ORSIF
Organization for Occupational Radiation Safety in Interventional Fluoroscopy

Economic Impacts of **Radiation Exposures** Associated with Interventional Fluoroscopy

PERSPECTIVE

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Introduction

Minimally invasive treatment of many cardio-, neuro-, and peripheral vascular conditions has surpassed open surgeries driven by numerous benefits, including fewer major adverse events, shorter hospital stays, and faster recovery. These endovascular procedures would not have been possible without fluoroscopy, which provides real-time images of the location and movement of therapeutic catheters inside the body. However, over the past two decades, there's been increasing scientific and clinical evidence that chronic exposure to fluoroscopy, which emits low-dose ionizing radiation, is putting interventional medical professionals at risk for serious health conditions, including cancer.

To date, there has not been an economic analysis of the impact of these health-related occupational hazards. The Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF) sought to quantify the economic costs associated with common health consequences of chronic exposure to ionizing radiation, specifically the development of cancer and orthopedic injuries. Based on the incidence of these adverse effects, ORSIF estimates the annual economic costs to be at least $49 million in the United States alone. This estimate excludes the treatment of non-acute medical conditions, such as precursors to cataracts, cognitive decline, and risks to reproductive health. It also does not account for turnover costs of experienced physicians nor potential litigation from physicians or patients. Absent investment in radiation exposure control technologies, economic costs will likely increase based on the continued shift to minimally invasive procedures.

Number of At-Risk Clinicians and Career Exposure to Interventional Fluoroscopy

Physicians in several medical specialties, including cardiovascular, neurovascular, and radiology, perform minimally invasive catheter-based procedures requiring the use of fluoroscopy. Based on data from medical colleges and boards, there are approximately 8,500 interventional physicians in the US: 3,255 interventional cardiologists, 3,358 vascular and interventional radiologists, and about 1,925 electrophysiologists.[1,2] In addition, there are approximately 13,000 nurses and 11,300 technicians involved in fluoroscopy-guided interventional procedures.[3]

While the exposure to low-dose ionizing radiation varies by specialty and type of intervention, most of the scientific literature on the health hazards of chronic exposure to fluoroscopy is based on clinical studies and surveys of interventional cardiologists. As a result, the incidence rates of adverse effects and economic costs discussed in this analysis are largely derived from interventional cardiology and the cardiac catheterization lab (cath lab).

It's estimated that an interventional cardiologist is exposed to an estimated 50 mSv-200 mSv of ionizing radiation over the course of his or her career. This equates to 2,500-10,000 chest X-rays.[4] Given the physician's position during a percutaneous coronary intervention (PCI), the brain has the greatest exposure to the radiation beam. The career exposure to the head has been estimated at 1,000 mSv—the equivalent of 50,000 chest X-rays.[5] These estimates are likely understated, as they were made prior to complex PCI becoming commonplace and prior to the use of radial access, both of which are associated with increased radiation exposure. Complex PCI now accounts for approximately 40% of all PCIs,[6] and radial access grew 13-fold in 2007-2012.[7]

Health Effects of Chronic Exposure to Ionizing Radiation in Fluoroscopy

Malignant brain tumors among interventional healthcare providers (HCPs) were first reported in 1997.[8] Since that time, the number of malignant brain tumors recorded for interventional teams has grown to 43.[9] In addition, a spate of scientific evidence documenting the health risks that interventional HCPs face while performing life-saving, minimally invasive procedures has been published over the past several years.

CANCER:

Exposure to even low-dose radiation increases the risk of developing cancer. The Biological Effects of Ionizing Radiation (BEIR) Committee found that there is a linear dose-response relationship between exposure to radiation and the development of cancer.[10] There has not been a randomized controlled trial evaluating the carcinogenic effects of occupational fluoroscopy, likely because of the long latency period for the onset of cancer and because of ethical considerations for patient enrollment.[11]

Case reports and small observational studies of interventional HCPs have focused on brain cancer. However, one recent study by the Mayo Clinic showed notably higher rates of breast cancer and leukemia among interventional HCPs compared to non-interventional HCPs: while the size of interventional group was roughly double that of the control, the rates for breast cancer and leukemia were more than double that recorded for control. There were two instances of brain cancer in the interventional cohort versus none in the control arm.[12] The Mayo Clinic study did not record the average case load or monthly radiation exposure in the interventional group. However, since there is a linear dose-response relationship between radiation exposure and the development of cancer, HCPs who perform complex or radial-access cases are likely to have a higher risk profile for cancer.

ORTHOPEDIC INJURY:

Interventional medical professionals wear leaded aprons and other personal protective equipment (PPE) to shield their bodies from scatter radiation. The weight of leaded PPE exerts continuous pressure on the spine, neck, hips, knees, etc. In addition to routine standing and leaning over the patient table, interventionalists often have to place their bodies in awkward positions to view monitors or maintain positioning behind radio-protective shields, which intensifies the strain that PPE places on the musculoskeletal system, leading to orthopedic pain and injury.[13]

In the first survey performed by the Society for Cardiovascular Angiography and Interventions (SCAI), 53% of interventional cardiologists reported they had been treated for neck or back pain, a rate substantially higher than that of orthopedic surgeons and the general population.[14] Interventional cardiologists also were significantly more likely to have cervical disc disease and multiple spinal levels of disc involvement—and were nearly twice as likely to miss work because of orthopedic complaints—as other physician groups.[15] The high incidence has led to concern that physicians in cath labs may face shortened careers, leading to a depletion of trained interventionalists.[16]

PRE-MATURE DEVELOPMENT OF CATARACTS:

Cataracts, which are the clouding of the eye's natural lens, typically occur after the age of 60 and become more common after the age of 70 for most individuals. In order to restore eyesight, the natural lens is typically replaced with a multifocal or monofocal intraocular lens (IOL).

The eye is known to be sensitive to radiation. Based on findings from epidemiological studies, in 2012 the International Commission on Radiation Protection (ICRP) lowered its annual threshold to 20 mSv (from 150 mSv previously) for eye exposure to ionizing radiation for workers, including HCPs.[17] Notably, it has been estimated that the eye threshold of 20 mSv would be met with just 23.4 hours of exposure to ionizing radiation.[18] To put this in context, an interventionalist using fluoroscopy for 12 minutes during each procedure for an average number of cases of 125 per year would exceed this threshold. Against this backdrop, the majority of interventional physicians who have lens opacities do not consistently wear radio-protective eyewear.[19] It's unclear why some interventional physicians do not regularly use protective glasses.

Clinical studies show that roughly 50% of cath lab physicians develop detectable posterior subcapsular (PSC) lens opacities, the precursor to a cataract.[20,21] PSC lens opacities occur in interventional physicians up to 5 times more frequently than unexposed individuals in medical professions of the same age and sex.[22] Nurses and techs also have more PSC lens opacities than unexposed individuals of the same age, sex, and profession, but not as many as cath lab physicians.

However, a recent report noted that PSC lens opacities are subclinical and do not impair vision.[23] The average length of time for a recorded PSC lens opacity to progress to a cataract, at which point a medical intervention would be needed, is unknown. As a result, the ORSIF model does not assume an economic cost for this highly prevalent occupational hazard of fluoroscopy.

REPRODUCTIVE ISSUES:

Occupational exposure to low-dose ionizing radiation may also put HCPs' reproductive capability at risk. If cumulative exposure "below the apron" reaches 0.5-1.0 Sv, sperm count can be reduced.[24] Pregnant women may have a greater likelihood to spontaneously miscarry, particularly during the first trimester. With exposure of 1-2 Sv, fetal abnormalities can occur.[25]

PREMATURE AGING:

Two studies within the Healthy Cath Lab project have shown that chronic exposure to fluoroscopy leads to the early onset of cognitive decline and subclinical atherosclerosis.[26,27] The average age of interventionalists who participated in neuropsychological testing was 46 for men and 43 for women. Compared to a control group, the interventionalists had lower scores on verbal long-term memory and fluency—left hemisphere activities—as well as short-term visual memory. The investigators commented that premature aging of the brain was a "neglected and underestimated" effect of chronic exposure to ionizing radiation.[28] Another Healthy Cath Lab study showed premature vascular aging among interventionalists who had higher carotid intima-media thickness (CIMT), a marker of subclinical atherosclerosis, and shorter leukocyte telomere length (LTL), a marker of biological aging and a predictor of cardiovascular disease and mortality, compared to the control group. The average age of interventionalists participating in the study was 45.[29]

Estimated Incidence of Occupational Hazards Related to Interventional Fluoroscopy

The starting point for assessing the economic impact of occupational health hazards related to fluoroscopy is determining the number of HCPs affected each year. Assumptions for the prevalence and incidence of these health hazards are discussed below. The model does not include the economic impact of non-acute medical conditions, such as that related to early onset of cataracts, reproductive risk, or premature aging.

CANCER RISK ESTIMATES FOR INTERVENTIONAL HCPs IN THE US

The lifetime mean occupational exposure for interventional physicians is estimated to be 100 mSv. At 100 mSv, the risk of cancer from ionizing radiation (fluoroscopy) is 1%.[30,31] Although 1% may seem low, the Occupational Safety and Health Administration (OSHA) considers 0.1% excess risk to be "significant". In addition, the incremental risk of 1% for cancer (1 in 100) is comparable to the risk of dying in a motor vehicle accident (1 in 112) or unintentional poisoning (1 in 109).[32] If there are 600 new physicians in residency or fellowship training for fluoroscopic procedures each year, 6 of these clinicians would be expected to develop cancer in their lifetime owing to exposure to occupational ionizing radiation. Although mortality rates vary by cancer type, stage at diagnosis, and treatment, in general, nearly half of cancers are fatal.

Physicians: Assuming 1% of the current cohort of 8,535 interventional physicians develop cancer stemming from chronic exposure to ionizing radiation, 85 interventional physicians will develop cancer from occupational fluoroscopy, and 43 clinicians will have fatal cancer during their professional lives. Assuming a 25-year career, this equates to an annual incidence of 3 cancers, with 1.5 fatal cancers.

Nurses/Technicians: There is scant data on the career exposure to scatter radiation for nurses and technicians in the cath lab. The economic model assumes that nurses and technicians have a mean lifetime exposure of 50 mSv, half that of physicians. This estimate is predicated on interventional medical staff being positioned farther from the patients and source of X-ray beams. The economic model assumes that approximately 120 nurses and technicians working with fluoroscopy (0.5% of the 24,300) will develop occupational-related cancer, with 60 individuals having fatal cancer. On an annual basis, the model assumes 5 nurses or technicians with develop fluoroscopy-related cancer, with 2.5 fatal cancers.

OCCURRENCE OF MUSCULOSKELETAL DISORDERS (MSDs) IN HEALTHCARE PROFESSIONALS

Recent research performed by SCAI and the Mayo Clinic found a high prevalence of MSDs among interventional HCPs. Nearly half of respondents to a SCAI survey (n=314) reported at least one MSD. One quarter of respondents had cervical spine disease, more than one third had problems in the lumbar region, and 20% had complaints in the hips, knees, or ankles.[33]

Among those with spinal complaints, 70% reported lumbosacral problems, 40% cited cervical disc disease, and over one-third missed work due to their symptoms. Musculoskeletal complaints related to the hips, knees, or ankles were reported in one quarter of all respondents. Interventionalists with more than 20 years of experience reported the highest rates of back pain, with spinal disease in nearly 60%. Age, years in the cath lab, and case load were associated with orthopedic injury. Of respondents who had been in practice for at least five years, 85% had at least one musculoskeletal problem.[34]

More than half of the interventional HCPs (n=1042) in a Mayo Clinic study had significantly higher instances of work-related orthopedic pain than non-interventional medical personnel, which served as a control group. Half of interventional HCPs reported taking pain medication occasionally, with about 10% indicating daily usage. Cath-lab techs and nurses reported more MSD pain than physicians. All interventional HCPs had more back pain than controls (same occupations, located elsewhere in hospital). Interventional staff reported high levels of a history of work-related pain: techs-62%; nurses-60%; and physicians-44%. Three variables were associated with work-related pain: female gender, more hours spent in the interventional lab, and greater use of leaded aprons.[35]

It is estimated that 30%-60% of interventional HCPs experience one or more MSDs during their careers.[36] Assuming a career duration of 25 years, this suggests an annual incidence of 1.2% on the lower end of the range and 2.4% on the upper end of the range. The annual incidence in the economic model reflects the average of these two rates, or 1.8%, which translates to 154 interventional physicians having a serious MSD each year. Although the Mayo Clinic study showed a higher prevalence of MSDs among nurses and technicians, the economic model assumes a similar annual incidence rate for these interventional HCPs. This may underestimate the economic impact of MSDs on nurses and technicians, however, given limited data on the prevalence of occupational orthopedic injury among these HCPs, ORSIF opted for conservatism. Of note, even a “low” incidence rate of 1.8% equates to 437 interventional nurses or technicians experiencing an MSD requiring treatment each year. For simplicity purposes, the model assumes an annual occurrence of 155 MSD cases for physicians and 435 cases for nurses and technicians.

Valuing Adverse Health Effects of Occupational Interventional Fluoroscopy

Two valuation techniques, based on commonly accepted standards, were used to arrive at the economic cost per case of cancer and major MSD. In brief, the value of a statistical life (VSL), which is a market-based statistic used by regulatory agencies to provide a monetized value for an occupational fatality, was used to estimate the cost per case of fatal cancer. Studies of occupational MSDs from workers' compensation records were the basis for estimated medical costs and lost productivity following a major MSD.

CANCER

Fatal cancer: VSL is based on wage premiums paid for riskier jobs, such as higher pay awarded to ironworkers on skyscraper projects compared to carpenters working on single-story buildings. If one group of 1,000 workers suffers, on average, one more death per year than another group and the higher-risk workers earn $3,000 more per year, the collective payment to the high-risk workers is $3 million.

Regulatory agencies use VSL to represent a value of life that can be compared to the costs of measures taken to avoid fatality risk and to assess the benefit of life-saving measures. OSHA and the EPA currently use a value of $9 million for VSL. While the average salary for interventional physicians is 8-10 times higher than the occupations studied to arrive at the VSL,[37,38] the economic model conservatively does not assume a higher VSL for interventional physicians.

Nonfatal: Non-fatal cancer valuations from economics may be based either on a cost-of-illness approach or on surveys that represent a "willingness to pay" to avoid an adverse outcome. In recent analyses OSHA has estimated the cost of treatment and lost productivity from a nonfatal case of lung cancer at $188,000.[39] This valuation approach does not account for pain and suffering, family distress, impact of caregivers' earnings and productivity, etc.

The economic model conservatively assumes a valuation of $200,000 per incidence of non-fatal cancer, which reflects medical treatment and lost productivity. It does not place a value on potential diminished competitiveness for hospitals related to an interventionalist being unable to perform procedures and other clinical duties, such as seeing patients and taking call; speaking at major medical meetings; participating in major clinical trials; publishing scientific manuscripts; and partaking in other activities that enhance a hospital's competitive standing.

MSDs

Back injury is a common workplace occurrence. While there are several methods to assess the cost of MSDs, lost productivity is a common valuation technique. Data are typically taken from workers' compensation systems, which capture both the amount of time lost from work as well as medical treatment costs. One study derived from six years of Ohio workers' compensation data on more than 150,000 cases serves as a reliable benchmark for the costs of back injury experienced by interventional HCPs. The study showed average medical costs of $7,160 and mean wage indemnity payments of $4,724 for lumbar spine injuries for Ohio workers.[40] The $12,000 total cost is used to value the economic cost of MSDs for interventional nurses and technicians.

However, this cost estimate does not sufficiently account for the higher salaries of interventional physicians. Increasing the wage indemnity component of the Ohio workers' compensation study by 8x suggests a wage indemnity of $37,790. Including average medical costs of $7,160, the model assumes a total cost per MSD incidence of $45,000 for interventional physicians.

Of note, the cost and lost productivity attributed to an MSD depends on the severity and location of the injury. The aforementioned SCAI survey revealed that 34.0% of interventional physicians had lumbar spine pain/injury and one quarter had cervical spine problems, both of which "consistently" had the highest costs per claim in the Ohio workers' compensation study.[41,42] In the Ohio study, 27% of workers had lumbar spine injury.[43] Thus, the assumptions in the model may underestimate the economic impact of significant MSDs experienced by interventional physicians. In addition, the model does not attempt to quantify the impact of interventional physicians taking early retirement owing to ongoing orthopedic pain.

Estimated Economic Impact of Chronic Exposure to Interventional Fluoroscopy

Based on the incidence and valuation assumptions discussed in the preceding sections, the economic cost of adverse health effects of occupational exposure to interventional fluoroscopy is estimated to be at least $49 million annually in the US. In general, interventional physicians have a higher risk than nurses and technicians. The annual number of physicians affected by a given condition is lower than the number of nurses and technicians affected simply owing to cohort size (8,535 physicians versus 24,300 interventional nurses and technicians).

Cancer: The model assumes an excess risk for cancer of 1% for interventional physicians and 0.5% for interventional nurses and technicians. Assuming an average career of 25 years, this suggests that a total of eight cancers related to chronic exposure to ionizing radiation will occur among interventional HCPs annually (three physicians and five nurses/technicians). It is estimated that half of the cancers would be fatal. Based on OSHA valuation methods, the economic costs of fatal and nonfatal cancers are estimated to be $9 million and $200,000, respectively. Combined, the economic cost of excess cancer risk associated with occupational exposure to interventional fluoroscopy is estimated to be $36.8 million annually.

MSDs: The economic cost of major MSDs for interventional HCPs is estimated to be $12.2 million each year based on conservative assumptions of an incidence of 1.8% and an average cost of $45,000 per significant MSD for physicians and $12,000 for nurses and technicians.

Table 1. Summary of Costs/Valuations of Health Effects Associated with Exposure to Interventional Fluoroscopy in the United States

Exposed Group	Estimated Cases per Year	Cost/Valuation per Case	Total Annual Cost/ Valuation
Fatal Cancer			
Physicians	1.5	$9,000,000	$13,500,000
Nurses and Techs	2.5		$22,500,000
Non-Fatal Cancer			
Physicians	1.5	$200,000	$300,000
Nurses and Techs	2.5		$500,000
Musculoskeletal Disorders (MSDs)			
Physicians	155	$45,000	$6,975,000
Nurses and Techs	435	$12,000	$5,220,000
TOTAL			**$48,995,000**

LIMITATIONS

The economic model does not attempt to quantify for several consequences that could arise from adverse health effects of chronic exposure to ionizing radiation owing to a lack of literature or absence of models to use as a basis for valuation. The following have not been assessed for the potential economic impact:

- **Reduction in number of procedures performed annually.** In the case of nonfatal cancer or major MSD, an interventional physician could face substantial work absences. If the absence were short term, other interventional physicians would likely be able to absorb the case load. For longer-term absences, there is likely to be a negative impact on the total number of procedures performed annually. This would likely impact hospital revenues, given that cath lab procedures tend to generate considerable revenue for facilities.

- **Physician replacement costs.** As mentioned above, some interventional physicians may opt to retire early because of adverse occupational hazards, notably MSDs. While concrete data is limited, this is an area of concern among interventionalists. Replacement costs have been estimated at $1 million for non-specialty physicians[44] and, thus, are likely to be higher for interventional physicians.

- **Lawsuits.** If hospitals don't invest in available tools and technologies that reduce HCPs' exposure to occupational radiation, it seems inevitable that HCPs will bring forth a lawsuit at some point in time. It's also possible that a malpractice claim from a patient who experienced unexpected procedural complications could reveal that occupational hazards related to interventional fluoroscopy was a factor in the adverse outcome.

- **Diminished competitive position of hospitals.** Any of the factors discussed above would likely have a negative effect for a hospital's competitive position in a non-remote geographic area. In general, competitive risk has become more pronounced in recent years, given the trend of patients seeking health information on the Internet and "shopping" for healthcare services.

Conclusion

With the growing evidence regarding the occupational hazards of fluoroscopy, steps need to be taken to safeguard the health of interventional teams who perform life-saving procedures, particularly as demand for complex, minimally invasive treatments is expected to increase. Because of lengthening procedure times, clinicians are assuming greater risk for a host of conditions—brain tumors, premature brain and vascular aging, early development of cataracts, and heightened risk of musculoskeletal injury—in their pursuit of improving the health of others. As is well known, there are shortcomings with current PPE and radio-protective drapes, most notably orthopedic injury. Immediate attention from all stakeholders is needed to implement interventional lab tools, technologies, and protocols to safeguard HCPs from the adverse health effects of radiation, avoid the nearly $50 million in economic costs in the US, and enable the continued minimally invasive treatment of patients.

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