Organization for Occupational Radiation Safety in Interventional Fluoroscopy

Occupational Exposure to Ionizing Radiation in Interventional Fluoroscopy: **Severity of Adverse Effects of a Growing Health Problem**

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Organization for Occupational Radiation Safety in Interventional Fluoroscopy
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Over the last decade, there has been a growing body of evidence on the adverse health effects of occupational exposures to ionizing radiation from interventional fluoroscopy. This paper, prepared by the Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF), examines the existing scientific evidence on the alarming incidence of cancer, pre-cursors to cataracts, and other serious adverse effects among medical professionals who perform interventional procedures. The paper focuses on data collected on the adverse health impacts recorded for interventional cardiology teams, as roughly 40% of non-radiotherapy medical radiation stems from ionizing radiation used to diagnose and treat cardiovascular conditions.[1] The paper also discusses the musculoskeletal hazards stemming from use of personal protection equipment (PPE) and contrasts US radiation-exposure thresholds against those recommended by international radiation protection agencies and widely adopted by foreign countries. This document will be updated regularly to incorporate new clinical evidence, reports or initiatives from federal agencies, changes to regulatory standards, and emerging engineering and technological solutions.

[1] R. Fazel, et al., Approaches to Enhancing Radiation Safety in Cardiovascular Imaging: A Scientific Statement from the American Heart Association. Circulation. 2014;130:1730-48.

About ORSIF

The Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF) raises awareness of the health risks of occupational ionizing radiation exposures and associated musculoskeletal risks occurring in interventional fluoroscopy laboratories. ORSIF develops support for medical professionals and hospitals for new and better ways to create the safest possible work environment for those dedicated to the wellness of others. ORSIF is composed of members from industry and will expand to include physicians and staff from interventional fluoroscopy labs and will partner with other physician associations, academic institutions, labor groups, and government bodies.

INTRODUCTION

Catheter-based technology has enabled the minimally invasive treatment of conditions that previously required invasive surgery. Since the emergence of the cardiac catheterization laboratory ("cath lab") in the 1980s, the use of percutaneous coronary intervention (PCI) has grown exponentially to treat millions of Americans with life-threatening cardiac disease or congenital defects. Minimally invasive procedures have also been developed to treat cardiac rhythm disorders, peripheral vascular disease, and neurovascular conditions. The trade-off for these less-invasive procedures is typically viewed in terms of patient outcomes compared to open surgery. However, an unforeseen trade-off relates to the health of the medical professionals who perform these procedures and who are exposed to procedure-related ionizing (low-dose) radiation.

Ionizing radiation exposure in the United States (U.S.) rose 74%, on a per-capita basis, from the early 1980s to 2006, with nearly half of the exposure related to medical imaging.[2] While there has been an increasing focus on reducing patient exposure to radiation, less attention has been paid to lowering the risk for medical professionals who have cumulative exposure that is significantly higher than that for patients. There have been reports of malignant brain tumors in the left hemisphere for interventional cardiologists[3] who are subjected to radiation exposure rates that are two to ten times higher than those experienced by other medical specialties and correlate with the physician's proximity to the radiation source in the cath lab.[4] As this paper will show, sustained exposure to low-dose radiation is causing other serious adverse health consequences—including the development of several cancer types, pre-mature development of cataracts, onset of thyroid disease, and damage to reproductive organs—for interventional medical teams.

"As low as reasonably achievable" (ALARA) is the principle governing radiation exposure in both medical and dental procedures.[5] Existing measures to implement ALARA, including the use of personal protection equipment (PPE), radiation shielding, and dose optimization, may not offer sufficient protection to medical professionals, as there is no known safety threshold that prevents damage to DNA stemming from cumulative exposure to low-dose radiation.[6] This risk has been acknowledged by several regulatory bodies, including the U.S. Environmental Protection Agency (EPA), which assumes that exposure levels exceeding those in the natural background heighten the risk of long-term adverse health effects.[7] A re-design of interventional laboratories with the inclusion of new technologies could modernize—and transform—what constitutes ALARA.[8] The immediate benefit to the patient cannot come at the price of medical professionals' long-term health.

[2] Center for Devices and Radiological Health & U.S. Food and Drug Administration, Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (February 2010).

[3] A. Roguin, et al, Brain and Neck Tumors among Physicians Performing Interventional Procedures. 111 American Journal of Cardiology 9: 1368-72 (May 2013).

[4] E. Picano, et al, Occupational Risks of Chronic Low Dose Radiation Exposure in Cardiac Catheterisation Laboratory: The Italian Healthy Cath Lab Study, European Medical Journal International, 50-58 (2013).

[5] NRCP Report No. 117, Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, December 31, 1990.

[6] U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page, Health Effects. http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

[7] *Id.*

[8] LW Klein, et al., Occupational Health Hazards in the Interventional Laboratory: Time for a Safer Environment. J Vasc Interv Radiol. 2009;20:147-153.

PART 1

Low-Level, Long-Term Ionizing Radiation Exposure Dangers

BACKGROUND

It is widely known that exposure to ionizing radiation can cause serious adverse health effects, ranging from "radiation poisoning" to terminal brain cancer.[9] Individual factors, such as age of initial exposure, gender, ethnicity, and genetic factors, influence the potential disease process.[10] Ionizing radiation can also alter the structure of DNA, including that in the reproductive organs.[11] The adverse health effects caused by radiation exposure are generally categorized either as stochastic or non-stochastic. The latter is associated with acute, immediate adverse health effects.[12] Scientific literature indicates that medical professionals exposed to recurrent, low doses of ionizing radiation can experience stochastic effects, which are longer term in nature and chronic. Stochastic health effects include many types of cancers as well as teratogenic and inheritable genetic mutations that can cause birth defects.[13]

The adverse health impact on an individual is determined primarily by the dose to which he or she is exposed. While the threshold for "safe" doses to avoid acute non-stochastic effects has been determined, there is no known safety threshold for long-term exposure to relatively low radiation.[14] In fact, the EPA has determined that there is a linear dose-response relationship with no safe level of exposure that will protect against stochastic effects.[15]

Various government agencies have monitored and tracked adverse health effects associated with radiation exposure for several decades. The BEIR (Biological Effects of Ionizing Radiation) Committee, sponsored by the National Research Council and supported by several federal agencies[16], has issued seven reports since 1972 to aid the U.S. government in understanding the link between ionizing radiation exposure and overall human health. The most recent BEIR Committee report focused on understanding and creating a risk model for low-dose exposure. While the report relied mostly on studies surrounding the atomic bomb survivors from Japan, it also reviewed risk related to occupational hazards in the medical setting.[17] Like the EPA's conclusions, the BEIR report concluded that low-dose radiation exposure has a linear dose-response relationship,[18] suggesting that a "linear-no-threshold" risk model is the appropriate manner in which to assess risk associated with radiation exposure. Accordingly, the BEIR report concludes that even extremely low-dose exposures present a risk of developing cancer.[19]

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9 U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects, http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

10 GM Allen, Genetic susceptibility to radiogenic cancer in humans, Health Physics, 95:677-686 (2009); Steven Simon, Radiation-Exposed Populations: Who, Why and How to Study, Health Physics, 106(2) 182-195 (2014).

11 National Research Council, Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII – Phase 2 (2006).

12 U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects. http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

13 U.S. Environmental Protection Agency, Radiation Protection, http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014). Non-stochastic or deterministic health effects, the second EPA category, results from acute, high-dose exposure to ionizing radiation. The severity of these effects is dose-dependent and includes symptoms of "radiation poisoning" such as nausea, vomiting, weakness, alopecia, premature aging, cellular damage, skin changes, and death.

14 *Id.*

15 U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects.

16 Supporting agencies include Environmental Protection Agency, Nuclear Regulatory Commission, U.S. Department of Commerce and the National Institute of Standards and Technology Grant. The National Research Council pulled members of the committee from Institute of Medicine, National Academy of Science and the National Academy of Engineering.

17 National Research Council, Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII – Phase 2 (2006).

18 *Id.*

19 *Id.*

Radiation in the Interventional Lab

The healthcare industry is particularly affected by ionizing radiation exposure through the diagnostic and therapeutic use of radiology and nuclear medicine, the largest source of man-made ionizing radiation.[20] It can be argued that the benefit of increased utilization of such diagnostic and therapeutic imaging procedures, such as x-rays, computerized tomography (CT) scans, and fluoroscopy, often outweighs the risk of radiation exposure to the patient due to the limited time frame the patient is actually exposed. However, the exposure risk for the health care professional who is exposed to low doses of ionizing radiation on a more consistent, repetitive basis has failed to garner the appropriate attention.

Image-guided medical procedures using interventional fluoroscopy are the leading source of occupational ionizing radiation exposure for medical personnel.[21] There are several medical specialties using fluoroscopy labs for image-guided procedures including interventional cardiology, vascular surgery, electrophysiology, and interventional neurology. The two primary modalities of ionizing radiation in an interventional lab are fluoroscopy and cine angiography. For nearly all other radiation-based diagnostic medical procedures, the medical staff exits the area of potential radiation exposure prior to the use of the radiation device. However, health care providers who participate in interventional lab procedures have not historically had access to the same protection due to limitations with technology. During procedures, an overwhelming majority of interventionalists and other medical personnel are typically positioned within four feet of the x-ray sources, which are used to provide a visual guide for physicians manually controlling devices inside the patient's vasculature. Accordingly, interventional teams have the greatest risk of exposure to ionizing radiation.[22] *In fact, interventional cardiologists have a radiation exposure rate documented to be two to ten times higher than that of diagnostic radiologists.*[23]

While exposure to radiation during individual procedures is typically low and often within existing regulatory limits for acute exposure, occupational hazards arise from the cumulative effect of exposure over time (stochastic effects).[24] Sustained exposure to low-dose radiation from procedures performed daily over the course of a career may cause serious, long-term and possibly fatal adverse health consequences. A growing body of evidence casts doubt on whether interventional medical professionals exposed to ionizing radiation are being adequately protected.

Figure 1 Image showing cardiac interventionalist standing immediately adjacent to x-ray source while performing a case in the cath lab

[20] S. Zhonghua, et al. Radiation-Induced Noncancer Risks in Interventional Cardiology: Optomisation of Procedures and Staff and Patient Dose Reduction, BioMed Research International (2013).

[21] U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects, http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

[22] MG Andreassi, The Biological Effects of Diagnostic Cardiac Imaging on Chronically Exposed Physicians: The Importance of Being Non-Ionizing, 2 Cardiovascular Ultrasound, 25 (November 22, 2004).

[23] E. Picano, et al, Occupational Risks of Chronic Low Dose Radiation Exposure in Cardiac Catheterisation Laboratory: The Italian Healthy Cath Lab Study, European Medical Journal International, 50-58 (2013).

[24] U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects, http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

Adverse Health Effects of Sustained Low-Level Radiation Exposure

Collection of data on the risk of adverse health effects caused by exposure to ionizing radiation is in an early stage, with most of the data coming from the effect on interventional cardiology teams or from studies evaluating the effects of radiation in general. Mounting evidence shows a link to a series of significant stochastic health effects, including left-sided brain tumors,[25] skin cancer,[26] posterior subcapsular lens changes (a precursor to cataracts),[27] thyroid disease,[28] and neuro-degenerative disease.[29] More generalized adverse health effects, such as cardiovascular disease and diminishment of reproductive capacity, also may be linked to general chronic, low-dose radiation exposure.[30] Significant recent findings in these areas include:

Cataracts

The Occupational Cataracts and Lens Opacities in Interventional Cardiology (O'CLOC) study revealed that 50 percent of interventional cardiologists and 41 percent of cardiac cath nurses and technicians had significant posterior subcapsular lens changes, which are not age related and are typical of ionizing radiation exposure.[31]

Thyroid Disease

Studies have reported structural changes of the thyroid as a result of radiation exposure.[32] Structural changes, such as malignant and benign thyroid tumors, develop at a linear rate to dose exposure.

Cardiovascular Changes

Recent studies suggest evidence of a link between low- to moderate-dose radiation exposure and cardiovascular changes, despite the proper utilization of PPE.[33]

Reproductive Health Effects

For males, ionizing radiation has demonstrated a reduction in sperm.[34] Medical professionals who may become pregnant while working in the cath lab must also take into consideration the effects that ionizing radiation can have on the developing fetus. Exposure to radiation in the first few weeks following conception can result in spontaneous expulsion of the embryo. The National Council on Radiation Protection (NCRP), which was chartered by Congress to monitor and publish information on radiation and radiation protection, and the EPA believe personal protective gear, e.g., leaded aprons, is sufficient to shield the fetus from radiation.[35,36] Despite this, some women may choose to minimize time spent in the interventional lab—or eschew participation in minimally invasive procedures altogether—owing to concern over harming the fetus.

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[25] A. Roguin, et al. Brain and neck tumors among physicians performing interventional procedures. 111 American Journal of Cardiology 9: 1368-72 (May 2013).

[26] S. Yoshinaga, et al., Nonmelanoma skin cancer in relation to ionizing radiation exposure among U.S. radiologic technologists. Int J Cancer. 2005;115:828-34.

[27] E. Vano, et al. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. 24 Journal of Vascular Interventional Radiology 2: 197-204 (2013).

[28] E. Ron, E, Brenner, Non-malignant thyroid diseases after a wide range of radiation exposures. Radiation Research, 174:877-888 (2010).

[29] R. Rola, Indicators of hippocampal neurogenesis are altered by 56Fe-particle irradiation in a dose-dependent manner. Radiation Research, 162:442-6 (2004).

[30] U.S. Environmental Protection Agency Office of Radiation Protection Programs Home Page; Health Effects, http://www.epa.gov/rpdweb00/understand/health_effects.html (Accessed on November 10, 2014).

[31] E. Vano, et al., 2013.

[32] E. Ron, R. Brenner, 2010.

[33] E. Picano, Cancer and non-cancer brain and eye effects of chronic low-dose ionizing radiation exposure, BMC Cancer, 12:157 (2012).

[34] A. Budorf, Effects of occupational exposure on the reproductive system: core evidence and practical implications, Occupational Medicine 56: 516-520 (2006).

[35] National Council on Radiation Protection (NCRP) Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

[36] U.S. EPA. Federal Guidance Report No. 14. Radiation protection guidance for diagnostic and interventional X-ray procedures. November 2014.

While study in these areas is ongoing, the sections below compile the significant work conducted to date. This paper will be updated as additional work is published.

Brain Tumors and Brain Disease

It was once believed that the brain, unlike the eye or thyroid, is radio-resistant, and therefore not susceptible to the same effects as other more radio-sensitive organs.[37] However, recent research has linked brain tumors, both benign and malignant, to low-level radiation exposure. For interventionalists who develop brain tumors, one study revealed that 85 percent of tumors originated on the left side of the brain.[38] Interventionalists typically stand anteriorly to the patient, with the left side of their body closest to the patient's chest, and hence, most proximate to the source of radiation. Often, the least protected area from the ionizing radiation in the cath lab is the provider's head and neck area, and the left side of the head can receive twice the radiation as the right side.[39] The personal protective wear for these areas is heavy and restrictive, curtailing provider compliance. Without protection, an interventionalist receives an estimated 1-3Sv to their head over the course of their career, which corresponds to about 500mSv to the brain.[40] Considering these factors, there is a high likelihood these left-sided brain tumors directly correlate to the ionizing radiation that these health care providers are exposed to on a regular basis. Of note, other studies have correlated an increased incidence of nervous system tumors with that of radiation doses of less than 1 Sv.[41]

Many studies have evaluated the neuro-cognitive effects of low-dose brain irradiation on patients with brain tumors. Although not completely analogous to the radiation exposure experienced by medical staff in the interventional lab, the cumulative life-time dose exposure to the interventionalist is equivalent to, or more than, the typical patient. Therefore, these effects must also be considered. The negative changes observed in these studies included white matter damage and subsequent cognitive dysfunction to radiation exposure[42] as well as reduction in olfactory neurons that lead to long-term memory dysfunction.[43] One study looked at the radiation effects on the brain of astronauts from radiation exposure and noted cell changes in hippocampal formation that also leads to cognitive deficits.[44]

Cataracts

Cataracts, often considered a deterministic effect of radiation exposure, are now considered stochastic in nature, as an increasing number of cataracts are developing subsequent to low radiation dose exposure.[45] The interventional cardiologist's head and neck area is generally exposed to approximately 20-30 mSv per year.[46] As such, a primary health complication observed most often in cath lab team members is cataract development. A cataract is the clouding of the lens that affects vision and is often due to protein buildup on the lens itself.[47] Although cataracts often develop with age, corticosteroid treatment, diabetes, or chronic uveitis, the development of posterior subscapular cataracts (PSC), commonly seen in interventionalists, are most closely linked to the chronic exposure of ionizing radiation.[48] The

[37] E Picano, et al, 2012.

[38] A. Roguin, et al. Brain and neck tumors among physicians performing interventional procedures. 111 American Journal of Cardiology 9: 1368-72 (May 2013).

[39] E. Picano, et al, 2012.

[40] *Id.*

[41] DL Preston, et al, Tumors of the nervous system and pituitary gland associated with atomic bomb radiation exposure, Journal of National Cancer Institute, 94: 1555-1556 (2002).

[42] D. Marazzitti, Cognitive, psychological and psychiatric effects of ionizing radiation exposure, Current Medical Chemistry, 19:1864-1869 (2012).

[43] F. Lazarini, et al, Cellular and behavioral effects of cranial irradiation of the subventricular zone in adult mice, PLOS One 4: 7017 (2009).

[44] R. Rola, 2004.

[45] D. Miller, et al., Occupational Radiation Protection in Interventional Radiology: A Joint Guideline of the Cardiovascular and Interventional Radiology Society of Europe and Society of Interventional Radiology, Cardiovascular and Interventional Society of Europe & the Society of Interventional Radiology (2010).

[46] L Renaud, et al., A 5-year follow-up of the radiation exposure to in-room personnel during cardiac catheterization, Health Physics, 62:10-15 (1992).

[47] National Eye Institute, Facts about Cataracts, http://www.nei.nih.gov/health/cataract/cataract_facts.asp (Accessed on July 21, 2014).

[48] E Vano, et al. Radiation cataract risk in interventional cardiology personnel. 170 Radiation Research 4: 490-495 (2010); GR Merrian, Experimental radiation cataracts – its clinical relevance, Buff. N.Y. Acad. Med. 59: 372-392.

mechanism for cataract development is unclear but it is thought that disruption of the proper division of epithelial cells of the lens can lead to cataract formation. The changes to the DNA of these epithelial cells, caused by radiation, triggers the genesis of cataracts.[49] The time in which cataracts develop is inversely related to the radiation exposure dose.[50] In other words, the higher the radiation dose, the more rapidly cataracts develop.

The Occupational Cataracts and Lens Opacities in Interventional Cardiology (O'CLOC) study revealed that fifty percent (50%) of interventional cardiologists and forty-one percent (41%) of cardiac cath nurses and technicians had significant posterior subcapsular lens changes, which as described above is typical of ionizing radiation exposure.[51] The International Atomic Energy Agency's ongoing project RELID (Retrospective Evaluation of Lens Injuries and Dose) is studying interventional cardiologists from Asia, Europe and South America. Thus far, RELID has found an increased amount of eye lens opacities in the cardiac cath lab personnel.[52] RELID and other studies have shown that, due to the radiosensitive nature of the eye lens, the relative risk for interventionalists for developing cataracts is significantly increased when compared to non-exposed controls.[53]

Thyroid Disease

Interventional lab personnel are also at risk for potential thyroid disease owing to the thyroid's radiosensitivity and anatomical location.[54] Although the effects of chronic, intermittent low-dose radiation are largely unknown, studies have reported structural changes of the thyroid as a result of radiation exposure.[55] Structural changes such as malignant and benign thyroid tumors develop at a linear rate to dose exposure. Functional changes that would result in hyper- or hypo-thyroidism have been reported at elevated doses of external and internal radiation exposure.[56]

Reproductive Health Effects

The reproductive health of both males and females can be affected by ionizing radiation if the cumulative exposure dose to the testes or ovaries reaches 0.5-1 Sv.[57] For males, ionizing radiation has demonstrated a reduction in sperm.[58] Medical personnel who may become pregnant while working in the interventional lab must also take into consideration the effects ionizing radiation has on the developing fetus. Effects of ionizing radiation exposure on the fetus include intrauterine growth retardation, microcephaly, reduced IQ, and congenital malformations.[59] These effects have been observed at exposures that exceed those typical of the interventional lab. The NCRP does not recommend that pregnant medical staff limit their participation in fluoroscopy-guided procedures as long as protective gear is worn and radiation control procedures are followed.[60] However, some women may choose to avoid work in an interventional lab during pregnancy, particularly if they are concerned about fetal development abnormalities or long-term health risks to the child. Longitudinal studies are needed to determine whether exposure to low-dose ionizing radiation during pregnancy is associated with an increased risk of cancer for the child.

[49] S. Jacob, et al. Ionizing radiation as a risk factor for cataract: What about low-dose effects? J Clinic Experiment Opthalmol. 2011;S1:005.

[50] E. Vano, et al. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. 24 Journal of Vascular Interventional Radiology 2: 197-204 (2013).

[51] *Id.*

[52] IAEA, Radiation and cataracts, https://rpop.iaea.org/RPOP/RPoP/Content/News/radiation-and-cataract.htm (Accessed on July 21, 2014).

[53] E Vano, et al., Radiation cataract risk in interventional cardiology personnel. 170 Radiation Research 4: 490-495 (2010).

[54] E. Ron, R. Brenner, Non-malignant thyroid diseases after a wide range of radiation exposures. Radiation Research, 174:877-888 (2010).

[55] *Id.*

[56] *Id.*

[57] G. Latini, Reproductive effects of low to moderate medical radiation exposure, Current Medical Chemistry, 19:6171-6177 (2012).

[58] A. Budorf, Effects of occupational exposure on the reproductive system: core evidence and practical implications, Occupational Medicine 56: 516-520 (2006).

[59] P. Best, et al, SCAI Consensus Document on Occupational Radiation Exposure to the Pregnant Cardiologist and Technical Personnel, 77 Catheterization and Cardiovascular Interventions, 232-241 (2011).

[60] National Council on Radiation Protection (NCRP) Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

Surrogate Endpoints Being Investigated

As the volume of interventional procedures rises, more studies will continue to focus on the health effects related to the cumulative, chronic ionizing radiation exposure faced by the interventional lab workforce. While the studies that have been performed to date often suffer from limitations such as cohort size, length of evaluation time and complete follow-up, preliminary findings nonetheless provide a strong basis for concern. Existing studies showing an increase in head and neck tumors in interventional cardiologists have encouraged more focused and credible research in this area, such as the Healthy Cath Lab (HCL) study. This study is currently evaluating radiation effects using a "cohort of 500 highly exposed subjects (interventional cardiologists, nurses and technicians working in the cath lab > 3 years) and a 'best match' control group of 500 unexposed subjects".[61] The study is not only looking at actual disease diagnosis but early indicators or surrogate endpoints of particular disease states, including chromosome aberrations for cancer, carotid intima-media thickness, telomere shortening for cardiovascular disease and olfactory dysfunction for neurodegenerative disorders.[62]

Radiation Exposure Control Methods

To address the risk of ionizing radiation present in interventional fluoroscopy labs, hospitals have universally adopted and implemented exposure contact programs and procedures under the guiding principle of ALARA. Three basic concepts form the basis of all ALARA-oriented radiation exposure control programs:

- Limitation of exposure time (source reduction),
- Distance from the radiation source (engineering/administrative controls), and
- Establishment of a physical control or barrier (personal protective equipment).[63]

It is well recognized that the most effective methods for controlling occupational exposures are source reduction and/or the implementation of engineering or administrative controls, such as increasing the distance between the exposed individual and the radiation source.[64]

The type and complexity of medical procedures is what drives the amount of exposure time—and often the proximity to the radiation source—needed to achieve positive patient outcomes. Accordingly, physical controls historically have been the dominant method used to control occupational radiation exposures in medical settings. Physical controls essentially serve to create barriers between operators and sources of radiation. With the advent of minimally invasive treatments, personal protective equipment (PPE) was designed to shield operators from ionizing radiation exposure in the interventional lab.[65,66] However, PPE's effectiveness as a radiation exposure control method relies, in part, on the willingness and training of medical professionals to wear the full complement of PPE—including lead-lined vests/aprons, lead thyroid collars and shields, and lead-enhanced face masks, eyeware and gloves—in the proper manner for the duration of fluoroscopy for every procedure performed. To be and remain effective, PPE must be fitted to the individual user and be inspected and tested frequently. In addition, there have been reports that gloves only offer modest radiation dose reduction,[67] and leaded eyeglasses may provide substantially less protection on the sides of the glasses compared to frontal exposure reduction.[68]

61 E. Picano, et al, Occupational Risks of Chronic Low Dose Radiation Exposure in Cardiac Catheterisation Laboratory: The Italian Healthy Cath Lab Study, European Medical Journal International, 50 (2013).

62 *Id.*

63 U.S. Environmental Protection Agency, Radiation Protection Basics (Jul. 6, 2012), http://www.epa.gov/rpdweb00/understand/protection_basics.html (Accessed on November 10, 2014)

64 OSHA's long-established hierarchy of controls demonstrates a clear preference for source reduction and implementation of engineering/administrative controls designed to shield the exposed individual from the hazardous chemical over the use of personal protective equipment.

65 LW Klein, et al. Occupational Health Hazards in the Interventional Laboratory: Time for a Safer Environment, 20 Vasc Interv Radiol 147, 147 (2009).

66 G. Dehmer et al., Occupational Hazards for Interventional Cardiologists, The Society for Cardiovascular Angiography and Interventions, 68 Catheterization and Cardiovascular Interventions 974, 975 (2006).

67 NCRP Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

68 D. Miller et al., Occupational Radiation Protection in Interventional Radiology: A Joint Guideline of the Cardiovascular and Interventional Radiology Society of Europe and Society of Interventional Radiology, Cardiovascular and Interventional Society of Europe & the Society of Interventional Radiology (2010).

PPE-Related Adverse Health Impacts

Although lead-based PPE is designed to significantly decrease the ionizing radiation exposure to interventionalists and assisting personnel, these technologies are not ideal solutions: they are voluntary and, even when used properly (i.e., wearing a leaded vest, skirt, thyroid collar, cap, and glasses), fail to fully protect medical personal. This leaves interventional personnel exposed to a significant amount of ionizing radiation especially to the head and neck, arms, and leg area.

Additionally, there is a serious risk that utilization of PPE can inadvertently cause debilitating chronic injuries in the form of spinal and other severe musculoskeletal and orthopedic conditions to the back, neck, hips, knees, and ankles.[69] Surveys of cath lab cardiologists show staggering rates of orthopedic health impacts associated with the long-term, sustained use of heavy lead aprons while standing for prolonged periods of time to perform PCI and other interventional procedures.[70] Among interventional cardiologists with at least 21 years of work, a 2004 Society for Cardiovascular Angiography & Interventions (SCAI) report showed a 60 percent incidence of spine problems compared to 26 percent for those with less than five years of work.[71] Severe spinal injuries among cath lab cardiologists are so common that they are now sometimes labeled "interventionalist's disc disease."[72] The ergonomics of the cath lab, the required work positions, and the duration and quantity of procedures amplify the taxing effect of heavy lead aprons and other PPE.[73]

In addition to spinal issues, interventional cardiologists, especially those over the age of 35, are reported to experience significant pain in their neck, back, hips, knees, and ankles. The 2004 study by SCAI found that over 25 percent of respondents experienced health issues "related to their hips, knees, or ankles."[74] The associated debilitating pain contributes to increased absenteeism and, in some cases, early retirement.[75]

Perhaps because of the serious orthopedic issues caused by the use of PPE, interventionalists may not be wearing the recommended "armor" of PPE during all procedures. In addition, some PPE (e.g., eyewear and gloves) may not offer sufficient protection. Accordingly, ORSIF concludes that reliance on PPE to shield medical staff from radiation sources is not an adequate solution.

Professional Societies: Call for Action

A plethora of professional medical associations, including SCAI, American College of Cardiology (ACC), American College of Radiology (ACR), Society of Interventional Radiology (SIR), Society of Invasive Cardiovascular Professionals (SICP), Heart Rhythm Society (HRS), American Association of Physicists in Medicine (AAPM), and Society of Neurointerventional Surgery (SNIS), recognize the deficiencies in research on the chronic low-dose radiation exposure risks. However, many medical societies believe existing evidence already demonstrates that interventional laboratories are rife with occupational hazards, given the health risks related to fluoroscopic technology and PPE, as well as the poor ergonomic design of labs and equipment.[76]

In 2005, the Multi-Specialty Occupational Health Group (MSOHG) was formed to foster collaboration and identify, educate and conduct research on the occupational hazards in the interventional setting.[77] MSOHG has partnered with the Radiation Epidemiological Branch of the National Cancer Institute to assist in research studies related to mortality of

69 *Id.*

70 LW Klein, et al. Occupational Health Hazards in the Interventional Laboratory: Time for a Safer Environment, 20 Vasc Interv Radiol 147, 147 (2009).

71 G. Dehmer, et al, 2006.

72 LW Klein, et al, 2009.

73 *Id.*

74 *Id.*

75 Dehmer, et al., 2006.

76 LW Klein, et al., Occupational Health Hazards in the Interventional Laboratory: Time for a Safer Environment. J Vasc Interv Radiol. 2009;20:147-153.

77 D. Miller, et al. Occupational Health Hazards in the Interventional Lab: Progress Report of the Multi-specialty Occupational Hazard Group, Journal of Vascular Interventional Radiology, 21:1338-1341 (2010).

interventional cardiologists. Together, these groups initiated the Interventional Fluoroscopist Occupational Health Study which focuses on mortality rates of interventionalists.[78] A "call to action"[79] for a safer work environment has emanated from MSOHG, with member associations creating a Joint Task Force on Occupational Hazards in the Interventional Laboratory. The Joint Task Force published a paper in 2009 that advocates for a complete redesign of interventional labs and equipment such that medical professionals do not need PPE and have "as close to a zero radiation exposure work environment as possible."[80]

Beyond their participation in MSOHG, the supporting medical societies have released a variety of guidelines and expert consensus documents that recognize the health risks associated with radiation exposure and provide recommendations on dose optimization, appropriate use, quality metrics, laboratory standards, and clinician competence. Although a detailed discussion of these guidance documents is beyond the scope of this paper, these documents in aggregate reinforce the need for:

- Radiation dose reduction to the patient and provider, including appropriate use of imaging technologies that emit ionizing radiation and dose optimization;
- Medical education and training on radiation protection methods, e.g., PPE, use of dosimeter badges, positioning of equipment, reduction in the number of acquired images, minimal use of high-dose fluoroscopic rates, etc.; and
- Quality assurance/quality improvement programs that include review of facility radiation safety.

The SIR's joint guideline with the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) merits special attention. The CIRSE/SIR guideline examines exposure levels and their implications, as well as the tools available to shield professionals from exposure to ionizing radiation.[81] The document also compares the differences in exposure levels set by European countries to the higher levels currently accepted in the U.S., which are discussed in detail in the next section. Of note, the CIRSE/SIR guideline highlights that even lower exposure levels than those currently advocated may cause serious health issues, such as the onset of cataracts.[82] This suggests that the higher European regulatory exposure limits may be insufficient, necessitating greater protective measures for medical personnel. As national standards in U.S. and Europe have not been changed to address this recent data, the CIRSE/SIR recommend the development and implementation of voluntary measures to limit exposure of health care professionals, particularly interventionalists subjected to higher cumulative levels of ionizing radiation.

[78] *Id.*

[79] LW Klein, et al., 2009.

[80] *Id.*

[81] D. Miller et al., 2010.

[82] *Id.* Specifically, the guidelines state that "New data from exposed human populations suggest that lens opacities (cataracts) occur at doses far lower than those previously believed to cause cataracts." This document was published prior to the ICRP implementing its new, lower exposure limit for lens of an eye, which the ICRP revised in 2011.

PART 2

RADIATION EXPOSURE LIMITS – THE REGULATORY LANDSCAPE AND CURRENT U.S. STANDARDS

Domestic Exposure Limits – OSHA and the NRC

Regulation of occupational exposure to ionizing radiation is achieved through the establishment of maximum permissible exposure limits setting the amount of radiation to which employees may be exposed in the workplace. In the U.S., exposure to ionizing radiation in occupational settings is regulated by two separate agencies: the Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA). It is OSHA that is authorized to regulate exposure to ionizing radiation generated from medical imaging devices during procedures performed in a hospital cath lab.[83]

OSHA Regulations

OSHA's exposure limits for ionizing radiation were set in 1971 (well before the invention of interventional specialties and procedures, such as PCI).[84] The regulations were adopted from the first radioactive exposure limits set by the Atomic Energy Commission (AEC; now the NRC) in the late 1960s, and have not been updated since their implementation over 40 years ago.[85]

The OSHA limits (Table 1) are based on a calendar quarter measurement window. Similar to NRC standards, OSHA has established exposure limits for the whole body as well as for specific anatomy. It is notable that OSHA has not established a limit specifically for eye lens exposure.[86]

Anatomy	Rems per Calender Quarter	Annualized Exposure Limit
Whole Body	1.25	5 rems
Hands and forearms, feet and ankles	18.75	75 rems
Lens of eye	Included in whole body limit	Included in whole body limit
Skin of whole body	7.5	30 rems

Table 1. OSHA Ionizing Radiation Exposure Limits [87]

[83] 29 C.F.R. § 1910.1096(2014).

[84] As a point of reference, percutaneous coronary interventions were conducted for the first time in the U.S. in 1978, but did not come into wide use until the 1990s.

[85] 70 Fed. Reg. 22828, 22831 (May 3, 2005).

[86] 29 C.F.R. § 1910.1096 (2014).

[87] 29 C.F.R. § 1910.1096(b)(1) (2014).

OSHA allows the quarterly exposure limits to be exceeded when the following two conditions are satisfied:

- The whole-body exposure in any one calendar quarter does not exceed 3 rems; and
- Cumulative lifetime exposure does not exceed 5x(N-18)rems (where N represents the exposed individual's age in years).[88]

By retrospectively creating an annualized exposure limit from the allowable cumulative lifetime exposure limit, OSHA theoretically permits up to a 12 rem annual exposure.[89]

In 2005, OSHA released a request for information regarding the ionizing radiation exposure regulations,[90] recognizing the agency's standard as potentially obsolete, given that other federal guidance, scientific information, and international standards have been more recently revised.[91] No regulatory action has been taken by OSHA subsequent to this request for information almost 10 years ago.

NRC Regulations

Although emanating from the same set of AEC limits established in the late 1960s, the NRC has separate radiation exposure limits (Table 2).

Anatomy	Rems per Year
Whole Body	5
Lens of eye	15
Skin of whole body	30

Table 2. NRC Ionizing Radiation Exposure Limits [92]

[88] Id. § 1910.1096(b)(2).

[89] 29 C.F.R. § 1910.1096 (2014).

[90] 70 Fed. Reg. 22828, 22828 (May 3, 2005).

[91] Id. at 22832.

[92] 10 C.F.R. § 20.1201 (2014).

Similar to OSHA's exposure limits, the current NRC limits are significantly less stringent than international recommendations; however, the NRC guidelines are considered at least somewhat more protective than OSHA's standards in that they do not allow for exceeding dose limits under any circumstances.[93] In contrast to OSHA's theoretical annual exposure limits of 12 rems, the NRC's methodology establishes a significantly lower, non-variable annual limit of 5 rems.[94] Moreover, the NRC standards include a dose limit of 15 rems per calendar year applicable to the eye lens,[95] whereas OSHA does not require a separate annual limitation of exposure to this anatomy, grouping it with whole body exposure.[96] In what may be an indication of the agency's recognition of the inadequacies of its current standard, the NRC recently indicated interest in considering a revision to the eye lens limit. A 2011 request was issued by the agency asking for public comment on this revision in light of international pressure to lower the annual dose limit applicable to the lens of the eye from 15 rems per year to an annualized 2 rems[97] based on emerging evidence that lens damage may manifest with lower exposures than what had initially been recognized.[98] While the NRC is apparently still contemplating this revision, no formal change has been proposed.

International Recommendations and Standards

In contrast to antiquated U.S. limits, international occupational exposure limits for ionizing radiation in many First World countries follow the recommendations of international bodies, such as the International Council on Radiation Protection (ICRP) and the International Atomic Energy Agency (IAEA).[99] These bodies are independent, international organizations that have developed widely recognized standards for radiological protection. Unlike U.S. standards, the ICRP and IAEA routinely update their standards as new scientific information becomes available. Currently, the limits recommended by these agencies are generally more than twice as stringent as U.S. limits.

The ionizing radiation occupational standards adopted by the European Union, Canada, and Australia (based on ICRP recommendations) set an annualized whole body dose limit of 2 rem, compared to the 5 rem annualized dose limit set by OSHA and NRC for exposures in the U.S.[100] Additionally, the IAEA and ICRP recommend a 2 rem limit for eye lens exposure. Comparatively, as described above, the U.S. occupational standards set by OSHA establish no specific limit for eye exposure and the NRC limit is 15 rems.

The following table lists current ICRP recommended radiation exposure limits:[101]

Anatomy	Rems per 5 years	Annual Maximum	Annualized Exposure
Whole Body	10	5 rems	2 rems
Lens of Eyes	10	5 rems	2 rems
Skin, Hands and Feet	50	–	50 rems

Table 3. ICRP Radiation Exposure Limits

[93] 10 C.F.R. § 20.1001 et seq. (2014).

[94] 10 C.F.R. § 20.1001 et seq. (2014).

[95] 10 C.F.R. § 20.1201 (2014).

[96] 29 C.F.R. § 1910.1096 (2014).

[97] 76 Fed. Reg. 53847 (August 30, 2011).

[98] ICRP, Publication 118 Statement on Tissue Reactions, 41 Ann ICRP 1 (2012).

[99] Radiation dose limits recommended by international entities and countries are originally listed in the milliSievert unit of measurement, not rems. These dose limit quantities have been converted to rems for the purposes of this paper.

[100] ICRP, Publication 103 The 2007 Recommendations of the International Commission on Radiological Protection, 37 Ann. ICRP 1 (2007).

[101] *Id.*

In sum, a comparison of U.S. regulatory limits to maximum limits recommended by international radiation agencies and adopted by most Western countries shows a troubling disparity:

Anatomy	Annualized Exposure Limit (rems)		
	NRC[102]	OSHA[103]	ICRP[104]
Whole Body	5	5	2
Lens of Eyes	15	Included in whole body limit	2
Skin of whole body	50	30	–
Hands and Forearms, Feet and Ankles	–	75	50 rems

Table 4. Comparison NRC, OSHA, and ICRP Radiation Exposure Limits

Mounting Concern Over Allowable Exposures

The inadequacy of current regulatory dose limits established in the U.S. is gaining increasing attention on a national and international level in light of the mounting concern that severe adverse health impacts are resulting from sustained low-dose exposures. Although there have been no recent changes to U.S. national standards, several federal government agencies and international bodies have been engaged in efforts to bring attention to patient and medical professional radiation exposure.

The U.S. Food and Drug Administration (FDA) sets standards for, reviews, and approves, medical equipment that emits ionizing radiation. Its charter does not include setting thresholds for patient and provider radiation exposure. However, it can—and does—advocate for public health. Regarding medical radiation exposure, the FDA recommends the adoption of ALARA, which includes dose optimization, i.e., the use of techniques that administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention. In addition, the FDA's Center for Devices and Radiological Health (CDRH) released a white paper calling "radiation exposure from medical imaging an important public health issue", noting that ionizing radiation exposure increased from 3.6 mSv in the early 1980s to 6.25mSv in 2006 on a per-capita basis, with medical imaging accounting for 48% of the radiation exposure.[105] The paper identifies interventional fluoroscopy as having much higher patient exposure to radiation compared to diagnostic tests, such as chest X-ray, mammogram, and CT scans. During interventional fluoroscopy, patient exposure can range from 5 mSv to 70 mSv (which equates to 0.5 to 7 rems) compared to only 0.02 mSv for a chest X-ray and 0.4 mSv for a mammogram.[106] Whereas medical technologists who perform the lower radiation-emitting diagnostic scans typically leave the room during image acquisition, the design of interventional labs and the requirements of the procedures do not provide the same protection to medical professionals involved in interventional procedures.

[102] 10 C.F.R. § 20.1201 (2014).

[103] 29 C.F.R. § 1910.1096 (2014).

[104] ICRP, Publication 103 The 2007 Recommendations of the International Commission on Radiological Protection, 37 Ann. ICRP 1 (2007).

[105] Center for Devices and Radiological Health & U.S. Food and Drug Administration, Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (February 2010).

[106] *Id.*

The FDA intends to set new safety standards for CT and fluoroscopic equipment, which may include the display and recording of radiation doses as well as alerts when radiation doses exceed certain levels. The agency also plans to partner with the Centers for Medicare and Medicaid Services (CMS) to enhance quality measures and accreditation criteria and advocates the incorporation of radiation exposure into electronic health records.[107] It should be noted that CDRH's white paper is primarily aimed at reducing exposure to patients, not medical professionals.

The EPA has recently proposed to revise and update its Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures,[108] which would be the first update since the EPA issued guidance in 1976. (The 2012 guidance document was released for public comment in April 2013, with comments to be submitted by June 3, 2013. Submitted comments had not been made publically available as of the printing of this report.) While the proposed EPA guidance is focused primarily on protection of patients exposed to ionizing radiation through medical procedures such as fluoroscopy, the issues are relevant to occupational exposures as well.[109] The draft guidance recognizes that improvements in fluoroscopy detector systems and other equipment have facilitated an increase in these types of interventions, requiring reassessment of current procedures and development of new techniques to reduce radiation exposure.[110] It provides some recommendations for personnel administering these tests, however, some medical societies do not believe the guidance sufficiently addresses the protection of medical personnel specifically.[111] In addition, the draft guidance discusses the difficulty in determining whether exposure levels—even the less stringent limits used in the U.S.—are being met due to possible inaccuracies in monitoring data.[112] The issue of whether exposure data is being accurately monitored and collected via dosimeter badges worn by medical personnel in interventional labs is beyond the scope of this paper. However, it should be noted that some clinicians may not wear badges to avoid triggering exposure limits.[113,114,115] Thus, exposures experienced by interventionalists and other medical professionals may be significantly higher than recorded.

The National Council on Radiation Protection (NCRP) issued guidance for management of ionizing radiation dose exposure to patients and medical professionals in 2010. Overall, the report concluded that use of PPE and shielding, if worn and used properly, is sufficient to protect interventional teams.[116] NCRP exceptions to adequate protection included medical professionals not wearing dosimeters, deficits in certain PPE (e.g., leaded gloves), and higher exposure during emergent procedures.[117] However, the NCRP recently formed a special committee to update another NCRP report, Limitation of Exposure to Ionizing Radiation, released in 1993.[118] The NRCP sees a "pressing need" to update its 1993 guidance, given evidence that relatively low radiation doses can result in adverse health effects, such as cataract formation. It is anticipated that the report will include a contemporary framework for ALARA in medical procedures.[119]

ORSIF believes a new framework that does not rely on optional radiation control methods (such as PPE) is needed, given that even medical societies concede that interventionalists may not routinely wear dosimeters.[120] This latter point was included in a medical guideline on occupational radiation exposures, suggesting that failure to wear dosimeters is a common occurrence. While it is possible that medical professionals wear PPE but not dosimeters, anecdotal evidence suggests that some interventionalists may not wear the full complement of PPE. Even if medical professionals do wear

[107] *Id.*

[108] U.S. Environmental Protection Agency, Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures, Federal Guidance Report No. 14 – Draft Proposal (2012).

[109] *Id.*

[110] *Id.*

[111] SCAI Comments on U.S. Environmental Protection Agency Radiation Safety Document for Cath Labs, June 03, 2013.

[112] U.S. Environmental Protection Agency, 2012.

[113] LW Klein, et al., 2009.

[114] A. Duran, et al., A summary of recommendations for occupational radiation protection in interventional cardiology. Catheter Cardiovasc Interv. 2013;81:562-7.

[115] D. Miller et al., 2010.

[116] NCRP Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010

[117] *Id.*

[118] National Council on Radiation Protection (NRCP). Current Program. CC 1: Radiation Protection Guidance for the United States. http://www.ncrponline.org/Current_Prog/CC_1.html Accessed on January 14, 2015.

[119] *Id.*

[120] D. Miller, et al, 2010.

the recommended protective gear, PPE has limitations that impact its effectiveness, as discussed in the next section.

Of note, previous NCRP reports were instrumental in creating the framework for ALARA in medical and dental facilities.[121] It is unclear whether NCRP's update to its 1993 report on Limitation of Exposure to Ionizing Radiation will include recommendations for minimizing stochastic health effects other than cataract formation. For example, it is unknown whether NCRP will address evidence of left-sided brain tumors among interventional physicians. It has been suggested that lead caps could reduce occupational radiation exposure to the brain. However, the Joint Inter-Society Task Force on Occupational Hazards in the Interventional Laboratory has concluded that such a "solution" would "add yet more weight to the load already being worn",[122] which may limit implementation in the clinical setting.

Concern about existing levels and dangers of radiation exposures to medical professionals has also been expressed by—and the subject of papers from—several organizations, including:

- 2009 International Commission on Radiological Protection (ICRP); Publication 113, Education and Training in Radiological Protection for Diagnostic Interventional Procedures;
- 2010 Special Communication issued by Cardiovascular and Interventional Radiological Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR); Occupational Radiation Protection in Interventional Radiology: A Joint Guideline noting the prevalence of lens opacity occurring at low-dose exposures and concerns over the accuracy of dosimetry results; and
- 2011 U.S. Joint Commission of International Atomic Energy Agency issuance of Sentinel Event Alert calling for immediate action to reduce the exposures to ionizing radiation dangers associated with radiological procedures.

While this paper does not purport to comprehensively report on all such activity, there is a growing concern over radiation exposures occurring in the cath lab, fluoroscopy lab, and other medical settings in light of antiquated U.S. exposure standards. In the absence of more stringent regulatory limits—or in order to comply with potentially lower exposure standards in the future—it's critical to identify methods, procedures, and technologies that can effectively control exposures to medical professionals.

[121] NRCP Report No. 117, Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, December 31, 1990.

[122] LW Klein, et al., 2009.

PART 3

The Future of the Laboratory

Expected Growth in Interventional Procedures

The number of PCI procedures has increased over fifty percent since 2000.[123] Advancements in tools, technologies, and techniques have enabled interventional cardiologists to perform increasingly complex minimally invasive procedures, such as treatment of multi-vessel and left main disease. This is expanding the addressable patient population and portends growth in interventional procedures (with concomitantly fewer open surgical procedures).[124] Separately, radial access, which involves the insertion of a catheter through the radial artery near the wrist instead of the conventional approach of insertion through the femoral artery at the groin, is being increasingly used in PCIs because of reduced vascular and bleeding complications as well as increased patient comfort.[125] Both radial access and the treatment of complex conditions are associated with longer procedure times and the duration of fluoroscopy guidance, which adds to the stochastic risks medical professionals face.

While stenting of coronary arteries has declined in recent years,[126] other fluoroscopy-guided procedures—including percutaneous treatment of valvular disease[127] and peripheral artery disease (PAD) and endovascular aneurysm repair (EVAR)— have risen dramatically. In fact, the number of EVAR procedures and percutaneous PAD treatments now exceed the number of open surgical cases.[128,129] Existing PPE are not designed for clinician positioning during endovascular PAD treatments, i.e., interventionalists performing these procedures are more exposed to ionizing radiation. Other fluoroscopy-guided interventions, such as carotid and neurovascular stenting as well as cerebral aneurysm repair, are also on the rise.

SOLUTIONS

Interventionalists have been aware of the occupational risks they face during procedures for many years. However, a lack of technological innovation, and perhaps clinical or administrative inertia, may have limited attempts to improve the safety and ergonomics of the interventional lab. As mentioned earlier, PPE (e.g., leaded aprons, thyroid shields, etc.) is the dominant form of radiation exposure control used in interventional labs. However PPE has limitations. It must be used consistently, maintained and inspected frequently, and tested to ensure that it provides adequate protection.[130] Lead-based PPE is heavy and uncomfortable, which affects wearers' compliance. Although lighter-weight materials have been developed and are frequently used, there is a wide variation in actual attenuation values[131] for these lighter-weight aprons and other PPE. Protective eyewear must be fitted to the individual and contain the vision correction appropriate to the individual wearer. When protective eyewear is not equipped with side shields, their effectiveness is greatly reduced.[132]

[123] P. Best, et al, 2011.

[124] LW Klein, et al., The Catheterization Laboratory and Interventional Vascular Suite of the Future: Anticipating Innovations in Design and Function. Catheter Cardiovasc Interv. 2011;15:447-55.

[125] P. Best, et al, 2011.

[126] RF Riley, et al, Trends in Coronary Revascularization in the United States from 2001 to 2009: Recent Declines in Percutaneous Coronary Intervention Volumes. Circ Cardiovasc Qual Outcomes. 2011;4:193-197,

[127] MJ Mack, et al., Outcomes Following Transcatheter Aortic Valve Replacement in the United States. JAMA. 2013;310:2069-2077.

[128] DC Levin, et al. Endovascular Repair vs. Open Surgical Repair of Abdominal Aortic Aneurysms: Comparative Utilization Trends from 2001- to 2006. J Am Coll Radiol. 2006;6:506-9.

[129] PP Goodney, et al. National Trends in Lower Extremity Bypass Surgery, Endovascular Interventions, and Major Amputations. J Vasc Surg. 2009;50:54-60.

[130] NCRP Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

[131] D. Miller, et al, 2010.

[132] Id.

Lead gloves, a particularly problematic form of PPE, can provide a false sense of security when a worker must position the hands in the primary radiation beam. As a result, the use of lead gloves can actually lead to an increase in the radiation dose to which the hands are exposed. In addition, they do not substantially lower radiation exposure.[133] Other physical controls include ceiling-mounted or table-attached shields, which have been incorporated into many labs. However, through "gaps" in these structures, medical professionals can be exposed to radiation.[134] In addition, ceiling- and equipment-mounted shields cannot be used in every situation. For example, they often cannot be used when the x-ray gantry is at a steep oblique or lateral position.[135]

The NCRP and EPA believe that a rigorously implemented combination of shielding, PPE, and exposure assessment using dosimetry can dramatically reduce dose exposure.[136,137] However, as mentioned earlier, medical professionals may not wear dosimeters in an effort to avoid investigation of high exposures levels.[138,139,140] The reasons for not using dosimeters, which are typically attached to PPE, are unclear. Some interventionalists may find PPE too cumbersome or painful to wear. Others may feel that PPE disrupts performing the procedure. Regardless of the impetus for not wearing dosimeters, ORSIF believes solutions to minimize radiation exposure must be easily integrated into clinical practice to ensure that they readily adopted by interventional teams.

Therefore, reducing exposure may be better achieved through non-PPE radiation controls. Technologies that allow operators to be positioned farther from the source of radiation are now available that can reduce or eliminate the potential for long-term health risks imposed on the medical staff without compromising patient outcomes. For instance, the use of power injectors to inject contrast agents[141] and robotic devices to perform image-guided procedures remove medical personnel from the radiation source.[142] These techniques have proven to be extremely effective in exposure reduction. For instance, clinical studies have shown that robotic devices that allow operators to be positioned safely in a radiation-shielded cockpit reduce the median radiation exposure to the interventional cardiologist by 95.2 percent.[143] This technology not only dramatically reduces source radiation exposure, but also negates the need for heavy PPE, thus reducing or eliminating the orthopedic impact on the operator.[144]

Because there are no known "safe" levels to avoid the stochastic health effects of recurrent exposure to low-dose ionizing radiation, it is believed that "the future interventional laboratory must be designed so that radiation safety is not predicated on the voluntary cooperation, sensitivity, and education of operators, but rather is constructed into the design of laboratory."[145] As mentioned earlier, MSOHG believes medical societies should strive for a "zero radiation work environment"[146] that doesn't require the use of PPE. To achieve this, it is believed that interventional labs must be re-designed and incorporate technology that uses non-radiation sources for imaging and/or limits exposure to radiation and musculoskeletal injury through robotic systems.[147]

133 NCRP Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

134 LW Klein, J Maroney. Optimizing Operator Protection by Proper Radiation Shield Positioning in the Interventional Cardiology Suite. JACC Cardiovasc Interv. 2011;4:1140-1.

135 D. Miller, et al., 2010.

136 NCRP Report No. 168. Radiation dose management for fluoroscopically guided interventional procedures. July 2010.

137 U.S. EPA. Federal Guidance Report No. 14. Radiation protection guidance for diagnostic and interventional X-ray procedures. November 2014.

138 LW Klein, et al., 2009.

139 A. Duran, et al., 2013.

140 D. Miller, et al., 2010.

141 Interventional radiologists receive the bulk of their radiation exposure while manually injecting contrast media during digital subtraction angiography (DSA). Power injectors allow medical personnel to move away from the radiation source and reduce their exposure.

142 American Society of Radiologic Technologists, Occupational Radiation Safety (Jun. 2013), http://www.asrt.org/docs/default-source/publications/occupational_radiation_safety.pptx?sfvrsn=4 (Accessed on Jul 18, 2014)

143 Weisz et al, Safety and Feasibility of Robotic Percutaneous Coronary Intervention, 61 J. Am. C. Cardiology 15 (2013)

144 The CorPath Vascular Robotic System enables the precise, robotic-assisted control of coronary guidewires and balloon/stent devices from the safety of a radiation-protected, ergonomic interventional cockpit. http://www.corindus.com/about-corpath/how-corpath-works

145 LW Klein, J Maroney, 2011.

146 W Klein, et al, 2009.

147 LW Klein, et al, 2010.

CONCLUSION

Low-level, long-term ionizing radiation exposure causes stochastic-type health effects that alter the underlying DNA structure, increasing one's risk of developing cancer, which often materializes 10-20 years post exposure.[148] Some cancers linked to this chronic ionizing radiation exposure include brain, skin, colon, prostate, thyroid, lung, stomach, breast, and leukemia.[149] Stochastic health effects also include teratogenetic and genetic mutations that can cause birth defects or can be passed on to one's children.[150] It's likely that the magnitude of the consequences of cumulative exposure for interventional medical teams will not be known for several years, if not decades, given the time lag between exposure and appearance of stochastic health effects. Still, the preliminary body of case studies and formative scientific literature referenced in this paper show an alarming level of serious illness: elevated incidences of left-sided brain tumors and neck cancer; skin injury, including cancer; and significant subcapsular lens changes.

U.S. radiation exposure limits have not been updated in roughly 40 years and remain significantly higher than limits recommended by international radiation protection bodies and broadly adopted worldwide. Given the rising evidence of serious stochastic health impacts related to low-dose radiation exposure, U.S. limits may need to be revisited. Even if this should occur, more stringent regulatory requirements may not be sufficient to protect medical personnel over the course of their careers. It would be imprudent to assume PPE—the least effective type of radiation control methodology, the cause of debilitating orthopedic issues, and potentially underused by interventional teams—can offer a panacea.

The design of interventional labs has not changed dramatically in several decades.[151] In light of the growing number of minimally invasive procedures, it is time to design—and outfit— interventional labs with contemporary radiation exposure controls to assure the protection of medical personnel. New technologies that provide extremely effective control for protecting interventionalists and other medical personnel should be given serious consideration. Distancing and shielding operators from the source of radiation is paramount and would have a concomitant benefit of reducing orthopedic injury related to traditional PPE. Absent effective controls, interventional lab medical professionals jeopardize their own health—facing radiation exposure rates up to 10 times higher than that for other medical specialties—in pursuit of improving the lives of others. Immediate attention from all stakeholders is needed to implement interventional lab tools, technologies, and protocols to safeguard these health care providers from the stochastic effects of radiation and enable the continued minimally invasive treatment of patients.

[148] E. Stephen Amis, Jr et al, American College of Radiology White Paper on Radiation Dose in Medicine, 4 Journal of the American College of Radiology, 272, 273 (2007).

[149] National Research Council, Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII – Phase 2 (2006).

[150] U.S. Environmental Protection Agency, Radiation Protection, http://www.epa.gov/rpdweb00/understand/health_effects.html

[151] LW Klein, J Maroney, 2011.

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