Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 15, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.10.092

VIEWPOINT AND COMMENTARY

Patient-Centered Imaging

Shared Decision Making for Cardiac Imaging Procedures With Exposure to Ionizing Radiation

Andrew J. Einstein, MD, PhD,* Daniel S. Berman, MD,† James K. Min, MD,‡ Robert C. Hendel, MD,§ Thomas C. Gerber, MD, PhD,‖ J. Jeffrey Carr, MD,¶ Manuel D. Cerqueira, MD,# S. James Cullom, PhD,** Robert DeKemp, PhD,†† Neal W. Dickert, PhD, MD,‡‡ Sharmila Dorbala, MD,§§ Reza Fazel, MD,‡‡ Ernest V. Garcia, PhD,‡‡ Raymond J. Gibbons, MD,‖ Sandra S. Halliburton, PhD,# Jörg Hausleiter, MD,‖‖ Gary V. Heller, MD, PhD,¶¶ Scott Jerome, DO,## John R. Lesser, MD,*** Gilbert L. Raff, MD,††† Peter Tilkemeier, MD,‡‡‡ Kim A. Williams, MD,§§§ Leslee J. Shaw, PhD‡‡

New York, New York; Los Angeles, California; Miami, Florida; Rochester and Minneapolis, Minnesota; Nashville, Tennessee; Cleveland, Ohio; Kansas City, Missouri; Ottawa, Ontario, Canada; Atlanta, Georgia; Boston, Massachusetts; Munich, Germany; Morristown, New Jersey; Baltimore, Maryland; Royal Oak and Detroit, Michigan; and Providence, Rhode Island

The current paper details the recommendations arising from an NIH-NHLBI/NCI-sponsored symposium held in November 2012, aiming to identify key components of a radiation accountability framework fostering patient-centered imaging and shared decision-making in cardiac imaging. Symposium participants, working in 3 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. The 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 informed 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. 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. (J Am Coll Cardiol 2014;63:1480–9) © 2014 by the American College of Cardiology Foundation

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 have identified deficiencies in radiation safety patterns, including unwarranted exposure levels and underutilization of the American College of Cardiology's appropriate use criteria to

See page 1490

From the *Columbia University Medical Center and New York-Presbyterian Hospital, New York, New York; †Cedars-Sinai Medical Center, Los Angeles, California; ‡Weill Cornell Medical College, New York, New York; §University of Miami Miller School of Medicine, Miami, Florida; ‖Mayo Clinic, Rochester, Minnesota; ¶Vanderbilt University, Nashville, Tennessee; #Cleveland Clinic Foundation, Cleveland, Ohio; **Mid-America Heart Institute, Kansas City, Missouri; ††Ottawa Heart Institute, Ottawa, Ontario, Canada; ‡‡Emory University School of Medicine, Atlanta, Georgia; §§Brigham and Women's Hospital, Boston, Massachusetts; ‖‖Technische Universität München, Munich, Germany; ¶¶Morristown Medical Center, Morristown, New Jersey; ##University of Maryland, Baltimore, Maryland; ***Minneapolis Heart Institute, Minneapolis, Minnesota; †††William Beaumont Hospital; Royal Oak, Michigan; ‡‡‡Brown University, Providence, Rhode Island; and the §§§Wayne State University, Detroit, Michigan. Funding for this symposium was provided by the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (grant 1R13 HL112549-01), Astellas Healthcare, Bracco Diagnostics, Lantheus Medical Imaging, and MedSolutions. Dr. Einstein was supported in part by grant R01 HL109711 from

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 more than a decade ago defined key dimensions of quality healthcare delivery as those that provide services on the basis of 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 6 aims for quality improvement are safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (5); 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 health care. 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 regard to radiation safety. The current report details the recommendations arising from an symposium sponsored by the National Heart, Lung, and Blood Institute and the National Cancer Institute titled Patient-Centered Imaging: Shared Decision Making for Cardiac Imaging Procedures With Exposure to Ionizing Radiation, held at Emory University, November 15 to 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 patients and laboratories, 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) patients; 2) laboratories; and 3) the overall population. The goals and discussion points for each track are detailed in Table 1.

Abbreviations and Acronyms

ASNC = American Society of Nuclear Cardiology

CT = computed tomographic

DRL = diagnostic reference level

SPECT = single-photon emission computed tomographic

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 tomographic (CT) imaging or single-photon emission CT (SPECT) imaging 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 referring and laboratory physicians should share responsibility for both justification of the test exposure to ionizing radiation (6) and patient education.

Any approach to facilitate patient decision making must acknowledge this shared responsibility. Ideally, both the referring provider and the imager should be sufficiently knowledgeable about the benefits and risks of the requested imaging study, and discuss this in sufficient detail with the patient, to optimally guide decision making. In practice, the referring provider typically has the best understanding of the benefits of an imaging procedure for a 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

the NHLBI and by Victoria and Esther Aboodi and Herbert Irving Assistant Professorships. Dr. Dorbala was supported in part by grant K23 HL092299. Dr. Shaw was supported in part by grant U01 HL105561. Dr. Einstein has received research grants from GE Healthcare, Philips Healthcare, and Spectrum Dynamics. Dr. DeKemp is a consultant for Jubilant DraxImage and receives royalties for rubidium positron emission tomographic technology. Dr. Dorbala has received a research grant from Astellas Healthcare; and holds stock in GE. Dr. Garcia has received research grants from GE Healthcare. Dr. Gibbons has served as a consultant to Lantheus; and has received honoraria from AstraZeneca. Dr. Halliburton is a speaker for Philips Medical Systems. Dr. Hausleiter has received a research grant from Siemens Medical Solutions; and speaker's honoraria from Abbott Vascular. Dr. Heller is a consultant for GE Healthcare; and is a member of the science advisory board for Lantheus Medical Imaging. Dr. Jerome has received a research grant from the Intersocietal Accreditation Commission. Dr. Raff has received a research grant from Siemens. Dr. Williams served on a research advisory board that was funded by Astellas. Dr. Williams is currently affiliated with the Rush University School of Medicine, Chicago, Illinois. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received September 25, 2013; revised manuscript received October 28, 2013, accepted October 28, 2013.