed reference levels for use as benchmarking and quality assurance tools that may be helpful in estimating anticipated exposure from proposed procedures.

Creation of a safe environment and education of ordering and rendering providers must also occur before imaging is performed. The increased attention to the importance of radiation protection has led to both professional society and accreditation body recommendations in these areas.⁴¹

During imaging: Each rendering physician, laboratory, and hospital must be responsible for optimizing the dose delivered for each test or procedure. The need for greater standardization is demonstrated by significant variations (up to 13-fold) in radiation doses for similar types of imaging procedures, within and across institutions for both coronary CT angiography and nuclear imaging.^{3,4,49} Professional societies have addressed these challenges through the creation of robust procedural and safety guidelines, including those from the American Society of Nuclear Cardiology, the Society for Cardiovascular Angiography and Interventions, the Society for Cardiovascular Computed Tomography, and the Society of Nuclear Medicine.^{25,37–40,50} Newer technology has already enabled dramatic dose reductions for cardiac computed tomography angiography (eg, prospective electrocardiogram-triggered axial imaging) and nuclear (eg, use of technetium instead of thallium, reduced-dose imaging using high-sensitivity cameras) and holds promise for additional future dose reduction. Additional attention to dose management and optimization would be facilitated by equipment capable of automatically providing radiation exposure estimates for benchmarking, quality improvement, and research, and by

ensuring that users understand how to properly operate the equipment.

After imaging: Although it is likely that more appropriate utilization and further improvements in technology will reduce overall radiation exposure to patients, these necessary interventions are not sufficient to ensure patient safety across multiple episodes of care for multiple diseases delivered by many providers. Although cumbersome and burdensome to providers of imaging services, reporting doses from individual exams using the electronic medical record or alternative methods is essential as a quality improvement tool for the purposes of benchmarking and radiation minimization. However, tracking cumulative dose in a given individual is both difficult to do accurately and has no clear value for improving long-term patient safety, given the inherently random nature of stochastic events. Further, whether or not such information can be used to better inform decision making on types of diagnostic studies to be performed for each episode of care is unproven. One exception to this is tracking exposure during a single episode of care involving repeated or high exposure, such as percutaneous coronary interventions or ablative treatment of arrhythmias, which may put a patient at risk for deterministic effects. Similarly, it is recommended that short-term follow-up be performed after high-dose fluoroscopic procedures (ie, >5 Gy) to detect and treat any resulting deterministic effects.

Developing an Action Plan for Cardiovascular Radiation Safety Stakeholders

The uncertainties surrounding the actual levels of patient dose related to cardiovascular care, the assessment of potential competing benefits and risks, and the need to develop practical approaches to radiation safety and education of physicians, patients, and the public require the input and expertise of many relevant stakeholders. Such collaboration and cooperation recognizes the unique knowledge, perspectives, and experiences of each group. Therefore, 1 of the critical strategies in achieving the Think Tank goals was to identify and bring together these stakeholders to join in radiation safety improvement:

- **Research scientists; funding agencies:** Radiation biologists and physicists working in both the basic and applied sciences perform much needed research about the biological effects of radiation exposure and how to quantify radiation dose.
- **Healthcare professionals; professional and scientific organizations:** Physicians and physician societies are primary stakeholders as requestors and providers of testing that has been demonstrated to improve morbidity and mortality and as the guarantors of optimum safety for their patients. These groups are responsible for developing and implementing optimal imaging procedures and educational initiatives and should play a collaborative role in developing standards and regulations regarding radiation safety. In addition, they are responsible for defining the content of undergraduate, graduate, and continuing medical education. Nonphysi-

cian staff are also critical to development and implementation of standards.

- **Medical physicists:** Although the role of physicists in many cardiovascular facilities has been limited to quality control testing of equipment and ensuring compliance with state and federal regulations, their knowledge base is invaluable in quality improvement and education.
- **Regulators:** Federal agencies, including the Food and Drug Administration and Nuclear Regulatory Commission, and the state radiological health agencies are responsible for creating testing standards and monitoring and ensuring compliance through regulation, and for responding to proposed changes in protocols/dosing that would minimize radiation exposure. Other regulators, including accreditation agencies such as the Joint Commission, the American College of Radiology, and the Intersocietal Accreditation Commission, promote safety and standardization through accreditation of imaging and procedural laboratories.
- **Payers:** At a national level, the Centers for Medicare and Medicaid Services (CMS) sets guidelines for any facilities (hospital and independent imaging facilities) seeking CMS reimbursement for imaging procedures. Government and private payers are also in a unique position to identify and possibly flag duplicate imaging tests and procedures, especially when care may be provided by multiple caregivers. In addition, payers are able to provide incentives to providers to improve care and radiation safety on multiple levels and need to be open to rapidly “covering” and reimbursing/paying for modified procedures that would minimize radiation exposure. On a patient level, payers should not use radiation history alone as an independent factor in determining authorization for a procedure.
- **Industry:** Industry can uniquely advance the development of new technologies and make these features available to providers and patients. Such features include the ability to ensure diagnostic accuracy while delivering lower doses of radiation, tracking exposure, and transferring dose values to structured reports and the electronic health record. Both individually and through organizations such as the Medical Imaging and Technology Alliance, industry is able to assist with standardization of dose measurement across tests, protocols, and healthcare providers and with dissemination through education regarding exposure and promotion of facility quality assurance practices.
- **Patients, public, and media:** In the absence of a universal medical record, the patient may be the only source of information regarding prior procedures and radiation exposures. Further, as with all care, patients should be educated to make informed decisions, which implies a basic level of knowledge as well as provider disclosure of potential radiation-associated risks related to testing and procedures. In the absence of a universal medical record, the patient can take an active role by keeping a record of his/her exams and question the need for tests so they are not repeated unnecessarily.

Critical Areas and Strategies for Action

The Think Tank organizers identified 4 critical areas for which experts were charged with defining 3 to 5 goals and associated strategies required to achieve these including methods, responsibilities, stakeholders, and implementation time frame. The time frame was meant to convey the urgency of the issue as well as relative priorities of different recommendations. The topics were

1. Quantifying the estimated stochastic risks of low-dose radiation associated with cardiovascular imaging and therapeutic procedures.
2. Measuring and reporting radiation dose in cardiovascular imaging and procedures.
3. Minimizing radiation dose for single episodes of care and across entire systems of care.
4. Educating and communicating with multiple groups to increase awareness and achieve goals in minimizing exposure.

Group 1: Quantifying the Estimated Stochastic Risks of Low-Dose Radiation Associated With Contemporary Cardiovascular Imaging and Therapeutic Procedures

Current, ongoing radiation biology and epidemiology research efforts are robust but still insufficient to fully address critical questions raised by the need for improved radiation safety.⁵¹ Identified needs are presented in Table 1 and as follows.

Basic and translational research into the mechanisms by which radiation-induced cellular DNA damage and cellular repair and misrepair mechanisms affect radiation-related carcinogenesis^{52,53} should be encouraged and supported, with particular attention to the low-dose–response relationship at the molecular and cellular level. Several areas of research were identified as important:

1. Biological markers of injury. Currently, it is unknown which, if any, clinically obtainable biological markers of radiation injury (such as DNA double-strand breaks or sister chromatid exchanges in blood samples) predict radiation-induced cancer. Identification and clinically available testing for such markers may allow better patient risk stratification.
2. Models of injury. Mechanistic biology-based dose-response models at the level of cellular protein abnormalities hold the promise of predicting malignancy induction with better resolution than epidemiological studies. Such new models are being used to study recently identified potential confounders of the current understanding of the dose-response relationship at low-dose ionizing radiation, such as genomic instability,⁵⁴ bystander effects,⁵⁵ or adaptive responses.⁵⁶ A National Institutes of Health workshop to further explore the opportunities in this area would be an important first step toward dedicating funding.
3. Because the science and methods of radiation dosimetry are complex, better techniques for modeling and simulation are needed to estimate radiation dose and the potential biological impact. These same methods would

Table 1. Strategies for Quantifying the Estimated Stochastic Risks of Low-Dose Radiation Associated With Contemporary Cardiovascular Imaging and Therapeutic Procedures

Strategy	Primary Responsibility	Stakeholders	Implementation Time Frame
Basic and translational research in radiation biology <ul style="list-style-type: none"> Evaluate biological markers of cellular radiation injury as predictors of radiation-induced cancer Determine the dose-response relationship between radiation and molecular and cellular effects Better techniques for modeling and simulation to estimate radiation dose 	<ul style="list-style-type: none"> Research scientists Physicists Funding agencies 	<ul style="list-style-type: none"> Professional and scientific organizations Industry 	Ongoing; funding for additional research by 2014
Epidemiological research on population effects of radiation <ul style="list-style-type: none"> Long-term studies of patients at high risk (eg, children, high exposures due to occupation or accidents) Large prospective registries focused on defining stochastic risks of radiation exposure Develop models of risk related to chronic or serial exposure to low-dose medical radiation 	<ul style="list-style-type: none"> Research scientists Physicists Funding agencies Industry 	<ul style="list-style-type: none"> Professional and scientific organizations Hospitals and testing/procedural labs Payers 	Ongoing; registry by 2014

likely have relevance to the public secondary to application related to occupational exposures, nuclear accidents, or acts of war/terrorism.

Implementation: 2014 and ongoing.

Epidemiologic research is required to define the true long-term risks of exposure, especially in those at high risk (such as children or those with multiple, serial exposures). The stochastic risks of serial low-dose exposures are inadequately defined; research into statistical and mathematical models should be encouraged. Another area for research is how repeated exposure should be added to calculate risk as there are widely varying recommended adjustment factors (dose and dose-rate effectiveness factor). Creation of multi-specialty registries with large sample sizes or augmentation of existing registries is a promising prospective approach that would support development of novel methods for modeling absorbed dose to provide more accurate patient specific doses. However, significant obstacles exist, including statistical validity and power, incorporation of epidemiological expertise, length of follow-up, obtaining accurate estimates of relevant organ doses, tracking nonmedical radiation exposure, generalizability of findings, and sources and availability of funding. At present, a number of populations with prolonged exposure to higher than average levels of radiation (ie, radiation accidents or limited radiation protection) are being studied.

Implementation: 2014–2015.

Group 2: Measuring and Reporting Radiation Dose in Cardiovascular Imaging and Therapeutic Procedures

The accurate estimation of dose for even a single medical exposure requires numerous assumptions and complex modeling performed by medical physicists. Thus, rigorous radiation dose estimates are typically obtained only in specific situations, when detailed dosimetry is required (such as suspected overexposure, equipment malfunction, and exposure during pregnancy). Despite having significant inherent uncertainty and unclear utility and not intended to be used in

individual patients, the radiation protection quantity of effective dose is sometimes used for this purpose in the absence of a better estimate. This is especially true in the range of <50 mSv, a threshold that is rarely crossed by single exposures for diagnostic imaging purposes. Measuring and communicating effective dose provides only a limited estimate of potential biological risk and should be used only with great caution to estimate benefit-to-risk analyses. However, given the heightened concern regarding radiation exposure and potential deleterious effects on health, effective dose is an estimate of potential detriment that can be used to compare biological risk of different medical procedures against each other or against background radiation, as well as to optimize safety of procedures requiring radiation. Ongoing efforts to develop a better and easily obtained measurement for tracking and assessing biological risk are needed. The following 4 strategies were recommended (see also Table 2).

Strategy 1: Establish and Implement Standards to Ensure Consistent and Complete Recording of Radiation Exposure and Patient Parameters Required to Estimate Dose

The measures of exposure and patient parameters necessary to accurately model patient radiation dose (age, sex, height, weight, detailed anthropometry, and part of the body exposed) are well established for most modalities, although the biokinetics of nuclear radiopharmaceuticals are less well known. When applicable, exposure or dose estimates should be systematically and automatically captured at the time of medical imaging. Properly formatted through a newly developed Digital Imaging and Communications in Medicine (DICOM) standard, this metadata combined with measured procedural dosimetric data could be used to provide source data for population-based studies and research to improve our understanding of exposure, absorbed dose, and potential biological effects. Resources to define and implement the new standards that would be required to embed needed patient and technical factors within the practice of medical imaging should be made a high priority at this time. Once established, collection of these data should be automated and

Table 2. Strategies for Measuring and Reporting Radiation Exposure and Dose in Medical Imaging

Strategy	Primary Responsibility	Stakeholders	Implementation Time Frame
Create standards and mandate recording of relevant radiation exposure and patient parameters	<ul style="list-style-type: none"> • Industry • Healthcare professionals • Radiation physicists 	<ul style="list-style-type: none"> • Patients, public, media • Regulators • Professional and scientific organizations 	2012
Expand or develop central registries with radiation exposure data to support best practices	<ul style="list-style-type: none"> • Payers • Funding agencies • Professional and scientific organizations • Industry 	<ul style="list-style-type: none"> • Healthcare professionals • Professional and scientific organizations • Certifying and accrediting organizations • Payers • Regulators 	2013 and ongoing
Develop and implement standards and systems for communicating radiation exposure beyond effective dose	<ul style="list-style-type: none"> • Healthcare professionals • Radiation physicists • Funding agencies • Professional and scientific organizations • Industry 	<ul style="list-style-type: none"> • Patients, public, media • Regulators • Payers 	Ongoing
Reduce exposures that cause deterministic effects through enhanced exposure monitoring and warning procedures	<ul style="list-style-type: none"> • Industry • Hospitals and testing/procedural labs • Certifying and accrediting organizations • Regulators 	<ul style="list-style-type: none"> • Patients, public, media • Professional and scientific organizations • Industry • Healthcare professionals 	2012

universal. Until this can be accomplished, all reports should document radiation dose in terms of the standard measurable dosimetry parameters that are used to define diagnostic reference levels. For example, for CT the CTDI(vol) is displayed on all scanner consoles manufactured after 2006.

Implementation: 2012 and ongoing.

Strategy 2: Expand or Develop Central Registries Related to Radiation Exposure and Cardiovascular Imaging to Support Best Practices and New Research

Development of an automated, multispecialty national dose registry (and incentives for participation) would collect objective data for research and allow facilities to compare doses to national reference levels, which would be a major improvement to quality assurance practices. The Food and Drug Administration and other organizations have promoted the development of registries for the purposes of developing national diagnostic reference levels and best practices for facility quality assurance.¹² The value of benchmarking providers to their peers has been amply demonstrated to rapidly reduce radiation dose to levels consistent with best practices for a given exam or device.⁵⁷ Registries would help with transparency by providing authoritative and objective data on actual exposures, which in turn would inform more meaningful discussions by public, governmental, health advocacy, scientific, and professional groups. Work to ensure that patient privacy and validity of the data should be supported as part of the process.

Implementation: 2013 and ongoing.

Strategy 3: Develop and Implement Standards for Communicating Radiation Exposure and the Systems to Facilitate Adoption Within the Healthcare Community

Given the complexity of developing standards in the science and terminology of communicating radiation exposure, dose, and potential risk from medical imaging studies to patients,

providers, and the broader community, this task will require the resources and investment of many stakeholders. In the short term, available measures of exposure such as dose-area product should be documented in clinical care and reported as part of all clinical trials involving radiation use.⁵⁸ To avoid conflicting language and variable implementation, a standard vocabulary to reduce jargon and the development of systems to support these standards are needed to provide consistent and complete information to patients and providers and to promote appropriate utilization. Once created, use of these standards should be mandatory.

Implementation: 2012 and ongoing.

Strategy 4: Minimize Deterministic Effects

Although much of the concern revolves around late, stochastic effects, in very rare situations, high exposures to diagnostic radiation can result in short-term deterministic effects that may occur when thresholds for biological damage are exceeded. Since these deterministic effects are predictable, all healthcare professionals and imaging laboratories should be aware of them, and the dose actively managed throughout the procedure. In addition, robust safety practices should be instituted to ensure real-time detection if dose thresholds are ever approached, with mandated reevaluation of the imaging or therapeutic strategy of the particular procedure.

Implementation: 2012.

Group 3: Strategies to Minimize Radiation Dose: From Single Episodes of Care Involving Cardiovascular Tests and Procedures, to Systems Change

Methods exist to achieve substantial reduction in radiation dose. However, gaps in provider knowledge, differences in image acquisition protocols, and limited transparency lead to delays and fragmentation in the implementation of existing

dose-reduction opportunities. Reducing the population burden of medical ionizing radiation will require collaboration, interventions, and accountability at the level of individual patient care episodes, healthcare providers, radiation physicists, imagers, and healthcare systems. The Joint Commission has recognized the need for such systems change and provided a strong incentive for compliance with its Sentinel Event Alert.⁴¹

Appropriate patient selection reinforced through decision support tools and provider education can reduce the performance of inappropriate medical imaging procedures.¹⁶ The lack of incentives to “do the right thing” and engrained practice routines that may reflect medical–legal and economic concerns may hinder the adoption of appropriate imaging use. Application of existing ACCF appropriate use criteria could reduce these barriers. Tools in development include multimodality appropriate use criteria, which will simultaneously assess the appropriateness of testing alternatives in specific clinical scenarios, including methods that do not involve ionizing radiation and imaging performance measures. To fully implement any of these, the healthcare system should develop incentives for their use.

In performing appropriate studies, substantial radiation dose reductions can be achieved by application of existing technologies. For example, adjustments in cardiac CT acquisition protocols can lead to significant dose reductions through the application of reduced tube potential, and performance of prospectively triggered versus retrospectively gated image acquisition in properly selected patients.⁵⁹ However, diagnostic image quality must not be compromised, and the point at which dose minimization may have an unintended negative consequence on diagnostic accuracy remains uncertain. Prospective implementation studies of optimal techniques and protocols suggest that diagnostic image quality can be retained while using dose-reduction techniques,^{57,60} making inconsistencies in the application of dose-reduction strategies a lost opportunity.

There are many opportunities to reduce variability in the performance of procedures that use ionizing radiation for guidance, such as patient shielding during fluoroscopic procedures, reduction of fluoroscopy and cineangiography procedural times, and image processing techniques to eliminate unnecessary duplicated images and radiation exposure. Following existing and future guidelines and implementation of robust quality control measures can be accomplished immediately. In addition, novel complementary stereotaxic and magnetic resonance navigation technologies and nonfluoroscopic techniques such as optical coherence tomography ultrasound guidance (OCT/US) for anatomical assessments are promising.³⁶ Similarly in the area of radionuclide imaging, recommendations have been made for the use of stress-only imaging, positron emission tomography, and adaption of new camera technology that allows a dramatic reduction in the dose normally administered.³⁹ Further technical refinements will lead to new opportunities for dose reduction, and an initial focus on standardizing terminology and harmonizing methods will facilitate their implementation across technical platforms, with avoidance of overly proprietary techniques. Preventing the emergence of unproven modalities

confused by proprietary jargon will require demonstration of benefit/risk during the regulatory approval process and be reimbursed such that providers of services are strongly encouraged to adopt innovative protocols.

Sustained education and quality improvement programs can lead to meaningful radiation dose reduction.^{61,62} Such programs should recognize the opportunity to engage, not only imagers, but also ordering physicians in efforts to achieve population dose minimization through education on test and procedure selection. For example, dose administration should be a routine part of laboratory quality programs. Leverage of payment models emphasizing appropriate use and quality imaging performance could further bolster efforts at dose minimization.

Recommended strategies toward dose minimization that leverage existing and future technologic advances include the following (see also Table 3).

Strategy 1: Education to Create a More Uniform Understanding and Approach to Dose Minimization Techniques

Method 1: Adopt mandatory annual live or online training on basic radiation safety techniques for healthcare providers involved in the ordering or performance of medical procedures using ionizing radiation. A model for this approach is provided by current requirements for training for universal precautions procedures mandated through hospital accreditation organizations and current state mandates for fluoroscopy training. Topics could include radiation safety, alternatives to use of tests with ionizing radiation, and principles of patient selection. Because there are few current requirements for any form of radiation training for providers who order procedures, such education should be integral to general as well as procedural cardiology training programs and continuing medical education.

Implementation: Before 2014.

Method 2: Adopt a professional approach through emphasis on the principles and practice of radiation dose reduction as core knowledge within professional education including cardiology and subspecialty board certification materials and examinations.

Implementation: Before 2015.

Strategy 2: Quality Metrics—Quantitative Reporting of Quality Metrics on Testing

Method 1: Implement internal reporting of quality metrics, including appropriateness of testing, use of dose minimization strategies, objective image quality assessments, and facility-level radiation exposures for common testing categories.

Method 2: Once in place and validated, internal metrics should be elevated to become national, publically reported standards.

Implementation: Before 2013.

Strategy 3: Common Industry/Technology Standards

Method 1: Develop common protocols, definitions, parameter settings, and device settings that ensure satisfaction of basic standards while allowing innovation. From a public health standpoint, robust quality control measures which

Table 3. Strategies to Minimize Radiation Dose Exposure From Single Episodes of Care to Systems Change

Strategy	Primary Responsibility	Stakeholders	Implementation Time Frame
Education: training <ul style="list-style-type: none"> Mandatory annual online training on basic radiation safety techniques for healthcare professionals involved in the ordering or performing of medical procedures using ionizing radiation 	<ul style="list-style-type: none"> Certifying and accrediting organizations 	<ul style="list-style-type: none"> Healthcare professionals 	Before 2014
Education: professionalism <ul style="list-style-type: none"> Emphasize the principles and practice of radiation dose reduction as core knowledge within professional certifying education for all healthcare professionals 	<ul style="list-style-type: none"> Professional and scientific organizations Certifying and accrediting organizations 	<ul style="list-style-type: none"> Healthcare professionals 	Before 2015
Quality metrics <ul style="list-style-type: none"> Develop quality metrics for internal reporting within organizations, with gradual transition to external reporting 	<ul style="list-style-type: none"> Professional and scientific organizations Hospitals and testing/procedure laboratories 	<ul style="list-style-type: none"> Healthcare professionals Payers Certifying and accrediting organizations Hospitals and testing/procedure laboratories 	Before 2013
Common industry/technology standards <ul style="list-style-type: none"> Develop common protocols, definitions, parameter settings, and device settings that ensure basic radiation dose minimization standards are met 	<ul style="list-style-type: none"> Industry Professional and scientific organizations Regulators 	<ul style="list-style-type: none"> Industry Regulators Physicists 	Ongoing

reduce variability may provide more benefit than the latest advances.

Method 2: Continue to reduce exposure through the development and use of improved equipment, technology and techniques, shielding, and validated uses of contrast agents and radiopharmaceuticals.

Implementation: Ongoing.

Group 4: Education and Communication for Physicians, Patients, the Public, and Media

Heightened concerns about the health effects of radiation associated with cardiovascular tests and procedures mandate education of healthcare professionals and the public about the benefits and risks associated with medical exposures. The ability to accurately assess radiation dose, to correlate the dose with biological response, and to communicate these complex scientific issues to the public represents a major challenge. There are 4 important strategies for communicating the balance between the health benefits of cardiovascular imaging and the risks to stakeholders, including patients, physicians, technologists, industry, and the general public (see Table 4). This information exists in various forms and is directed to varied audiences that often do not communicate with each other, and when they do, understanding may not occur due to differences in presentation and comprehension.

Strategy 1: Identify, Catalog, and Develop Educational Resources

Published scientific and Web-based information on the risks and benefits of ionizing radiation provided by professional and medical societies and government agencies should be

made available to the public, patients, and professional and medical practitioners. Because accessing this information at the appropriate level of understanding can be difficult, it should be modified and cataloged for the appropriate stakeholders so that it remains factual but does not require an advanced knowledge in radiation physics to be understood. Primary responsibility rests with professional and medical societies and government agencies that have sufficient knowledge to provide accurate information. Safeguards must be put in place to avoid having these organizations lobby or market on behalf of their technologies or members, but rather to create factual and bias-free material with the emphasis on full explanation of risks and benefits. Such efforts to date have included: <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.pedrad.org>, focused on lowering radiation doses in the imaging of children; and <http://www.radiationanswers.org>, focused on explanations of radiation and exploring myths and benefits; and the International Atomic Energy Agency's Radiation Protection of Patients (<https://rpop.iaea.org/RPOP/RPoP/Content/About.htm>). Once the existing resources have been identified, it is expected that knowledge gaps will require the creation of stakeholder-targeted educational resources by appropriate professional groups. Government agencies such as the National Institutes of Health, Food and Drug Administration, and Agency for Healthcare Research and Quality may have oversight and participatory roles in this effort.

Because the majority of the needed material already exists, the timeline is relatively short for this effort. The greatest

Table 4. Strategies for Education and Communication

Strategy	Primary Responsibility	Stakeholders	Implementation Time Frame
Identify, catalog, and develop education resources	<ul style="list-style-type: none"> Professional and scientific organizations Regulators 	<ul style="list-style-type: none"> Patients, public, media Healthcare professionals 	2011–2012
Identify and disseminate best practices	<ul style="list-style-type: none"> Professional and scientific organizations Certifying and accrediting organizations 	<ul style="list-style-type: none"> Healthcare professionals Industry Professional and scientific organizations Regulators Payers 	2012–2013
Heighten awareness of radiation	<ul style="list-style-type: none"> Professional and scientific organizations Healthcare professionals Research scientists Hospitals and testing/procedural labs 	<ul style="list-style-type: none"> Industry Healthcare professionals Funding agencies Industry 	Ongoing; 2015
<ul style="list-style-type: none"> Develop and test new methods of communicating the risk and risk benefit of low-dose medical radiation 	<ul style="list-style-type: none"> All stakeholders above 	<ul style="list-style-type: none"> Patients, public, media Healthcare professionals Payers 	Ongoing

need for development is for simplified material aimed at ordering physicians, patients, the general public, and the mass media. Management and coordination of the effort and the distribution process represent another challenge. Although Web-based access is the fastest and least expensive, accessibility maybe limited to many of the stakeholders, and development of alternative methods such as social media, mailings, radio, and television should be considered.

Implementation: 2012.

Strategy 2: Identify and Disseminate Best Practices in Diagnostic and Procedural Imaging

Medical and professional societies have developed guidelines for when and how to perform cardiovascular imaging studies.^{16,25,37–40,42–47} This approach first looks at the appropriateness of a given study and has been validated by evidence that incorporation of appropriateness guidelines into automated decision support systems limits growth in the numbers of medical imaging procedures.⁶³ If a study is inappropriate, there is usually minimal benefit, and even a minimal risk from ionizing radiation is too high. Once a study is deemed appropriate, it should be performed using the best available imaging equipment and protocols for dose optimization to get the most accurate diagnosis. Accreditation of laboratories providing services is recommended, and tests should be performed and images interpreted by certified physicians. Both should include requirements for demonstration of radiation safety knowledge and best practices. These best-practice methods for imaging using ionizing radiation need to be distributed to all the stakeholders and knowledge requirements implemented.

Implementation: 2012–2013.

Strategy 3: Heighten Awareness of Radiation Benefits and Risks

Media reports about radiation accidents engender fear of low-level radiation among the general public. Patients with apprehension about radiation may hesitate to receive appropriate cardiovascular imaging and should be included in conversations that recognize both benefits and risks, as befits

the need to ensure true informed consent. Healthcare providers need to be cognizant of this fear, as well as of the potential risks and benefits of imaging with ionizing radiation.

As part of these communications, it is important to convey the quantitative uncertainties about the continuous variables of dose and risk estimates. Given these uncertainties, the American College of Radiology has proposed an approach of categorizing imaging studies by relative radiation levels that differ by orders of magnitude rather than precise dose estimates. In addition to the difficulties in expressing exposure, expressing potential risks can also be challenging to accomplish in terms that are meaningful to patients and clinicians. For example, the concept of “attributable lifetime risk” of cancer mortality may be difficult to understand, even if it is compared with hazards of everyday life such as likelihood of dying from a motor vehicle accident or the risk of a medical error. Consideration of stochastic radiation risks in cardiovascular care should include, in addition to incidence and mortality of cancer, quality of life and cost to society, and should be compared with the burden of CVD, especially if not appropriately diagnosed or treated. Because decisions on care must be individualized, such potential risks are best communicated in the setting of a strong physician–patient relationship.

Implementation: 2015 and ongoing.

Strategy 4: Identify, Monitor, and Minimize Unintended Consequences

Healthcare providers need to help patients understand the benefits of cardiovascular imaging and minimize situations where patients avoid potentially life-saving procedures because they involve ionizing radiation. Avoidance of cardiac imaging procedures by the elderly or patients with short life expectancies may ultimately limit access to the benefits of earlier diagnosis and optimal management with improvement in quality of life. Primary responsibility for avoiding such unintended consequences for all the listed stakeholders rests with all providers of health care who are responsible for determining whether diagnostic or therapeutic procedures are

justified or whether there are other opportunities to obtain equivalent information/results. Monitoring will be an ongoing process.

Every effort must be made to keep the dose As Low As Reasonable Achievable (ALARA) while at the same time keeping the benefit from diagnosis and optimal management As High As Reasonably Achievable (AHARA). We recognize that implementing best clinical practice using ionizing radiation and monitoring and recording radiation exposure are essential steps that must be implemented by those providing the tests as well as by referring physicians. This is an ongoing process.

Summary and Next Steps

The DCRI, ACCF, and AHA Think Tank was convened to better define the issues and needs around patient radiation safety in cardiovascular imaging and to develop an action plan to guide future efforts. As a 1-day meeting, the discussion and recommendations are necessarily limited in scope, and should be seen as exploratory rather than definitive. Nevertheless, several important lessons can be gleaned.

Continuing the progress on improving radiation safety as it relates to cardiovascular medicine will require the efforts of numerous stakeholders in healthcare, government, and patient advocacy. Further enhancement of radiation safety will require the combined efforts and continued engagement of multiple and diverse professional groups, industry, and government. At the same time, it is unclear who will be the “convener” or facilitator for these efforts in cardiovascular medicine. This is a role that may fall naturally to professional societies, such as the ACC, although to date, imaging specialty societies such as the American Society of Nuclear Cardiology, Society for Cardiovascular Computed Tomography, Society for Cardiovascular Angiography and Interventions, and Society of Nuclear Medicine, and radiology organizations such as the American College of Radiology and the Health Physics Society have been more active. A first step in uniting the efforts of multiple organizations and stakeholders is the development of a glossary of organizations and a clearinghouse for ongoing and planned activities. This would allow for less overlap and a more comprehensive and collaborative approach to the issues of radiation safety.

The lack of clarity regarding the relationship between medical radiation and any untoward stochastic events in an individual patient is a significant impediment to setting specific patient safety exposure standards but does not preclude robust quality improvement efforts. Basic and clinical research (and the funding to support it) is needed to understand the risks of the low-dose, multiple exposures that are characteristic of most cardiovascular uses. Without accurate risk estimates, it is impossible to assess the benefit-to-risk relationship for an individual patient. However, efforts to better apply the basic principles of radiation protection and facility-level tracking are eminently feasible, with the collection of population-level dose data already demonstrated to improve patient care.¹⁸ Nevertheless, funding mechanism(s) for the many crucial initiatives outlined in this document remain a challenge.

At present, the infrastructure required to support dose assessment for quality improvement purposes is not in place. The needs range from standardization of terminology to adjustments in equipment capabilities to automatically track exposure, patient parameters, and dose during clinical workflow. Although the primary burden rests with industry, other stakeholders need to support and encourage these improvements, perhaps by requiring compliance to achieve implementation.

Careful patient selection and avoidance of inappropriate testing and procedures including use of ACCF appropriate use criteria is an important Think Tank recommendation. Another important strategy is balancing the requirement to effectively guide each episode of care with the need to minimize exposure. Enhancement of patient safety through adherence to the principle of As Low As Reasonably Achievable (ALARA) to guide protocol considerations, the development of lower-dose radiation equipment and complementary technology, and widespread application of proven dose-reduction techniques are critical. Recent society guidelines, technology development, and other research have been effective to date, but the collation, dissemination, and implementation of best practices is a particular need, and may require “encouragement” from governmental and accreditation agencies. Additional areas in which “encouragement” may be helpful include reporting of quality metrics and incorporation of requirements for professional certification and maintenance of certification of personnel.

Although safety is always paramount, consideration of the benefits as well as the risks of medical tests and procedures is in the patient’s best interest, as is the use of sufficient radiation to ensure diagnostic or therapeutic success. Attention must be paid to optimizing patient care and not merely technical information. Another unintended consequence of too-tightly controlled radiation exposure may be the introduction of unwarranted fear in the patient/public community leading to refusal of necessary test and procedures. Although some of the recommendations of this Think Tank may appear onerous to some stakeholders, the most successful change management initiatives balance “carrot and stick” approaches.

It is only through focused attention on an improved understanding of the scientific and technical considerations related to radiation exposure and practical application of these principles in the day-to-day care of patients that radiation safety will be improved. For these efforts to be successful, they must be conducted by multidisciplinary teams of medical and nonmedical scientists, with support from professional societies representing the active commitment of the house of cardiology. Funding agencies, payers, and industry must recognize the importance of this work to public health and invest in radiation safety. Professional societies and regulators in particular need to ensure timely implementation of these recommendations, and monitoring must be implemented to guard against unintended consequences. It is hoped that these Think Tank proceedings will stimulate and support meaningful continued efforts in the future in this important area.

Abbreviations

ACCF=American College of Cardiology Foundation
 AHA=American Heart Association
 CT=computed tomography
 CVD=cardiovascular disease
 DCRI=Duke Clinical Research Institute
 LNT=linear no-threshold model of radiation risk

References

- Chen J, Einstein AJ, Fazel R, et al. Cumulative exposure to ionizing radiation from diagnostic and therapeutic cardiac imaging procedures: a population-based analysis. *J Am Coll Cardiol*. 2010;56:702–11.
- Fazel R, Krumholz HM, Wang Y, et al. Exposure to low-dose ionizing radiation from medical imaging procedures. *N Engl J Med*. 2009;361:849–57.
- Berrington de Gonzalez A, Kim KP, Smith-Bindman R, et al. Myocardial perfusion scans: projected population cancer risks from current levels of use in the United States. *Circulation*. 2010;122:2403–10.
- Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med*. 2009;169:2078–86.
- Brenner DJ, Hall EJ. Computed tomography—an increasing source of radiation exposure. *N Engl J Med*. 2007;357:2277–84.
- Tubiana M. Computed tomography and radiation exposure. *N Engl J Med*. 2008;358:850–3.
- Mezrich RS. Radiation exposure from medical imaging procedures. *N Engl J Med*. 2009;361:2290–2.
- Caoili EM, Cohan RH, Ellis JH, et al. Medical decision making regarding computed tomographic radiation dose and associated risk: the patient's perspective. *Arch Intern Med*. 2009;169:1069–71.
- Kim KP, Einstein AJ, Berrington de Gonzalez A. Coronary artery calcification screening: estimated radiation dose and cancer risk. *Arch Intern Med*. 2009;169:1188–94.
- U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health Hearing on Medical Radiation: An Overview of the Issues, February 26, 2010. Available at: <http://democrats.energycommerce.house.gov/index.php?q=hearing/medical-radiation-an-overview-of-the-issues>. Accessed August 1, 2011.
- United States Food and Drug Administration Public Meeting: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging, March 30–31, 2010. Available at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm201448.htm>. Accessed September 22, 2011.
- United States Food and Drug Administration. White Paper: Initiative to Reduce Unnecessary Radiation Exposure From Medical Imaging, February 2010. Available at: <http://www.fda.gov/downloads/RadiationDoseReduction/UCM200087.pdf>. Accessed September 22, 2011.
- Schauer DA, Linton OW. NCRP Report No. 160, Ionizing Radiation Exposure of the Population of the United States, medical exposure— are we doing less with more, and is there a role for health physicists? *Health Phys*. 2009;97:1–5.
- Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics—2011 update: a report from the American Heart Association. *Circulation*. 2011;123:e18–209.
- Gibbons RJ, Miller TD, Hodge D, et al. Application of appropriateness criteria to stress single-photon emission computed tomography sestamibi studies and stress echocardiograms in an academic medical center. *J Am Coll Cardiol*. 2008;51:1283–9.
- Hendel RC, Cerqueira M, Douglas PS, et al. A multicenter assessment of the use of single-photon emission computed tomography myocardial perfusion imaging with appropriateness criteria. *J Am Coll Cardiol*. 2010;55:156–62.
- Gibbons RJ. Finding value in imaging: what is appropriate? *J Nucl Cardiol*. 2008;15:178–85.
- International Commission on Radiological Protection. Draft Report for Consultation: Patient and Staff Radiological Protection in Cardiology: Available at: <http://www.icrp.org/page.asp?id=127>. Accessed September 22, 2011.
- Thomas GS, Sugino JM, Wann S. Where have all the patients gone? The decrease in the volume of work of cardiologists. *Am Heart Hosp J*. 2010;8:44–6.
- Shaw LJ, Narula J. Cardiovascular imaging quality—more than a pretty picture! *J Am Coll Cardiol Img*. 2008;1:266–9.
- The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. *Ann ICRP*. 2007;37:1–332.
- International Commission on Radiological Protection. ICRP Publication 105. Radiation protection in medicine. *Ann ICRP*. 2007;37:1–63.
- American Association of Physicists in Medicine. AAPM position statement on radiation risks from medical imaging procedures. December 13, 2011. Available at: <http://www.aapm.org/org/policies/details.asp?id=318&type=PP¤t=true>. Accessed February 10, 2012.
- Judkins MP, Abrams HL, Bristow JD, et al. Report of the Inter-Society Commission for Heart Disease Resources. Optimal resources for examination of the chest and cardiovascular system. A hospital planning and resource guideline. Radiologic facilities for conventional x-ray examination of the heart and lungs. Catheterization-angiographic Laboratories. Radiologic resources for cardiovascular surgical operating rooms and intensive care units. *Circulation*. 1976;53:A1–37.
- International Commission on Radiological Protection. Recommendations of the ICRP, ICRP Publication 26. *Ann ICRP*. 1977;1(3):3–6.
- Gerber TC, Carr JJ, Arai AE, et al. Ionizing radiation in cardiac imaging: a science advisory from the American Heart Association Committee on Cardiac Imaging of the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention. *Circulation*. 2009;119:1056–65.
- International Commission on Radiological Protection. Radiation dose to patients from radiopharmaceuticals (addendum 2 to ICRP publication 53). *Ann ICRP*. 1998;28:1–126.
- Bolch WE, Eckerman KF, Sgouros G, et al. MIRD pamphlet No. 21: a generalized schema for radiopharmaceutical dosimetry—standardization of nomenclature. *J Nucl Med*. 2009;50:477–84.
- Miller DL, Balter S, Noonan PT, et al. Minimizing radiation-induced skin injury in interventional radiology procedures. *Radiology*. 2002;225:329–36.
- McCullough CH, Leng S, Yu L, et al. CT dose index and patient dose: they are not the same thing. *Radiology*. 2011;259:311–6.
- Preston DL, Shimizu Y, Pierce DA, et al. Studies of mortality of atomic bomb survivors. Report 13: Solid cancer and noncancer disease mortality: 1950–1997. *Radiat Res*. 2003;160:381–407.
- NRC Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2. Washington, DC: National Academies Press, 2006.
- Brenner DJ, Doll R, Goodhead DT, et al. Cancer risks attributable to low doses of ionizing radiation: assessing what we really know. *Proc Natl Acad Sci U S A*. 2003;100:13761–6.
- Cardis E, Vrijheid M, Blettner M, et al. The 15-Country Collaborative Study of Cancer Risk among Radiation Workers in the Nuclear Industry: estimates of radiation-related cancer risks. *Radiat Res*. 2007;167:396–416.
- Langner I, Blettner M, Gundestrup M, et al. Cosmic radiation and cancer mortality among airline pilots: results from a European cohort study (ESCAPE). *Radiat Environ Biophys*. 2004;42:247–56.
- Amis ES Jr., Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. *J Am Coll Radiol*. 2007;4:272–84.
- National Council on Radiation Protection & Measurements. NCRP Report No. 168: Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures. Bethesda, MD: National Council on Radiation Protection and Measurements, 2010.
- Halliburton SS, Abbara S, Chen MY, et al. SCCT guidelines on radiation dose and dose-optimization strategies in cardiovascular CT. *J Cardiovasc Comput Tomogr*. 2011;5:198–224.
- Voros S, Rivera JJ, Berman DS, et al. Guideline for minimizing radiation exposure during acquisition of coronary artery calcium scans with the use of multidetector computed tomography: a report by the Society for Atherosclerosis Imaging and Prevention Tomographic Imaging and Prevention Councils in collaboration with the Society of

- Cardiovascular Computed Tomography. *J Cardiovasc Comput Tomogr.* 2011;5:75–83.
39. Cerqueira MD, Allman KC, Ficaro EP, et al. Recommendations for reducing radiation exposure in myocardial perfusion imaging. *J Nucl Cardiol.* 2010;17:709–18.
 40. Chambers CE, Fetterly KA, Holzer R, et al. Radiation safety program for the cardiac catheterization laboratory. *Catheter Cardiovasc Interv.* 2011; 77:546–56.
 41. The Joint Commission Sentinel Event Alert: Radiation risks of diagnostic imaging. Available at: http://www.jointcommission.org/assets/1/18/SEA_471.pdf. Accessed September 14, 2011.
 42. Hendel RC, Patel MR, Kramer CM, et al. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR 2006 appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging: a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. *J Am Coll Cardiol.* 2006;48: 1475–97.
 43. Taylor AJ, Cerqueira M, Hodgson JM, et al. ACCF/SCCT/ACR/AHA/AASE/ASNC/NASCI/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance. *Circulation.* 2010; 122:e525–55.
 44. Patel MR, Dehmer GJ, Hirshfeld JW, et al. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 appropriateness criteria for coronary revascularization: a report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology. *Circulation.* 2009;119:1330–52.
 45. Douglas PS, Garcia MJ, Haines DE, et al. ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 appropriate use criteria for echocardiography: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Society of Echocardiography, American Heart Association, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance Endorsed by the American College of Chest Physicians. *J Am Coll Cardiol.* 2011;57:1126–66.
 46. Patel MR, Spertus JA, Brindis RG, et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol.* 2005;46:1606–13.
 47. Hendel RC, Berman DS, Di Carli MF, et al. ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 appropriate use criteria for cardiac radionuclide imaging: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the American Society of Nuclear Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, and the Society of Nuclear Medicine. *Circulation.* 2009;119:e561–87.
 48. Diagnostic reference levels in medical imaging: review and additional advice. *Ann ICRP.* 2001;31:33–52.
 49. Hausleiter J, Meyer T, Hermann F, et al. Estimated radiation dose associated with cardiac CT angiography. *JAMA.* 2009;301:500–7.
 50. Cardiovascular nuclear imaging: balancing proven clinical value and potential radiation risk. *J Nucl Med.* 2011;52:1162–4.
 51. Jacob P, Ron E. Late health effects of ionizing radiation: bridging the experimental and epidemiological divide. *Radiat Environ Biophys.* 2010; 49:109–10.
 52. Preston RJ. Radiation biology: concepts for radiation protection. *Health Phys.* 2004;87:3–14.
 53. Prise KM. New advances in radiation biology. *Occup Med (Lond).* 2006;56:156–61.
 54. Lorimore SA, Kadhim MA, Pocock DA, et al. Chromosomal instability in the descendants of unirradiated surviving cells after alpha-particle irradiation. *Proc Natl Acad Sci U S A.* 1998;95:5730–3.
 55. Leith JT. Correspondence Re: H. Nagasawa and J. B. Little, Induction of sister chromatid exchanges by extremely low doses of alpha-particles. *Cancer Res.* 52: 6394–6396, 1992. *Cancer Res.* 1993;53:2188.
 56. Wolff S. Aspects of the adaptive response to very low doses of radiation and other agents. *Mutat Res.* 1996;358:135–42.
 57. Bischoff B, Hein F, Meyer T, et al. Comparison of sequential and helical scanning for radiation dose and image quality: results of the Prospective Multicenter Study on Radiation Dose Estimates of Cardiac CT Angiography (PROTECTION) I study. *AJR Am J Roentgenol.* 2010;194: 1495–9.
 58. Calkins H, Brugada J, Packer DL, et al. HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm.* 2007;4:816–61.
 59. Hausleiter J, Meyer T, Hadamitzky M, et al. Radiation dose estimates from cardiac multislice computed tomography in daily practice: impact of different scanning protocols on effective dose estimates. *Circulation.* 2006;113:1305–10.
 60. Hausleiter J, Martinoff S, Hadamitzky M, et al. Image quality and radiation exposure with a low tube voltage protocol for coronary CT angiography: results of the PROTECTION II Trial. *J Am Coll Cardiol Img.* 2010;3:1113–23.
 61. Raff GL, Chinnaiyan KM, Share DA, et al. Radiation dose from cardiac computed tomography before and after implementation of radiation dose-reduction techniques. *JAMA.* 2009;301:2340–8.
 62. International Commission on Radiological Protection. ICRP Publication 113—Education and training in radiological protection for diagnostic and interventional procedures: chapters 1–5. *Ann ICRP.* 2009;(5):15–49.
 63. Sistrom CL, Dang PA, Weilburg JB, et al. Effect of computerized order entry with integrated decision support on the growth of outpatient procedure volumes: seven-year time series analysis. *Radiology.* 2009;251: 147–55.

Appendix. Author Relationships With Industry and Other Entities—Developing an Action Plan for Patient Radiation Safety in Adult Cardiovascular Medicine

Participant Name	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
J. Jeffrey Carr	Wake Forest University School of Medicine, Division of Radiologic Sciences—Professor & Vice Chair of Clinical Research	None	None	None	None	<ul style="list-style-type: none"> • DHHS/NIH Grants and Contracts* • NIH/NHLBI† • SCCT† 	None
Manuel D. Cerqueira	Cleveland Clinic Foundation—Chairman, Department of Molecular & Functional Imaging	<ul style="list-style-type: none"> • Astellas Pharma US* • Cardinal Health • CoreLab Partners • GE Healthcare* • Lantheus Medical Imaging 	<ul style="list-style-type: none"> • Astellas Pharma US* • GE Healthcare* 	None	<ul style="list-style-type: none"> • Perceptive Informatics* 	None	None
Jennifer E. Cummings	University of Toledo—Associate Professor of Medicine	<ul style="list-style-type: none"> • Boston Scientific • Corazon Consulting • Medtronic • St. Jude 	None	None	None	None	<ul style="list-style-type: none"> • Defendant, case regarding esophageal fistula, 2011
Pamela S. Douglas	Duke University Medical Center—Ursula Geller Professor of Research in Cardiovascular Diseases	<ul style="list-style-type: none"> • BG Medicine • CardioDX • Elsevier • Heart.org† • Medscape Genomic Medicine Institute Advisory Board/WebMD Advisor† • Pappas Ventures • Patient Advocate Foundation† • Universal Oncology† • UpToDate 	None	<ul style="list-style-type: none"> • CardioDX • Universal Oncology† 	<ul style="list-style-type: none"> • Abiomed† • AHRQ† • Atritech† • Department of Defense/Defense Advanced Research Agency† • The Duke Endowment† • Edwards Lifesciences† • FDA† • Gates Foundation† • Ikaria† • NIH† • Novartis† • Pfizer† • Viacor† • Walter Coulter Foundation† 	<ul style="list-style-type: none"> • David H. Murdock Research Institute† • Translational Research in Oncology (DSMB) 	None
Thomas C. Gerber	Mayo Clinic—Professor of Medicine, Radiology	None	None	None	<ul style="list-style-type: none"> • RESCUE Trial (NIH/ACRIN)† 	<ul style="list-style-type: none"> • AHA • American Journal of Radiology† • Mayo Clinic Proceedings† • NASCI† • SAIP† 	None
Debabrata Mukherjee	Texas Tech University Health Sciences Center—Chief, Cardiovascular Medicine	None	None	None	None	<ul style="list-style-type: none"> • Cleveland Clinic Foundation (DSMB) 	None

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Appendix. Continued

Participant Name	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Allen J. Taylor	Washington Hospital Center—Co-Director, Noninvasive Imaging	• Abbott*	None	None	None	<ul style="list-style-type: none"> • Certification Board of Cardiovascular Computed Tomography† • SAIP† • SCCT† 	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$10 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to <http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx> for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*Significant relationship.

†No financial benefit.

AHA indicates American Heart Association; AHRQ, Agency for Healthcare Research and Quality; DHHS, Department of Health and Human Services; DSMB, Data Safety Monitoring Board; FDA, Food and Drug Administration; NASCI, North American Society of Cardiovascular Imaging; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SAIP, Society for Atherosclerosis Imaging and Prevention; and SCCT, Society of Cardiovascular Computed Tomography.