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Patient-Centered Imaging: Shared Decision Making for Cardiac Imaging Procedures with Exposure to Ionizing Radiation

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Abstract

Objective—To identify key components of a radiation accountability framework fostering patient-centered imaging and shared decision-making in cardiac imaging.

Background—An NIH-NHLBI/NCI-sponsored symposium was held in November 2012 to address these issues.

Methods—Symposium participants, working in three tracks, identified key components of a framework to target critical radiation safety issues for the patient, the laboratory, and the larger population of patients with known or suspected cardiovascular disease.

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Results—Use of ionizing radiation during an imaging procedure should be disclosed to all patients by the ordering provider at the time of ordering, and reinforced by the performing provider team. An imaging protocol with effective dose 3mSv is considered very low risk, not warranting extensive discussion or written consent. However, a protocol effective dose <20mSv was proposed as a level requiring particular attention in terms of shared decision-making and either formal discussion or written informed consent.

Laboratory reporting of radiation dosimetry is a critical component of creating a quality laboratory fostering a patient-centered environment with transparent procedural methodology. Efforts should be directed to avoiding testing involving radiation, in patients with inappropriate indications. Standardized reporting and diagnostic reference levels for computed tomography and nuclear cardiology are important for the goal of public reporting of laboratory radiation dose levels in conjunction with diagnostic performance.

Conclusions—The development of cardiac imaging technologies revolutionized cardiology practice by allowing routine, noninvasive assessment of myocardial perfusion and anatomy. It is now incumbent upon the imaging community to create an accountability framework to safely drive appropriate imaging utilization.

Keywords

Radiation Safety; Appropriate Use; Image Quality; Imaging

Cardiac imaging procedures have come under increasing scrutiny as a result of high utilization volume, concerns over inappropriate use, a lack of adherence to quality control, and the potential of cancer risks attributable to ionizing radiation exposure. Recent surveys of cardiac laboratory practices identified deficiencies in radiation safety patterns including unwarranted exposure levels and underutilization of the American College of Cardiology's (ACC) appropriate use criteria (AUC) to guide patient referrals for testing (1-4). These issues have prompted concerns as to the extent to which current practice patterns are aligned with patient-centered imaging quality, particularly those related to radiation safety principles of justification and optimization.

The Institute of Medicine report on healthcare quality of nearly a decade ago defined key dimensions of quality healthcare delivery as those that provide services based on the highest level of scientific evidence and that demonstrate a clear benefit in terms of improved patient-centered outcomes (5). The Institute of Medicine's six aims for quality improvement are safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (3); all of these are critical elements for driving patient-centered imaging. Importantly, refraining from providing services that are unlikely to benefit is a key element of quality healthcare. The latter brings to the forefront the issue of patient safety and avoiding unnecessary potential harm to patients as a result of procedural overuse (5).

The goal of radiological protection is the safeguarding of people from potentially harmful effects of ionizing radiation, while ensuring the benefits related to its use. Accordingly, both dedicated radiological protection organizations (6,7) and medical societies (8-16) have put forth documents to educate members of the cardiovascular imaging community aimed at

improving physician decision making with regards to radiation safety. The current manuscript details the recommendations arising from an NIH-NHLBI/NCI-sponsored symposium entitled “Patient-Centered Imaging-Shared Decision Making for Cardiac Imaging Procedures with Exposure to Ionizing Radiation,” held at Emory University on November 15-17, 2012. The overarching goal of this symposium was to build on prior statements and identify key components of an accountability framework to guide the development of quality imaging and to target critical radiation safety issues for the patient, laboratory, and for management of the larger population of patients at-risk for cardiovascular disease. Three tracks were included in this symposium including risk as it pertains to radiation exposure for: 1) the patient, 2) the laboratory, and 3) the overall population. The goals and discussion points for each track are detailed in Table 1.

I. Focus on Patient-Physician Shared Decision Making

This section aimed to develop a framework for patient involvement in decisions about radiation exposure and to provide patients and the broader clinical community with language that clearly describes and properly contextualizes the risk of exposure to ionizing radiation. The approach outlined in this document is consistent with ethical responsibilities of respect to patients as decision makers and with the recognition that improved patient decision making is a means to advance quality and safety in health care (17).

Physician Locus of Responsibility for Shared Decision Making

A recent study revealed that most patients undergoing cardiovascular computed tomography (CT) or SPECT were either unaware that these procedures expose them to ionizing radiation or were insufficiently informed of the potential radiation exposure risk (18). An ensuing question is who should take primary responsibility for fully informing patients. The consensus from this symposium was that both the referring and laboratory physician should share responsibility for both justification of the test exposure to ionizing radiation (6) and for patient education.

Any approach to facilitate patient decision making must acknowledge this shared responsibility. Ideally, both the referring provider and imager should be sufficiently knowledgeable about the benefits and risks of the requested imaging study, and discuss this in sufficient detail with the patient, in order to optimally guide decision making. In practice, the referring provider typically has the best understanding of the benefits of an imaging procedure for the patient's specific clinical scenario. Referral must be based on appropriate use (19,20) and the referring provider's communication with patients should include some disclosure of radiation and other risks associated with the test. If a patient is confronted on arrival to the imaging laboratory with risk information that was previously unknown, the patient would likely have little context for using that information in a meaningful manner, so the primary discussion regarding the risks and benefits of imaging should be held at the time of ordering. Yet, the imaging provider has a better understanding of the amount of radiation to be used as well as types and probabilities of health risks related to radiation exposure. As such, imaging laboratories should assume the responsibility for providing educational materials to guide referring physicians' discussions with patients. In the imaging laboratory, the procedural information sheet (containing preparation requirements and procedural

methods) that is generally provided to patients should also acknowledge radiation exposure, justification for the procedure, and the laboratory's standard practice of dose optimization. Concerned professional societies and/or individual imaging centers should develop information booklets that can be provided, both at the point of referral and in the imaging laboratory, to patients who wish to learn, in greater detail, about the proposed cardiac imaging procedure. Throughout the referral and imaging process, patients should be encouraged to ask questions with regards to appropriate use, procedural justification, and dose optimization practices for a given laboratory (10).

Electronic decision support tools may play a role in assisting the referring practitioner and fostering improved referral patterns targeted toward high rates and improved identification of appropriate indications for testing at the point of ordering. The laboratory physician has the responsibility to confirm the appropriateness of the referral for that patient and to provide added guidance to the patient regarding projected radiation exposure risk. At times, discrepancies in understandings of the patient's clinical status and the particular implications of the proposed test should prompt direct communication between these providers. The current mandate for tracking of patient satisfaction within healthcare services should also help to promote improved communication between physician and patient (21).

Communicating Radiation-Related Health Risks

Communicating with patients in a way that facilitates effective shared decision making is a complex process that must account for patients' level of engagement, be sensitive to prevalent limitations in health literacy, and focus on elements that are most relevant to the medical decision at hand. Several specific elements are essential to communication regarding the description of a procedure exposing a patient to ionizing radiation. First, physicians and other healthcare providers should be aware that patients attribute both positive (i.e., a medical benefit of diagnosis/risk assessment) and negative (i.e., fear of the danger of cancer) feelings toward radiation exposure and that concerns regarding radiation risks are prevalent (22). Second, patients should be made aware that a given procedure requires exposure to ionizing radiation, and that radiation exposure is within the natural environment and a part of our everyday lives. Third, the patient should be informed qualitatively of the expected radiation dose, with comparison made to a familiar form of radiation, such as a chest x-ray, a transcontinental airplane flight, or annual background radiation, and of efforts to reduce exposure. Fourth, the potential risk related to radiation should be contextualized within the appropriateness of the procedure and the established benefit of accurate information to guide clinical decision making. Finally, available alternatives that do not require exposure to ionizing radiation (e.g., alternative imaging or no testing) and their relative risks and benefits should be discussed, where applicable.

Communicating remote and uncertain risks to patients is challenging for multiple reasons including limited health numeracy skills and comprehension difficulties in risk-based decision making; the latter of which is common in medicine but foreign to most patients (23). The framework for discussions on projected radiation risk should include comparison to the background population risk of cancer. Research has also shown that there is a greater patient understanding of risk when comparisons are made with common daily scenarios such

as the risks of dying from activities of everyday life (24), activities which increase the chance of death (25), and the concept of “lost life expectancy” related to activities of everyday life (26). Thus, a patient should have a frame of reference for a common scenario of risk, their average cancer risk, and how their risk would change following exposure to ionizing radiation.

In addition to these content items, there are established communication tools including the use of “plain language” (27) and the “teach back” method (28) which improve patient comprehension (29). The use of graphical representations of risk or other alternative ways of presenting risk information also promote engagement and improve comprehension of complex concepts of risk (30). Resources are available from the National Cancer Institute which recently published a series on patient-centered communication (31). Optimal ways of communicating radiation risk to the cardiovascular patient warrant further study.

The following list was synthesized by symposium participants to provide guidance for communicating risks and benefits following radiation exposure from cardiovascular imaging (32):

1. There is low “numeracy” literacy among the US population that impairs understanding of health risks; thus avoid statistical terms and constructs (33).
2. Use analogies for the projected risk of radiation exposure, using simple comparisons (34).
3. Keep denominators and time frames constant for comparisons.
4. Make clear the difference between the baseline risk of cancer and the projected risk of cancer following radiation exposure.
5. Provide patient decision aids to enhance comprehension including the use of pictographs and visual aids comparing incremental risk and benefit.

Defining Levels of Informed Consent

Standard practice across many institutions is not to obtain a formal written informed consent for or discuss the risks of radiation exposure with patients for many imaging procedures (35-39). Among the symposium participants, there was vigorous discussion about the prudence of written informed consent for patients, ultimately with divergent perspectives. Consensus was achieved with regards to the need for more robust disclosure and involvement of patients in these decisions, that radiation-related risks are in the public consciousness, and that formal disclosure of associated risks promotes transparency in physician decision making. Especially when alternative procedures exist, there is a case for also providing patients with that information. Given these prior statements, discussion of radiation exposure may serve to inform decisions, alleviate fears and misconceptions about radiation risk, and promote trust between the patient and physician.

A secondary line of discussions focused on whether a given threshold of radiation exposure should prompt patient-physician discussions and/or written informed consent. Symposium participants agreed that the answers to radiation-related questions depend significantly on the level of exposure. Rational tiers of radiation burden that were discussed relevant to the

patient-physician interaction were those that were based on levels of radiation exposure that are standard levels used in other contexts. These levels included 3 millisieverts (mSv) (the average annual background level of radiation in the US), 20 mSv (recommended average annual occupational dose limit for adults) (40), and 50 mSv (single-year occupational dose limit for adults) (41). Given the uncertainty in estimates for radiation dose and radiation-attributable risk, additional granularity of effective doses was not recommended by the symposium participants.

A procedure with effective dose that is less than the average annual background level of radiation in the US (i.e., 3 mSv) is considered to have very low radiation risk. Thus, general consensus opinion was reached that for imaging studies with an effective dose \leq 3 mSv, “radiation risk” need not be extensively discussed. Within the imaging laboratory, written information should be available that discloses the use of radiation and the associated very low projected risk that is associated with this low level of exposure; this approach is analogous to the common practice of prescribing medications that are of minimal risk, whereby an abbreviated discussion with a provision of written materials by the pharmacist is accepted practice.

For procedures for which the effective dose of the protocol expected to be used exceeds a threshold of 20 mSv, consensus opinion supported a recommendation whereby any patient undergoing such a protocol would have either a formal discussion with the physician or written informed consent with regards to radiation exposure and projected cancer risk. This threshold was recommended specifically for an individual procedure, for example a SPECT myocardial perfusion imaging stress testing procedure for assessment of ischemia and/or scarring, and not for appropriate sequential testing performed as part of the management strategy for a patient, such as stress testing with myocardial perfusion imaging, followed by assessment of myocardial viability or angiography. For individual patients, sequential tests, if carefully selected, may provide vital information not obtainable by other means. Such protocols in excess of 20 mSv (Table 2) include dual isotope nuclear stress testing protocols on conventional SPECT cameras, and many 120 kV low-pitch helical retrospectively-gated coronary CT angiography protocols (6,8,42). By identifying a threshold upon which a more formal discussion or written informed consent would occur, the majority of symposium participants felt that this would assure a level of consistency in disclosure across patient cohorts. This recommendation fosters shared decision-making for those procedures with the highest radiation exposures of all medical imaging procedures, and has the added benefit of potentially serving as a deterrent to using such protocols when not clinically warranted. A similar strategy is applied to the use of contrast media for imaging where informed consent for contrast-related risks (i.e., allergy, anaphylaxis, or nephropathy) is commonly obtained in current clinical practice, even though the risk is low and disclosure is not required by law. Specific dose-sensitive template language describing potential radiation risk was suggested by the symposium participants and could be included in a written informed consent or used during an informational discussion between the patient and physician (Table 3). The patient-physician discussion should be documented in the patient's procedural final report.

Some participants expressed practical concerns that clinical workflow would be impeded if written informed consent were routinely implemented for a large sector of patients.

Disruptions in workflow could then promote a rushed or ineffective communication to the patient without sensitivity to health literacy issues and may increase patient fears during the informed consent process. It was suggested that paradigms other than traditional written informed consent warrant exploration and may more effectively promote patient comprehension of radiation risk and test decision making.

Additionally, the inclusion of patient-specific dose and risk estimates during the discussion was thought to be generally impractical due to their predictive uncertainty and the logistical challenges of providing multiple strategies for discussions across varying patient ages, gender, life expectancies (43), and body sizes.

Summary Conclusions

The use of ionizing radiation during an imaging procedure should be disclosed to all patients by the ordering physician at the time of ordering and reinforced by the performing provider team. Simple and clear language should be used to communicate potential radiation risk. A scan with a protocol effective dose of 3 mSv is considered very low risk and was generally agreed not to require a detailed discussion or written consent. However, when the protocol effective dose exceeds 20 mSv, specific information regarding radiation risk should be included in a patient-physician discussion or in the form of written informed consent to ensure more substantial patient involvement in the decision. Studies evaluating the actual impact of different patient-involvement strategies on patient comprehension, satisfaction, and trust, as well as important logistical aspects of practice will help to refine patient-centered approaches to the inclusion of discussions on radiation between the physician and patient.

II. Focus on Laboratory Reporting and Tracking

The goals of this section were to address approaches for improving laboratory quality in regards to radiation exposure; its findings focus on the need for development of diagnostic reference levels (DRLs) and strategies for public reporting for imaging laboratories.

Demonstrated Physician/Staff Knowledge Base in Radiation Safety

Limitations in the knowledge base of physicians and other healthcare providers about radiological protection have been reported (4,44,45). In a recent American Society of Nuclear Cardiology (ASNC) survey, the proportion of physicians with adequate radiation dosimetry knowledge was found to be suboptimal; with only 1 in 10 physicians understanding comparative test radiation exposure levels (1). Physicians, technologists, and nurses working in an imaging laboratory need to have a working knowledge of radiation doses as well as have an awareness of radiation dose reduction strategies. Knowledge assessment and standardized curricula of radiation safety practices should be a part of the professionals' certification process and incorporated into maintenance of certification (MOC) programs. When compared to current standards, an increased rigor for radiation safety curricula is likely required for laboratory accreditation, board certification, and MOC requirements. Although an adequate knowledge of radiation risk is essential for the imager, a modicum of understanding is also necessary for referring physicians. Education aimed at ensuring a sufficient knowledge base for all physicians should begin in medical school

where educational programs have been demonstrated to improve long-term knowledge of radiological protection practices (44,45).

Fundamental Tools for Laboratory Reporting and Tracking: Performance Measures and Diagnostic Reference Levels

Recent work by the ACC Foundation / American Heart Association Task Force on Performance Measures has identified two specific types of performance measures that may be of particular use for evaluating the use of cardiovascular technology: appropriate use measures and structure/safety measures (46). For studies that expose patients to ionizing radiation, at least one pertinent appropriate use measure and one dosimetric safety measure should be identified and recorded for each procedure. It is recommended that these measures be incorporated as part of the patient's final report, as a necessary requirement of standardized reporting (46). Initial efforts in terms of appropriate use measures should focus on the overall rate of inappropriate (now termed "rarely appropriate") (14) use as well as rates of use for the most commonly used inappropriate indications, such as those identified in American Board of Internal Medicine Choosing Wisely (15) recommendations.

As requirements for laboratory accreditation, continuous quality initiatives should be aimed toward optimization of radiation dose reduction practices with a simultaneous goal of optimal diagnostic performance. Presently, imaging societies set standards for laboratory safety, imaging protocols, interpretation, and standardized reporting; as published in consensus statements and guidelines (8-11). Guidelines with regards to radiation exposure are increasingly providing content that offers guidance based on a specific, data-driven level of radiation delivered for a specific routine examination protocol. Such a radiation dose level is termed a diagnostic reference level (DRL) (47). DRLs are often defined in terms of a particular percentile (e.g., the 75th percentile) of the distribution of dose metrics for a particular study in a particular population. One benefit of defining a DRL is that it makes possible the identification of situations in which patient dose is unusually high. The use of DRLs, as a standardized tool for continuous quality initiatives, could be used to elicit positive improvements in mean radiation dose for a given laboratory.

While already developed in other patient populations (e.g., pediatric CT) (48-49). DRLs have not yet been established for standard cardiac imaging procedures. A new recommendation arising from this symposium is that DRLs should be developed for a variety of specific cardiac imaging indications (e.g. SPECT myocardial perfusion imaging in patients with chest pain, or asymptomatic screening with coronary artery calcium scoring). This will require considerable effort, and should be an important new initiative for the field.

We identified the >20 mSv threshold for a single procedure, while not formally a DRL, as an important metric to identify patients requiring more intensive discussions on radiation-related risk. It was the consensus of symposium participants that monitoring utilization practices that exceed this threshold was an important goal that should be monitored through laboratory accreditation quality initiatives. Currently, CT accreditation requires laboratories to develop procedures for tracking of patient radiation doses; this information is reviewed during audit or site visits. Based on the current symposium, minimal and justified use of procedures using a protocol with effective dose >20 mSv should be tracked, with excess

exposure beyond this level limited to a specified proportion of patients. In the case of >20 mSv, higher exposures may be acceptable for the very elderly where radiation risk is very small and the prevalence of coronary artery disease is high (i.e., the benefit-risk ratio balance is high). Of note, simplistic methods of estimating effective dose (a size-independent metric) such as multiplying dose-length product by a conversion factor, may result in erroneously high estimates when applied to obese patients. In the obese patient where suboptimal image quality is of concern, a protocol with effective dose of >20 mSv when estimated in such a manner may not be associated with higher actual absorbed doses to critical organs in the particular patient. Such estimates should not be used to deny services to patients who could benefit. Likewise, laboratories that provide services at appropriate exposures levels to obese individuals should not be penalized in activities that attempt to benchmark laboratory quality.

A second charge for societal guidelines is to set requirements for the collection and reporting of radiation dose practices from a laboratory database. Databases should have the capabilities of reporting radiation dose for a consecutive series of the laboratory's patient population. Societal guidelines should also detail the processes for documentation and the quality improvement initiatives, which should be linked to DRLs. Standards for image quality and diagnostic performance should be coupled with reporting rates of procedures which are in accordance with DRL-based radiation safety standards, in the form of a laboratory quality score.

Laboratories should maintain a database for tracking of radiation dosimetric safety metrics for all patients undergoing ionizing radiation procedures as a cumulative quality performance measure. Harmonization of the common data elements used for radiation dose measurement and reporting should be developed by imaging societies in collaboration with all diagnostic radiation stakeholders including patient representatives. Value-based reimbursement incentives should be considered which may improve the success of this important effort.

Public Reporting

While not currently available or required, the development of databases of radiation dosimetric safety metrics and the establishment of DRLs, more refined, data-driven report cards should be able to be developed. Radiation dose databases, including consecutive series of cases, should be required for accreditation, certification, and MOC purposes in order to enable laboratory tracking and reporting of patient radiation doses. Accrediting bodies, such as the Intersocietal Accreditation Commission, the American College of Radiology, and the Joint Commission should collect unselected data from laboratories and publicly report performance measures such as distributions of dosimetric safety measures, which can be used to track the frequency with which studies exceed the designated DRL. As well, these reports should be used by laboratories to measure their radiation-reduction performance efforts.

Issues of Test Layering, Dose Tracking, and Substitution

One issue that is ill-defined is the appropriate indications for serial testing within an episode of care. While radiation dose levels may be optimized for each individual test contributing to a diagnostic workup, the layering of multiple tests increases the cumulative radiation exposure. While a past history may include frequent testing, ultimately each individual test involving ionizing radiation needs to be justified independently, since the benefit-risk ratio of a given procedure is independent of whether the patient has received many previous tests or none. Specifically, under the linear no-threshold model (presently regarded as the best simple model describing the relationship between radiation dose and risk), the projected risk for a given procedure is considered to be independent of prior testing (50,51). Nevertheless, International Basic Safety Standards suggest that relevant information from a patient's previous radiological procedures should be taken into account in justifying a specific procedure involving radiation.(52)

Indeed, numerous organizations, such as the International Atomic Energy Agency, World Health Organization, and Food and Drug Administration, now advocate longitudinal patient radiation dose tracking (53). While not yet implemented in any country on a national level, it is beginning to be implemented across some healthcare systems (54), and there is widespread global interest in such cumulative dose tracking.(55) Goals of tracking include supporting accountability for patient safety, strengthening justification by enabling patient-specific data-informed decision making for referring providers, supporting optimization including enabling DRL development, providing information for risk assessment, and facilitating research and epidemiologic investigations.(53) One particularly important clinical aim of collecting longitudinal patient dose information is to minimize unnecessary, duplicate imaging use during and across episodes of care. Without this information, repeat imaging may occur without physician knowledge of prior procedures performed in laboratories in different facilities. However, some experts argue that tracking of numbers and types of procedures alone will accomplish this latter aim, and that tracking of cumulative doses across systems would be an extensive undertaking with the potential downside of misunderstanding of radiation dose history, and consequent alarmism and avoidance of clinically-indicated procedures involving ionizing radiation. A full treatment of the benefits and pitfalls of radiation dose tracking is beyond the scope of this document.

Importantly, the guideline-accepted diagnostic work-up of patients often includes the performance of a confirmatory, diagnostic procedure(s) following index testing demonstrating abnormal or indeterminate findings. Better characterization is needed of cumulative radiation dose levels that are necessary in order to complete an evaluation for a given diagnostic strategy or episode of care (e.g., the outpatient workup of chest pain).

In today's practice, test substitution of a non-ionizing radiation test for a CT or nuclear cardiology procedure is common. Test substitution can be a beneficial practice, if it is evidence-based, such as the shifting of low risk women from a stress nuclear procedure to a routine exercise treadmill test (19,20,56). Even so, caution must be exercised and routinized test substitution practices should be avoided. The International Commission on Radiological Protection, in defining the safety principle of *justification*, clarifies that “by introducing a

new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes” (40). Thus, test substitution requires a patient-centered benefit/risk rationale and should not be performed solely due to radiation exposure.

Summary Conclusions

Safety, image quality, and diagnostic performance are key elements of a laboratory's quality. Primary efforts should be directed towards avoiding testing in patients who do not need it and, importantly, supporting testing where appropriate. Improved laboratory adherence to AUC (19,20) and clinical practice guideline recommendations (56) are an important means to guide effective testing utilization patterns. Standardized reporting and development of DRLs for CT and nuclear cardiology are important for the primary goal of public reporting of laboratory radiation dose levels in conjunction with image quality and diagnostic performance.

III. Focus on Population Reporting and Tracking

To effectively reduce the radiation exposure associated with diagnostic imaging, it is important to consider multiple approaches when evaluating population-based methods. The most likely method to reduce population radiation exposure is to minimize test use for referral indications classified as inappropriate or rarely appropriate (10). Thus, the population track strongly endorsed the use of decision support tools at the point of physician order entry in order to promote appropriate referral patterns that would improve justification for radiation exposure and thereby foster population-wide reductions in radiation exposure. Prior research supports that a single-pronged approach is ineffective at improving physician education and behavioral change (57,58). As such, continuous quality initiative efforts should be employed and include physician feedback at all levels within the ordering and care management pathways as well as including “real time” educational interventions.

Substantially different radiation doses have been demonstrated from similar tests performed at different institutions and population-based approaches offer the opportunity to decrease unnecessary variability across patient cohorts. There are a number of nascent examples of such efforts, including the Advanced Cardiovascular Imaging Consortium (ACIC) and the upcoming ASNC registries (1,3,4).

ACIC is an ongoing quality improvement program incorporating 40 imaging centers in the state of Michigan that provide coronary CT angiographic services (2-4,59). The program is funded by Blue Cross - Blue Shield of Michigan and participation is required for reimbursement. Data collected includes demographics, procedural indications, technical details including radiation doses, and clinical outcomes through 90-days of follow-up. An essential part of the continuous quality initiative process is a quarterly report for participating sites that enables cross-center comparisons on an array of quality metrics. A dose-reduction “best practice” algorithm was established early as part of a consortium-wide intervention and this algorithm is regularly revised to incorporate improving technology. Sites are required to present their quality improvement methods annually, resulting in steady declines in median radiation dose (2).

ASNC is currently embarking on pilot projects that will provide the means to develop a multi-site laboratory registry. The ASNC registry is entitled ImageGuide™ and, in 2014, will initiate enrollment of consecutive series of patients across diverse laboratories, from the private practice setting to the academic medical center. The primary aims of the ASNC registry will be to document timely reporting, adherence to standardized reporting measures, develop standardized rates of appropriate and rarely appropriate studies (notably by key patient [e.g., gender, race, income] and physician [e.g., laboratory volume] characteristics), and to develop an effective strategy for public reporting of performance measures including radiation exposure. An important long-term goal of this registry will be public reporting of laboratory practice patterns of radiation safety including median dose, dose reduction practices, and rates of rarely appropriate studies.

As registries expand, it will be important for radiation tracking to develop standardized assessments of cumulative dose per episode of care. This will entail connectivity with current population-wide registries (such as the ACC's National Cardiovascular Data Registries). Subsets of patients who may receive larger amounts of radiation (e.g., patients undergoing multiple nuclear stress tests (57)) or those with a greater projected radiation risk (e.g., younger patients) should, in particular, be targeted for tracking purposes. These registries could also be used to target complex patient and provider profiles for those who more often receive unnecessary additional testing. We suggest applying the term “vulnerable populations” to patient subsets, such as children or younger patients, whose life expectancy may increase projected cancer risk estimates following radiation exposure. A summary of recommendations for laboratory- and population-tracking of radiation is listed in Table 4.

Symposium Conclusions

A synopsis of recommendations reveals 3 areas where radiation safety efforts are to be prioritized by professional organizations including a focus on patient, laboratory, and population safety. The concepts discussed in this document can form the basis for strategic priorities to target educational programs for shared decision making and healthcare provider knowledge in radiation safety practices. As well, laboratory reporting of radiation dosimetry is a critical component of creating the patient-centered laboratory that fosters a caring environment with procedural methodology transparent to the patient. A protocol effective dose of >20 mSv was proposed in this document as a level requiring particular attention in terms of shared decision-making and either a formal discussion or written informed consent. Cumulative dose measures for a given episode of care and subset analyses of vulnerable patient populations should be planned elements in the radiation tracking programs. Large registries to encourage widespread, public reporting of laboratory radiation dosimetry are being developed, and DRLs for cardiac imaging should be developed. Additional comparative effectiveness research is needed to justify radiation exposure when compared to tests that do not expose patients to ionizing radiation or to lower-exposure testing options.

The creation of the patient-centered imaging laboratory that prioritizes patient safety and effectiveness will require sizeable changes to the culture of imaging, which now focuses on volume and efficiency. With regards to radiation safety, core principles to guide measurement and quality efforts are detailed in Table 5. Patient groups, payers, and the

clinical community have expressed the need to place a greater emphasis on justification of use and widespread adoption of radiation dose optimization strategies.

The development of current cardiac imaging technologies revolutionized the practice of cardiovascular medicine by allowing for routine, noninvasive assessment of myocardial perfusion and anatomy. It is now incumbent on the imaging community to create an accountability framework to safely drive appropriate imaging utilization.

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Table 1

Conference Discussion Points

I. Focus on the Patient

- Transparent Explanation of Radiation Risk That Results in Informed Patient Decision Making
- Informed Consent – Patient & Physician Decision Aids
- New Communication Models to Optimize Patient Preferences for Test Selection & Timely Reporting

II. Focus on the Laboratory

- Demonstrated Safety Profile for Laboratory Accreditation
- Demonstrated Physician / Staff Knowledge for Certification
- Performance Metrics for Radiation Safety Tracking
- Public Reporting of Benefit and Risk
- Comparative Effectiveness – Integration of Safety into Multimodality Decision Making

III. Focus on the Population

- AUC as a Means to Drive Safety – Is it Sufficient?
 - Effective Assimilation of Low Dose Alternatives (e.g., Rb-82 PET) / Dose Reduction Techniques
 - Optimal Continuous Quality Initiatives – Hurdles Beyond the Research Environment
 - Future Information Technology and Research Developments – Tracking & Standardized Reporting
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Table 2

Typical effective doses for cardiac procedures

Modality	Protocol	Typical Effective Dose (mSv)
MDCT	Coronary CT Angiogram: Helical, No Tube Current Modulation	8-30
MDCT	Coronary CT Angiogram: Helical, Tube Current Modulation	6-20
MDCT	Coronary CT Angiogram: Prospectively-Triggered Axial	0.5-7
MDCT	Coronary CT Angiogram: High-Pitch Helical	<0.5-3
MDCT	CT Angiogram, Pre-TAVR: Coronary (Multiphase) and Chest/Abdomen/Pelvis	5-50
MDCT	Calcium Score	1-5
MDCT	Attenuation Correction	<0.5-2
EBCT	Calcium Score	1
SPECT	10 mCi Tc-99m sestamibi rest/30 mCi Tc-99m sestamibi stress	11
SPECT	15 mCi Tc-99m sestamibi rest/45 mCi Tc-99m sestamibi stress	17
SPECT	30 mCi Tc-99m sestamibi stress/30 mCi Tc-99m sestamibi rest	18
SPECT	10 mCi Tc-99m sestamibi stress only	2.7
SPECT	30 mCi Tc-99m sestamibi stress only	8
SPECT	10 mCi Tc-99m tetrofosmin rest/30 mCi Tc-99m tetrofosmin stress	9
SPECT	15 mCi Tc-99m tetrofosmin rest/45 mCi Tc-99m tetrofosmin stress	14
SPECT	30 mCi Tc-99m tetrofosmin stress/30 mCi Tc-99m tetrofosmin rest	14
SPECT	10 mCi Tc-99m tetrofosmin stress only	2.3
SPECT	30 mCi Tc-99m tetrofosmin stress only	7
SPECT	Tl-201 3.5 mCi	15
SPECT	Dual Isotope: 3.5 mCi Tl-201 rest/30 mCi sestamibi stress	23
SPECT	Dual Isotope: 3.5 mCi Tl-201 rest/30 mCi tetrofosmin stress	22
PET	50 mCi Rb-82 rest/50 mCi Rb-82 stress	4
PET	15 mCi N-13 ammonia rest/15 mCi N-13 ammonia stress	2
PET	10 mCi F-18 FDG	7
Planar	30 mCi Tc-99m-labeled erythrocytes	8
Fluoroscopy	Diagnostic invasive coronary angiogram	2-20
Fluoroscopy	Percutaneous coronary intervention	5-57
Fluoroscopy	TAVR, transapical approach	12-23
Fluoroscopy	TAVR, transfemoral approach	33-100
Fluoroscopy	Diagnostic electrophysiology study	0.1-3.2
Fluoroscopy	Radiofrequency ablation of arrhythmia	1-25
Fluoroscopy	Permanent pacemaker implantation	0.2-8

TAVR=Transcatheter aortic valve replacement. MDCT=Multidetector-row CT. EBCT=Electron beam CT.

Table 3

Possible Text for Physician-Patient Interaction about Radiation Dose from Cardiac Imaging Procedures^{*,†}

Effective Dose Level for Protocol	Suggested Language
3 mSv	<p>The test you are about to have provides useful information about your health. This test uses radiation to provide this information.</p> <p>We are all exposed to radiation from natural sources every day. The small amount of radiation to a typical patient from today's test is less than what most Americans are exposed to from their surroundings during 1 year of their life. The risk of this procedure is very low.</p>
>3 to 20 mSv	<p>The test you are about to have provides useful information about your health. This test uses radiation to provide this information.</p> <p>We are all exposed to radiation from natural sources every day. The amount of radiation to a typical patient from today's test is similar to or greater than what most Americans are exposed to every year from their surroundings. However, it is similar to or less than the maximum that is recommended in a typical year for people exposed to radiation as part of their job.</p> <p>While experts are not certain, some evidence suggests that there may be a very small increase in your risk of developing cancer at a later age, related to the radiation from this test. This risk is considered to be similar to the risks of many everyday activities and medical procedures.</p> <p>Your healthcare provider believes that the benefits of this test outweigh this small potential risk.</p> <p>You may have had tests that used radiation in the past. To the best of our current knowledge, your risk from today's test is not affected by how much radiation you have received from previous tests.</p>
>20 to 50 mSv	<p>The test that you are about to have provides useful information about your health. This test uses radiation to provide this information.</p> <p>We are all exposed to radiation from natural sources every day. The amount of radiation to a typical patient from today's test is greater than what most Americans are exposed to every year from their surroundings. It is also greater than what is recommended for people exposed to radiation in a typical year as part of their job. While experts are not certain, some evidence suggests that there may be a small increase in your risk of developing cancer at a later age, related to the radiation from this test.</p> <p>Your healthcare provider believes that the benefits of this test outweigh this small potential risk of developing cancer.</p> <p>You may have had tests that used radiation in the past. To the best of our current knowledge, your risk from today's test is not affected by how much radiation you have received from previous tests.</p>

* Note that dose levels are those for a typical patient undergoing protocol; the concept of effective dose is not designed for patient-level dosimetry and doses to individual patients may vary based on patient-specific characteristics such as weight, habitus, heart rate, etc.

† Text is only provided for protocols with effective dose up to 50 mSv. No cardiac imaging procedure in a general population should have a typical effective dose of more than 50 mSv. If the physician anticipates such a level of radiation, the physician-patient interaction needs to be carefully tailored to the patient, test, and clinical scenario.

Table 4

Summary of Level of Recommendations for Laboratory- and Population-Based Radiation Reduction. Although these recommendations were made in 2013, it should be emphasized that all recommendations should in time become mandatory.

Recommendation	2013 Level
Reporting of Appropriate Use Criteria Categories of Appropriate, May Be Appropriate (Uncertain), and Rarely Appropriate (Inappropriate)	Required
Dosimetry Reporting	Required
Development of DRLs for a variety of specific cardiac imaging tasks	Required
Implementation of Continuous Quality Improvement Programs	Required
Implementation of Decision Support Tools	Recommended
Continuing Medical Education For Referring Physicians	Recommended
Creation of a Repository from Electronic Health Record Data on Each Patient's Past History of Medical Imaging Radiation Exposure	Suggested

Definitions:

Required: Majority opinion that standardized laboratory practice of this recommendation is consistent with effective, patient-centered imaging.

Recommended: General agreement that standardized laboratory practice of this recommendation would enhance patient-centered imaging.

Suggested: Expert opinion that standardized laboratory practice of this recommendation would enhance patient-centered imaging.

Table 5

Three Basic Principles to Guide Patient-Centered Imaging and Exposure to Ionizing Radiation

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1. **Justification Principle:** Benefits and risks of all testing options should be compared, and if an exposure cannot be justified, the test should not be performed
 2. **Optimization Principle:** All doses due to medical exposure must be kept as low as reasonably achievable
 3. **Responsibility Principle:** Both the referrer and the imager are responsible for justification of the test involving exposure to ionizing radiation
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