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SCAI multi-society position statement on occupational health hazards of the catheterization laboratory: Shifting the paradigm for Healthcare Workers' Protection

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Dedicated to the memory of Dr. Chambers for his unrelenting work in this area to safeguard all health care professionals against occupational hazards of the fluoroscopy laboratory.

Author disclosure information is available in Supplemental Table 3.

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1 | INTRODUCTION

Renewed attention has focused on the occupational health hazards posed by working in the fluoroscopic laboratory.[1–6] Accumulated occupational radiation exposure is associated with health risks to physicians, nurses, and technologists working in this environment. Health care workers are subject to insidious health effects of radiation exposure over many years. Adverse effects include the established predilection to posterior subcapsular cataracts, as well as worrisome signals of lifetime risks of cancer induction, particularly in the unprotected brain.[7–12] A further consequence is the extensively documented incidence of orthopedic illnesses reported in physicians as well as nurses and technologists and injuries linked to the cumulative burden of bearing the weight of only partly protective lead aprons mandatory to reduce radiation risk.[13–16] The increased volume and complexity of procedures, together with the physical stresses inherent in procedural performance, have exacerbated the prevalence and magnitude of such orthopedic injuries.[17] The high prevalence of orthopedic afflictions not only affects individual health but also could be potential career ending, with workforce implications for both the profession as well as for society.[15]

1.1 | Limited progress to improve fluoroscopic laboratory occupational health

Advances in interventional imaging techniques and treatments over the last three decades have achieved significant success with clear benefits to our patients[18]; yet protective measures for workers have unfortunately lagged the pace, magnitude, and impact of this therapeutic progress. The purpose of this position statement is to review the data documenting occupational health injuries, summarize current equipment and processes that can be widely applied to optimize protection, emphasize the importance of investment by hospitals and health systems in protective equipment established to enhance workplace safety, examine barriers that need to be overcome to spur advances to enhance the occupational safety of the fluoroscopic laboratory environment, and propose enhanced advocacy for innovation.

Future processes and proposals to improve the fluoroscopic laboratory environment should be based on the following precepts: (a) there is ample clinical data documenting the prevalence of serious occupational health risks engendered by the fluoroscopic laboratory environment; (b) sufficient attention to these occupational health issues has been drawn in annual meetings and published clinical scientific studies; (c) despite these data and advocacy efforts, advances to improve worker safety in the fluoroscopic laboratory remain inadequate; and (d) a concerted effort by all stakeholders (physicians, catheterization laboratory nurses, and technologists, sonographers, hospitals, professional societies, and industry) in the fluoroscopic laboratory is necessary to further advance occupational safety and health.

1.2 | Radiation exposure: Risks and injuries

Radiation exposure is inherent to procedural performance in the fluoroscopic laboratory. Exposure to ionizing radiation imposes health risks to both patients and operators, resulting in an increased likelihood of numerous illnesses and diseases.[1–8] The association with posterior subcapsular cataracts is well documented.[11,12] There are growing concerns for cancer induction,[7,8] with recent reports of a cluster of predominantly left-sided brain cancers in interventionists,[9,10] as well as a signal for increased breast[19–22] and skin cancers.[23–26] Radiation exposure generally, not necessarily as part of occupational exposure, is associated with leukemia/lymphoma, myeloma, numerous gastrointestinal and bone cancers, and thyroid and parathyroid adenomas. These disquieting signals fuel the increasing anxiety regarding radiation exposure-related oncogenesis, though no mortality impact has been proven.[27]

Recent studies have also suggested that occupational radiation exposure is associated with hypertension, hypercholesterolemia, and possibly atherosclerosis.[28–30] Evidence of lengthening sarcomere length and early vascular aging in epidemiologic studies suggests that workers who are occupationally exposed to radiation during interventional procedures may be at increased risk to develop these same illnesses.[30,31]

1.3 | Orthopedic injuries: Collateral damage of working in the fluoroscopic laboratory

There is now overwhelming evidence demonstrating that working in the interventional laboratory is associated with an increased incidence of orthopedic illnesses, particularly those related to the cervical and lumbar spine. These orthopedic injuries have been linked to the cumulative effects of bearing the weight of leaded aprons.[5,15,16] Additionally, the design of the catheterization laboratory environment promotes awkward orthopedic ergonomic postures (e.g., monitors placed out of the line of natural working sight views). As procedures become increasingly complex and prolonged, and their volume increase in number, it should not be surprising that interventional

practice is attended by a high rate (40–50%) of occupational-induced orthopedic injuries.[15–17] Over a career's duration, the likelihood of suffering such illnesses are 2–7 times[27,28] higher than other medical occupations. Studies report substantial differences in orthopedic injuries between those wearing lead aprons working in the fluoroscopic laboratory compared to colleagues working in the same department not working in the fluoroscopic laboratory and thus not bearing the burden of wearing lead aprons.[27–29] These occupational-related injuries not uncommonly result in missed days of work, surgery, and, in some cases, curtailed careers. This issue has significant implications for the interventional workforce, particularly in view of the aging of the population and anticipated increased procedural demand concomitant with aging of the operators who pioneered these advances.[17,27–29]

1.4 | The scope of health care personnel at risk

These occupational health concerns potentially affect several medical specialties, including cardiologists, radiologists, and surgeons working with fluoroscopy, as well as pain management specialists performing nonvascular fluoroscopic procedures. Importantly, all such issues also pertain to the other personnel who are essential members of the "interventional team" (e.g., nurses and technologists, interventional imagers, and cardiac anesthesiologists) who are exposed to the harmful effects of scattered ionizing radiation.[30–33] Electrophysiologists and their team are also exposed to radiologic risks and orthopedic injury[34] and perhaps even more so, given the duration of their procedures and lack of upper torso shielding during device cases (e.g., implantable defibrillators and cardiac resynchronization therapy). These issues also have particular importance to women; although radiation effects on the fetus have not been demonstrated, women report concerns for adverse effects during reproduction as an obstacle to choice of an interventional career. These radiation exposure concerns have sometimes been considered a reason for disproportionately low representation of women in the field.[35] As noninvasive cardiologists specialized in imaging are now required to guide interventions in the catheterization and electrophysiology laboratories, pursuing career in imaging is no longer radiation free and a safer choice for women. This may result in shifts in gender distribution in various cardiology subspecialties, further impacting strategies to improve diversity and inclusion in out profession.

1.5 | Imperative to shift the paradigm for health care personnel protection

The past three decades have witnessed astounding progress in interventional equipment, technique, therapeutics, and the clinical research that catalyzed these advances. Progress in interventional laboratory protection and safety has comparatively lagged, despite the growing mounting data emphasizing occupational health concerns. A paradigm shift to dramatically improve the occupational safety for all stakeholders in the fluoroscopic laboratory (members of the interventional team, professional societies, hospitals, and industry) is required.

TABLE 1 Professional society "Best Practices"

Professional societies should assist its members to

- Understand the evidence demonstrating the risks of occupational radiation exposure, including both possible direct (cataracts, cancer risk, cardiovascular) and indirect (orthopedic injury) hazards;
- Champion use of protective measures including proper use of shielding and minimize unnecessary radiation usage in the laboratory;
- Ensure consistent application and adherence to established training and procedural processes;
- Insist on accurate monitoring of operator and laboratory personnel exposure;
- Encourage widespread adoption and utilization of new technologies for the reduction of occupational hazards;
- Acknowledge that current advocacy efforts have been inadequate and participate in more robust effective advocacy initiatives on behalf of the members;
- Undertake further efforts with industry, including encouragement and support to further develop effective equipment that fosters/facilitates enhanced safety and protection in the workspace, including fluoroless laboratories;
- Support individual physicians and practices to work with hospital administration to ensure worker safety;
- Initiate formal training programs to minimize the hazards of radiation exposure that should become mandatory for laboratory's certification;
- Commit to playing a leadership role in correcting these deficiencies and establishing a culture of safety;
- Assist hospitals and health systems to establish comprehensive programs for clinician health in the catheterization and electrophysiology laboratories which are consistent with recommended wellness programs;
- Use this issue as an opportunity to share and collaborate with international colleagues.

In particular, there is an opportunity and obligation for industry and hospitals, who clearly benefit from the workers' commitment to their profession, to play a leadership role in correcting these deficiencies. A template exists based on the collaboration established by recent FDA-led efforts aimed to reduce patient exposure.[36] Leveraging the concept and practice of the "Image Wisely" and "Image Gently" campaigns codified by Radiological Society of North America[37] and Pediatric Cardiology community[38] to minimize radiation exposure to patients, in 2010, the FDA Center for Devices and Radiological Health launched an Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. As part of this initiative, the FDA held a public meeting on ways to improve devices to reduce unnecessary radiation exposure to help the agency decide on any new, targeted requirements for manufacturers of computed tomographic and fluoroscopic devices. This effort resulted in an industry-driven enhanced awareness, with mandates to recognize both the needs for and market potential of innovations focused on minimizing patient radiation exposure. These initiatives rapidly resulted in dramatic changes to improve the X-ray systems. Examples of these improvements include minimizing radiation exposure through lower emission X-ray systems

as well as monitoring, recording of each procedure's patient exposure, and standardization in laboratory reports and patient charts. These efforts have also stimulated industry to develop X-ray systems that provide high-quality imaging at low-radiation exposure dose levels. Hospitals should be encouraged to invest in adopting such platforms that have potential to mitigate occupational risk.

1.6 | The goal: A comprehensive "Culture of Safety" in the fluoroscopic laboratory

Physicians working with our professional societies should strive to establish a culture of safety encompassing both patients and catheterization laboratory personnel (Table 1). The pathway forward should be focused to assure: (1) consistent application and adherence to established and procedural processes; (2) widespread adoption and utilization of novel commercially available protection systems; and (3) encouragement and support to further develop even more effective equipment and processes that facilitate enhanced safety and protection in the workspace.

Our professional societies must support individual physicians, teams, and practices, especially those that are hospital owned. It is critical that clinician leaders speak authoritatively to hospital administration and industry partners regarding these concerns without fear of reprisal; societal support could be influential in these situations. The following specific steps should be endorsed by our professional societies to enhance hospital and physician compliance:

1.6.1 | Optimal procedural practice: Processes and training to minimize injury

Whether or not to comply with appropriate shielding and other safety measures should not be at the discretion of the operator. The imaging team (physician, sonographer, radiologic technologist, physicist, and other medical personnel) should be responsible for developing optimized protocols, implementing regular equipment quality control tests, and monitoring radiation doses to patients and members of the team. This group and their products should be recognized as an essential part of the quality assurance program, present in all laboratories, for emphasizing radiation management. Operator dose is directly proportional to patient dose; thus, reducing the dose to the patient will benefit the operator. Knowledge of radiation and methods to reduce risk should be stressed to all operators who perform fluoroscopically guided interventions, practiced routinely, and all staff educated in these measures and assuring they are adhered.

These methods and concepts have been well described previously.[1–7] Recently, publications from the Society of Cardiovascular Angiography and Interventions, The Heart Rhythm Society, and the American College of Cardiology/multi-society consensus document[18] articulate detailed procedural systems and processes, as well as practical approaches, to assist cardiac catheterization laboratories in establishing optimal radiation safety program. The components of a radiation safety program include essential personnel, radiation monitoring, protective shielding (at minimum strict adherence to protective aprons and leaded glasses), imaging equipment, and training/education.[39–41]

1.6.2 | Novel equipment to enhance protection

Fundamental principles of radiation safety teach the tenet that radiation exposure should be "as low as reasonably achievable (ALARA)", with monitoring to assure individuals do not exceed annual or lifetime "safe limits." Unfortunately, the term "reasonably achievable" is ambiguous and not actionable, and may unintentionally inhibit innovative strides to improve safety both for patients who require medically necessary procedures and for workers in radiation-exposed environments. The phrase might incorrectly imply that as long as one's exposure is "minimized," then that is all that need to be accomplished. Rather, the ultimate goal of innovation efforts should strive to achieve a completely safe environment wherein the ultimate definition of ALARA translates to as close to a zero radiation exposure work environment as possible.

1.6.3 | Shielding systems to reduce operator radiation exposure

Meticulous application of established prudent radiation techniques is obvious and essential. Standard shielding combines laboratory based (e.g., movable ceiling suspended and fixed table-side shielding). Personal protective aprons and eyewear should be properly fitted and maintained, and hospitals should finance these protective devices for

TABLE 2 Future policy directions

- Operators should receive consultation by an ergonomics specialist to optimize posture, positioning, and equipment that might reduce orthopedic impact;
- Each laboratory should create and enforce policies and processes to assure continued operator education on best practices for radiation reduction and protection.
- Hospitals (and other facilities) should upgrade imaging equipment (hardware and software) and radiation-producing equipment to take advantage of the newer technologies that may significantly reduce radiation exposure, including investment in enhanced shielding.
- Clinicians and professional societies should support research, education, and advocacy efforts to advance the field of occupational safety and health.
- Hospitals should purchase their employees, including fellows, nurses, techs and physicians, protective goggles/eyeglasses (including prescriptions and bifocals where needed), personalized lead aprons (with shoulder shields when requested), and lead caps (if requested).
- Other protective equipment such as disposable radiation shielding pads should NOT be refused by hospitals due to their expense.
- Catheterization laboratories should implement evidence-based strategies/tools to reduce radiation exposure and decrease orthopedic burden.
- We should continue to acquire high-quality data to validate occupational hazards and the benefits of devices designed to mitigate them.

all of their employees, including trainees. Newer personal protective choices, including two-piece aprons that are much lighter, may be beneficial; accessory sleeves for arm protection are also available. Despite these advances, the orthopedic burden of only partially protective leaded apparel continues. Institutions and operators must partner to develop a program specific for their laboratory that will result in the adoption of appropriate recent innovations to reduce radiation exposure. Strategies should also include usage of adjunctive devices for which there is substantial data documenting their capability to reduce exposure. Specifically, there is now compelling data demonstrating reductions in exposure with accessory drapes[42] (Supplementary Tables); such disposable radiation shielding pads should NOT be refused by hospitals due to their expense. The use of leaded caps has been proposed with mixed results regarding reduction in exposure.[43,44] Simple accessory mobile shields afford significant protection to both nurses and technologists[45] as well as to the interventional imaging team.[30] More expansive and encompassing lead shielding systems are commercially available,[46] and there is a need for more clinical research data supporting their capabilities to reduce exposure.

Robotic systems developed to enhance procedural performance also provide protection from radiation exposure to the physician and reduce leaded apron orthopedic burden.[47] Thus far, robotics has had limited adoption, due mostly to cost considerations but also fear from the loss of a "hands-on" sensibility. In electrophysiology, intracardiac navigation systems[48] have shown efficacy to navigate catheters for ablation procedures with lesser exposure. Simultaneously, industry and physicians must partner to expedite development of a fluoroless catheterization laboratory, using echocardiography, magnetic resonance imaging, 3D mapping, or other technologies. Removing the necessity of lead aprons should be the ultimate goal. Although the proximate cause of many orthopedic complications may be wearing lead, there are other important factors, such as screen height and position, and other ergonometric considerations, which may account for much cervical spine pathology.[49] This growing portfolio of enhanced/innovative protective technology will continue to yield a growing pipeline of solutions providing optimism for a healthier work environment.

1.7 | Shifting the paradigm: Responsibility, innovation, and implementation

Table 1 summarizes the responsibilities of professional societies going forward. A direct role is a necessity to coordinate the policy matters raised in this document. Table 2 lists the specific future directions recommended for all stakeholders to achieve.

1.7.1 | The role of the physician and professional societies

It is essential to emphasize that the operator has the responsibility to understand how to use protective equipment optimally to minimize exposure to both patients and personnel.[50] Education in this area is already part of cardiology trainee education and is tested in certification exams. Nevertheless, formal training for those who are planning to be interventional operators and imagers should be considered, and compliance monitored on site. Real-time radiation dose monitoring should become standard. Further, physicians must accept the challenge to adopt new technologies for the reduction of occupational hazards. Expense is one reason that new innovations are often not adopted, as it is difficult to advocate for expensive nonrevenue-enhancing equipment in the current fiscal environment. Other obstacles to overcome include potential discomfort with the design modifications and the resistance to making changes in familiar techniques even if there are improvements. The question always arises as to "proof" as to whether the changes are really beneficial, which sometimes become a justification to maintain an unsatisfactory status quo. Therefore, it is incumbent on our profession to continue to produce high-quality clinical research that documents the capabilities of novel imaging equipment, protective devices, and processes designed to improve workplace safety and health.

As previously discussed, structural heart interventions depend on procedural image guidance/interventional echocardiography using transthoracic (TTE) or transesophageal echocardiography (TEE) in addition to fluoroscopy. Interventional imagers who operate the TTE or TEE probe and echo console are highly exposed to the harmful effects of scattered ionizing radiation. Protection for these workers also needs to be incorporated and mandated.[30,45,46]

Professional societies should develop programs to assist hospitals and health systems to address occupational safety. It is in everyone's interest to assure the health of medical caregivers.[17] The establishment of new, and coordination with existing, comprehensive programs for clinician health in the catheterization and electrophysiology laboratories consistent with recommended wellness programs are an opportunity to highlight this problem. This may include an on-site physical or massage therapist, programs for core strengthening and stretching, and improved posture techniques to prevent orthopedic injury.[34] Moreover, this issue can be an opportunity for societies to share and collaborate with international colleagues, who face similar problems.

1.7.2 | The role of industry

Since the inception of radiologic imaging, the biomedical industry has taken primary responsibility for development and refinement of catheterization laboratory equipment with associated financial benefits. As this equipment engenders intrinsic radiation exposure hazards, industry should assume a level of fiduciary responsibility to optimize the safety of the equipment they design and sell. It is our role to communicate the cardiology community's widespread support for innovations and catheterization laboratory design reformation.

Though definite progress has occurred in the past two decades, particularly the advent of high-quality X-ray systems that produce high-quality imaging at lower radiation dose, further innovations are needed to achieve maximal operator radiation protection. The goal is a laboratory design that achieves a completely radiation-safe environment that eliminates the need for personal protective apparel and thereby mitigates the orthopedic consequences. Remarkable progress has been made by the FDA directives to industry and medical institutions to improve equipment and processes designed to achieve reduced radiation exposure to patients. We are optimistic that analogous efforts can be marshaled to enhance operator safety by providing a collaborative template by which this may be achieved. Industrial innovation will be evident once convinced that market forces are favorable to such changes.

1.7.3 | The role of hospitals

Prioritization of worker health to increase worker longevity is both the ethical thing to do, and a stable workforce (physicians, nurses, and technologists) makes "good business sense."[17,33] Hospitals and health care systems should recognize that foregoing protective equipment and wellness processes to save expenditures at the expense of the long-term health of their workers is ultimately more costly, since it encourages increased turnover, more labor downtime, and increased training expenditures.

Hospitals have the legal responsibility to monitor and assure worker safety and optimal occupational radiation exposure. Each institution's radiation physicists provide training and monitoring of personnel and equipment. It therefore follows that hospitals have a "fiduciary type" responsibility for those working in their facilities and therefore an implicit responsibility not only to maintain and calibrate present imaging systems but also to equip catheterization laboratories with the most modern equipment (imaging and protective) established to offer benefits to the safety and welfare of their workforce.

Calibration of the X-ray system, modernization with updated features, replacement of outdated imaging systems, and equipment maintenance are the responsibilities of the hospital. Only time will tell if governmental authorities (e.g., Occupational Health and Safety Agency) might weigh in on these occupational safety issues and issue standards that require a plan for deployment of newer imaging and protective equipment.

In summary, this understanding of expectation and commitment on the part of hospitals is critical to stimulating industry to invest in research and development of innovations, secure in the knowledge that there is an interested and engaged marketplace. In concert, our professional societies play a key role to help establish what is considered reasonable and necessary for best practice in radiation safety and clinician wellness.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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