

## Special Communications

# Occupational Health Hazards in the Interventional Laboratory: Time for a Safer Environment

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This document is a consensus statement by the major American societies of physicians who work in the interventional laboratory environment. It reviews available data on the prevalence of occupational health risks and summarizes ongoing epidemiologic studies designed to further elucidate these risks. Its purpose is to affirm that the interventional laboratory poses workplace hazards that must be acknowledged, better understood, and mitigated to the greatest extent possible. Vigorous efforts are advocated to reduce these hazards. Interventional physicians and their professional societies, working together with industry, should strive toward minimizing operator radiation exposure, eliminating the need for personal protective apparel, and ending the orthopedic and ergonomic consequences of the interventional laboratory work environment. © SIR, 2009.

## HEALTH HAZARDS OF THE INTERVENTIONAL LABORATORY ENVIRONMENT

DURING the past 30 years, the advent of fluoroscopically guided interventional procedures has resulted in dramatic increments in x-ray exposure and physical demands that predispose interventionists to distinct occupational health hazards [1–5]. The hazards of accumulated radiation exposure have been known for years, but until recently the other potential risks have been ill-defined and underappreciated [1–11]. The physical stresses inherent in this career choice appear to be associated with a predisposition to orthopedic injuries, attributable in great part to the cumulative adverse effects of bearing the weight and design of personal protective apparel worn to reduce radiation risk, and to the poor ergonomic design of interventional suites [1,3–5,12,13]. These occupational health concerns pertain to cardiologists, radiologists, and surgeons working with fluoroscopy; pain management specialists performing nonvascular fluoroscopic procedures; and the many support personnel working in these environments.

Daily exposure to radiation, orthopedically burdensome personal protective apparel that is only partly protective, and poor ergonomic design of fluoroscopic equipment and procedure rooms constitute the “inconvenient truth” of our profession. When we chose an

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invasive career, we accepted these risks as “the cost of doing business.” Day to day, most of us try to ignore what we cannot see, even to the extent of not wearing the required radiation badges, afraid to know the truth, or even worse to be pulled out of the laboratory as a result of “excess” monthly exposures. This behavior is counterproductive. Although radiation exposure for health care workers has declined as awareness and technologic advances have improved, busy interventionists not uncommonly approach or exceed the limits previously believed acceptable [7].

Efforts to better define the occupational risks associated with working in a fluoroscopic laboratory led to the formation of the Multi-Specialty Occupational Health Group (MSOHG), whose main initial goal was to clarify the magnitude and impact of these occupational health concerns. Member organizations of the MSOHG include the Society of Cardiac Angiography and Interventions, Society of Interventional Radiology, Heart Rhythm Society, American College of Radiology, American College of Cardiology, Society of NeuroInterventional Surgery, American Association of Physicists in Medicine, and Society of Invasive Cardiac Professionals. The MSOHG is collaborating with experts in occupational health, epidemiology, and radiation effects from the United States Navy and the Radiation Epidemiology Branch of the National Cancer Institute to perform epidemiologic studies addressing the fundamental questions important to all those working in such an environment.

One purpose of this position paper is to review the available data delineating the prevalence of these occupational health risks and to summarize ongoing epidemiologic studies designed to further elucidate these risks. Another important purpose is to publicly state that the interventional laboratory poses workplace hazards that must be acknowledged, better understood, and mitigated to the greatest extent possible, and to advocate vigorously on behalf of efforts to reduce these hazards.

### THE EPIDEMIC OF ORTHOPEDIC COMPLICATIONS

Given the effects of spending a career standing for long hours bearing the weight of heavy personal protective apparel in positions that are often ergonomically unsound, it should not be surprising that one often walks out of the interventional laboratory after a busy day feeling internally satisfied over a job well done, but externally miserable with an aching neck and back. Data now strongly indicate that working in the interventional laboratory over time is associated with occupational health risks, including a high preva-

lence of orthopedic problems, particularly those related to the spine. These occupational-related injuries not uncommonly result in missed days of work, surgery, and, in some cases, curtailed careers.

Previous studies [1,3–5,12,13] have documented occupational orthopedic problems associated with the practice of fluoroscopic-based interventional medicine (Table 1). What appears to be an epidemic of orthopedic injuries is believed to be related to wearing heavy and uncomfortable personal protective apparel (ie, “lead” aprons) for radiation protection during procedures. Surveys of cardiologists and radiologists conclude that there is evidence of a relationship between wearing leaded aprons and spine problems [1,3,12,13]. In a 2004 Society of Cardiac Angiography and Interventions survey [3], nearly half of the 424 respondents reported spine problems, an incidence dramatically higher than the 27.4% incidence of chronic back conditions in adults in the United States [14]. More than one third indicated their spine problems had caused them to miss work [3]. One fourth of the respondents reported problems related to their hips, knees, or ankles. The survey also found a significant relationship between the number of years worked in the cardiac catheterization laboratory and the incidence of spine problems. Previous investigators have called attention to a distinct occupational hazard labeled “interventionalist’s disk disease” [1], attributing problems such as orthopedic injuries to the cumulative effects of bearing the weight of personal protective apparel and poorly designed interventional laboratory environments that promote awkward and ergonomically unsound postures (eg, monitors placed outside the operator’s natural line of sight in his/her working position).

### RADIATION-RELATED HEALTH ILLNESSES: IMPLICIT BUT POORLY DEFINED RISKS

Also of great concern to physicians performing invasive procedures requiring x-ray exposure are the potential adverse effects of occupational radiation exposure that may, over time, be associated with an increased incidence of cataracts, cancers, and possibly other diseases [2–11,15–27]. Compared with fluoroscopically guided diagnostic procedures, interventional procedures are more complex, lengthier, require the use of more radiation, and frequently require the use of imaging views that are unfavorable for operator exposure [15,16]. Recent reports on the biologic effects of radiation reaffirm the utility of the linear-no-threshold model of radiation risk for solid cancers [17,18]. This hypothesis states that any radiation dose carries with it an associated risk of cancer induction, and that the risk increases linearly with increasing dose.

**TABLE 1. Surveys of Orthopedic Complications in Interventionists**

Study	Methods	Findings
Ross et al. [1]	Survey of interventional cardiologists (852 surveys, 385 responses), orthopedists (577 surveys, 131 responses), and rheumatologists (978 surveys, 198 responses)	Increased spine problems in interventionists (75% incidence) vs orthopedists and rheumatologists
Goldstein et al. [3]	Survey of 1,600 interventional cardiologists (424 responses)	Prevalence of orthopedic complaints: spine, 42%; hip, knee, ankle, 28%; spine problem limited work in one third
Machan [12]	Survey of interventional radiologists (308 responses)	60% reported spine complaints; spine problems limited work in 25%
Moore et al. [13]	Survey of 608 radiologists (236 responses)	50% prevalence of back pain

Extrapolating from these basic principles of radiation safety that link the likelihood of disease to the extent of cumulative radiation exposure, it might be expected that physicians exposed to radiation in their work environment in the present era would be at higher risk of such illnesses (Table 2). As a result of the small numbers in the Society of Cardiac Angiography and Interventions survey study [3], no firm conclusions could be reached regarding increased rates of radiation-associated diseases. However, anecdotal reports of hematologic malignancies and other cancers are now common conversation at societal meetings. The brain is one of the least protected organs during interventional fluoroscopy procedures [19]. Recent anecdotal reports of hematologic malignancies and brain cancers in interventionists have alarmed members of our profession [10]. Although the impact of radiation dose to the brain from chronic low-dose exposure has not been well studied [15], ionizing radiation is one of the few established causes of neural tumors [20]. Studies of the incidence of nervous system tumors in atomic bomb survivors [20–22] concluded that exposure to radiation doses of less than 1 Sv is associated with an increased incidence of nervous system tumors. Epidemiologic evidence for radiation-induced brain cancer in fluoroscopists is suggestive, but by no means conclusive (Table 2). One study [23] found that the death rate from brain cancer in radiologists was almost three times that of other medical specialists who did not use radiation. A case-control study [24] of 233 patients with brain tumors reported that work as a physician with use of fluoroscopy increased the risk of developing a brain tumor, with an odds ratio of 6.0 (95% CI, 0.62–57.7), although there were only three such individuals among the 233 cases. Another case-control study [25] of 476 individuals diagnosed with glioma also observed an increased risk in physicians and surgeons (odds ratio, 3.5; 95% CI, 0.7–17.6). However, such studies cannot exclude other biologic agents and chemicals unrelated to radiation as causative, and other case-control studies [26–28] failed to identify a signifi-

cant risk of brain tumors as a result of exposure to medical ionizing radiation.

Radiation risk is not limited to the induction of malignancy. Recent epidemiologic studies of radiation-related cataract formation [29,30] suggest that the currently accepted threshold dose of 2–5 Gy for radiation-induced cataract formation may be too high. It is possible that there is no threshold dose, and that radiation-induced cataract formation is a stochastic effect, rather than a deterministic effect as previously believed [31]. In either case, the current International Commission on Radiation Protection occupational guidelines for radiation exposure to the eye (150 mGy/year) may be too high [18]. The International Commission on Radiation Protection is organizing a subcommittee to prepare a special report on this topic.

#### WHAT IS AN ACCEPTABLE LEVEL OF RADIATION EXPOSURE?

Recognition of the potential harm of radiation has led to long-established standards for occupational exposure that have been articulated in the policy of “As Low As Reasonably Achievable” (ALARA). But the question must be asked: What is “low” and what is “reasonably achievable”? In the past 30 years, interventional medicine has evolved dramatically, with remarkable advances in imaging and catheter technologies, as well as the basic and clinical science that support their application. During this period, our daily and career radiation and orthopedic risks have increased. The evolution of interventional procedures has necessitated that industry keep pace with dramatic leaps in imaging technology. Inexplicably, radiation protection technology is not much different than it was two decades ago, with little technologic development or innovation to improve the safety and comfort of operators. Complacency can be dangerous. If similar lack of technologic progress were evident in automobiles, vehicles would still be equipped with seat belts only, not the superior airbag systems that have made

**TABLE 2. Reports of Cancer Incidence in Interventionists**

Study	Methods	Findings
Finkelstein et al. [10]	Report of a case cluster	Brain cancer in two interventionalists
Preston et al. [21]	Review of solid cancers in atomic bomb survivors	Radiation dose response for nervous system tumors; exposure to dose <1 Sv associated with increased risk
Matanoski et al. [23]	Cohort study of mortality in radiologists over a 50-year period	Excess cancer risk among radiologists consistent with other physicians (especially for leukemia and lymphoma)
Carozza et al. [25]	Case-control study of occupation and glioma	Physicians at increased risk of glioma
Andersen et al. [26]	Population-based study of occupation and cancer incidence	Brain cancer increased among physicians in general; no breakdown by specialty

driving much safer. Yet we still stand at tableside with incomplete protection from aprons and small portable shields (think of them as seat belts), leaving our brains, arms, and lower legs exposed to radiation; at the end of the day, our spines, hips, and knees ache from the burden of the protective apparel we wear. Although numerous lead apron designs have been developed and marketed as ergonomically superior, no truly successful design exists. Substitution of other combinations of metals for lead has made aprons lighter than in years past, but they remain heavy, cumbersome, uncomfortable, and incompletely protective [5]. Even the use of the term “apron” harkens back to an earlier era of weight distributed entirely on the shoulders and upper trunk; newer designs are closer to kilts. There must be better ways to distribute the weight of operator-worn shielding and lighter materials that may be used.

The maximum permissible doses advised by the National Council on Radiation Protection and Measurements [32] and specified in most state health codes were established by setting the numeric values equal to the risks of “safe” nonradiologic occupations. There is no implication that doses lower than the maximum permissible dose are absolutely safe or that doses greater than the maximum permissible dose are always toxic. To minimize unnecessary dose, most radiation protection programs issue alerts when radiation badge readings exceed 10% and 30% of the maximum permissible dose. The Occupational Safety and Health Administration has a comprehensive set of guidelines on protection from bloodborne pathogens, and they may issue guidelines for occupational radiation exposure as well [33]. These will have a direct effect on the operation of interventional laboratories.

Concerns over radiation exposure to the modern interventionist were elegantly articulated by Clark [2], who posited the following: “There is ongoing concern about how experienced interventionists and younger ones with long careers ahead of them can avoid the potential ravages of x-ray exposure.” He asked, “Which illnesses can be caused by the type of x-ray exposure received in the laboratory by physicians and

at what potential level of exposure?”; “On a monthly, yearly, and lifetime basis, how much radiation exposure is acceptable, and how much radiation exposure puts an individual at increased risk of which complications?”; and “At what lifetime level of exposure should one consider retiring from laboratory practice in order to diminish the chance of radiation illness?” [2]. In summary, he stated: “Persisting questions for the physician are these: ‘How much am I being exposed?’ and ‘How much is too much?’” [2]. These issues have special pertinence to those in training, who are facing the choice of a career path that may last 30 years or longer and may be influenced by radiation exposure concerns; this issue is of particular importance in women of childbearing age already practicing or considering an interventional field.

To these questions, we need to add one more: how do we reduce our risks? Given the availability of materials (eg, lead) with the potential to completely block radiation, it must be asked whether it is “reasonable” or necessary to be exposed to scatter radiation on a daily basis while laboring in a workplace environment that requires wearing partly protective apparel that contributes to daily discomfort and career orthopedic injury?

### **MAKING THE INTERVENTIONAL LABORATORY A SAFER WORK ENVIRONMENT: A CALL TO ACTION**

The present position paper, commissioned by the member societies that constitute the MSOHG, was predicated on the widely held sentiment that there are already sufficient data to support the conclusion that the interventional laboratory workplace milieu and physical working lifestyle of interventional physicians potentially pose occupational hazards that exact a toll on physician’s health. Sadly, it may already be too late for some of our colleagues to avoid the occupational hazards we now appreciate.

Scientific study further delineating occupational risks is essential. The MSOHG has initiated epidemiologic studies designed to help answer fundamental questions



important to those working in fluoroscopic environments. Employing large populations, including age-matched control groups of noninvasive physicians, these studies are designed to address the following questions:

1. What is the true incidence of orthopedic and radiation-associated problems?
2. What radiation-induced diseases should we be concerned about, besides cancer and cataracts?
3. What are the mechanisms contributing to orthopedic problems (eg, heavy personal protective apparel, working positions, nonergonomic equipment designs)?
4. Are there individual operator factors associated with development of orthopedic and radiation-associated problems (eg, number of cases per year over a career, laboratory shielding, laboratory design)?

Despite these important ongoing studies, a fundamental message of the present article is that no further data are necessary to declare the fluoroscopy laboratory a hazardous place in which to work. It is now time for physicians and their professional societies to work together and with industry to make our working environment better for those who will follow us. We all share this "turf." This idea has prompted the present call to action by specialty societies representing those working in fluoroscopic laboratories to advocate for a safer laboratory environment. The ultimate goal is to eliminate all unnecessary radiation exposure to physicians and reduce substantially the incidence and severity of orthopedic complications.

Important questions regarding the interventional laboratory environment must now be asked. These include:

1. Why has there been so little improvement in workplace safety during the past 30 years?
2. Which agencies are responsible for introducing improvements into laboratory safety, and what are the mandates and motivations for doing so?
3. If laboratory equipment can be designed to improve safety, how will such additional expenses be covered?

#### **Which Agencies Are Charged with Monitoring Safety and Mandating Improved Workplace Standards?**

In the United States, radiation safety policy is largely determined at the national level and implemented by the individual states, which have regulatory agencies. Institutional radiation safety officers monitor

institutional policies and exposures to ensure compliance with governmental regulations, monitor individual operators, and provide education to operators to help minimize exposure. Although this traditional system has had many individual beneficial effects, it has not addressed the systemic issues of laboratory design and ergonomics.

#### **Which Entities Are Responsible for Designing and Implementing Workplace Improvements?**

The development of interventional procedures demanded improved catheter equipment and higher-resolution imaging. Physicians working in the field have been in great part responsible for stimulating industry to achieve dramatic technologic advances. In fact, the era of interventional medicine has stimulated the evolution of the biomedical device industry, with innovation often germinated by physicians working in the laboratory who identified problems, needs, and opportunities. Many of the solutions to these problems have been developed in partnership with industry, leading to a robust pipeline of tools and products. Clearly, we have moved from an older era in which industry conceived ideas and brought them to the bedside, to the modern era in which physicians/users identify needs and work together with industry to help find solutions. Until now, physicians have had little input in technologic development in the interventional laboratory environment.

#### **Will Hospitals Be Willing to Cover Costs for New Equipment to Enhance Workplace Safety?**

If, in fact, new laboratory designs can achieve enhanced workplace health and safety, the additional expenses incurred with such innovations must be considered. Presently available data are already sufficient to support the conclusions that orthopedic problems are common and are related at least in part to wearing lead aprons. Some risk of cancer is implicit in the ALARA policy; new innovations that significantly lower operator radiation exposure should be adopted following a sober weighting of costs, risks, and benefits. These simple concepts should guide interactions with hospitals that provide and pay for the laboratory workplaces.

#### **GENERAL METHODS FOR REDUCTION OF OPERATOR DOSE**

Individual operators need to have enough of a working knowledge of radiation and other risks to be able to make informed decisions regarding their personal safety. The choice is personal responsibility or potential governmental mandate.

Certainly, we bear primary responsibility for protecting our own health—radiologic and otherwise. It behooves us to be aware of our own occupational radiation dose and to minimize it to the extent we can. This means wearing personal dosimeters at all times in the interventional laboratory, and taking advantage of every opportunity to reduce dose through the intelligent application of time, distance, and shielding. Techniques and equipment for shielding operators (eg, aprons, glasses, thyroid collars, and various tableside and drop-down shields) are well known and should be the focus of daily attention. We cannot expect others to assume the burden and expense of improving our work environment if we are not interested enough and concerned enough to protect ourselves. Lead caps have been suggested as a method for reduction of occupational dose to the brain, but these seem potentially uncomfortable and add yet more weight to the load already being worn [34]. Ceiling-suspended lead shields reduce radiation dose to the brain, as well as to the rest of the organs in the head and neck.

The use of radiation-protective devices should be considered only part of minimizing total operator risk. (Full suits of radiation armor have been around for a century. Three millimeters of lead will reduce operator dose to nothing. Is this the best way to work?) Another basic concept cannot be overstated: operator dose is directly proportional to patient dose. Reducing the dose to the patient will also reduce the dose to the operator. The specific methods are beyond the scope of this document, but should be familiar to all operators who perform fluoroscopically guided interventions, and should be practiced routinely. These methods and concepts have been well described previously [4,35].

### WHAT NEEDS TO BE DONE NOW?

Our profession has numerous members who retired early or became seriously ill as a direct consequence of the interventional laboratory environment in which we work. Outfitting operators with aprons and thyroid collars for protection against radiation should be as outmoded as sending soldiers into battle wearing chain mail for protection against rifle bullets. It is time that the interventional community began working with industry to take a fresh look at laboratory design, leaving no innovation unconsidered, and this endeavor must be undertaken at the highest levels. Given the wide availability of effective radiation resistant materials, it seems reasonable to expect that advances in engineering, materials, and architecture should permit laboratory design that truly minimizes operator exposure and at the same time avoids the poor ergonomic designs with which we currently deal.

Interventional physicians and their professional societies, working together with industry, should strive toward the ultimate definition of ALARA as close to a zero radiation exposure work environment as possible, and ultimately eliminate the need for personal protective apparel and prevent its orthopedic and ergonomic consequences.

If the same level of ingenuity and commitment that produced the incredible innovations that have transformed the practice of interventional medicine were applied to enhancing workplace safety, the career of an interventionist would undoubtedly be more comfortable, healthier, and longer.

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