Cardiac Medical Imaging and Radiation Risk
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<tr>
<td>Three-dimensional</td>
<td>3-D</td>
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<tr>
<td>American Association of Physicists in Medicine</td>
<td>AAPM</td>
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<tr>
<td>American College of Radiology</td>
<td>ACR</td>
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<tr>
<td>American Heart Association</td>
<td>AHA</td>
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<tr>
<td>As Low As Reasonably Achievable</td>
<td>ALARA</td>
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<tr>
<td>Biological Effects of Ionizing Radiation VII</td>
<td>BEIR</td>
</tr>
<tr>
<td>Body mass index</td>
<td>BMI</td>
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<tr>
<td>Beats per minute</td>
<td>BPM</td>
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<td>Chief financial officers</td>
<td>CFOs</td>
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<tr>
<td>Cardiac rhythm management</td>
<td>CRM</td>
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<td>Cardiac resynchronization therapy</td>
<td>CRT</td>
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<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td>CMS</td>
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<tr>
<td>Computed tomography</td>
<td>CT</td>
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<tr>
<td>Cardiovascular disease</td>
<td>CVD</td>
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<td>Diagnosis-related groups</td>
<td>DRGs</td>
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<tr>
<td>Electronic box</td>
<td>EB</td>
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<tr>
<td>Electocardiogram</td>
<td>ECG</td>
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<td>Electromagnetic navigation</td>
<td>EMN</td>
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<tr>
<td>Electrophysiology</td>
<td>EP</td>
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<tr>
<td>U.S. Environmental Protection Agency</td>
<td>EPA</td>
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<td>U.S. Food and Drug Administration</td>
<td>FDA</td>
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<tr>
<td>Global positioning system</td>
<td>GPS</td>
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<tr>
<td>Gray</td>
<td>Gy</td>
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<tr>
<td>International Atomic Energy Agency</td>
<td>IAEA</td>
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<tr>
<td>Interconnection box</td>
<td>IB</td>
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<tr>
<td>International Commission on Radiological Protection</td>
<td>ICRP</td>
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<tr>
<td>Institute for Energy and Environmental Research</td>
<td>IEER</td>
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<tr>
<td>Independent Payment Advisory Board</td>
<td>IPAB</td>
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<tr>
<td>Kirschner wire</td>
<td>K-wire</td>
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<tr>
<td>Linear-no-threshold</td>
<td>LNT</td>
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<tr>
<td>Left ventricular</td>
<td>LV</td>
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<tr>
<td>Milligray</td>
<td>mGy</td>
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<tr>
<td>Millisieverts</td>
<td>mSv</td>
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<tr>
<td>Magnetic transmitter assembly</td>
<td>MTA</td>
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<tr>
<td>National Council on Radiation Protection &amp; Measurements</td>
<td>NCRP</td>
</tr>
<tr>
<td>U.S. Nuclear Regulatory Commission</td>
<td>NRC</td>
</tr>
<tr>
<td>Patient reference sensor</td>
<td>PRS</td>
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<tr>
<td>Posterior subcapsular</td>
<td>PSC</td>
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<tr>
<td>Percutaneous transluminal coronary intervention</td>
<td>PTCA</td>
</tr>
<tr>
<td>Red bone marrow</td>
<td>RBM</td>
</tr>
<tr>
<td>Society for Cardiac Angiography and Interventions</td>
<td>SCAI</td>
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<tr>
<td>International System Units</td>
<td>SI</td>
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<tr>
<td>Sociedad Latinoamericana de Cardiología Intervencionista</td>
<td>SOLACI</td>
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<tr>
<td>Sieverts</td>
<td>Sv</td>
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<tr>
<td>Transjugular intrahepatic portosystemic shunts</td>
<td>TIPS</td>
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<tr>
<td>Table side unit</td>
<td>TSU</td>
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<tr>
<td>Ventricular tachycardia</td>
<td>VT</td>
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1. Executive Summary

Introduction
The prevalence of cardiovascular disease (CVD) is increasing in the U.S., presenting substantial health and economic burdens. Treatment for CVD often involves medical imaging-assisted interventions, such as cardiac ablation and rhythm management. The increased use of medical imaging for CVD management has resulted in increased medical radiation exposure for both health care providers and patients. Along with this increased exposure comes higher risk for radiation-related illnesses, such as cancer, and ocular cataracts/lens opacities. This presents a financial burden for hospitals because interventional cardiologists and electrophysiologists must limit their yearly radiation exposure. Specifically, physicians who reach their annual radiation exposure limit may be unable to perform cardiac procedures for a substantial part of the year. Although no regulations currently exist for recording or reporting radiation dosing, clinical measures and guidance endorsed by regulatory agencies suggest a societal need for facilities and care providers to minimize radiation exposure as much as reasonably possible.

The Burden of Cardiovascular Disease and Medical Radiation Exposure
Currently, more than 1 in 3 Americans have some form of CVD, and the prevalence is steadily increasing.1 The costs associated with treatment are estimated to triple over the next 20 years, from $309 billion in 2012 to $834 billion in 2030.1 The high burden of CVD in the United States has led to the use of a substantial number of imaging-assisted interventions for disease treatment. However, radiation exposure from medical imaging procedures and tests has become the largest man-made source of human radiation exposure,2 and it is expected that the use of medical imaging for CVD management will continue to rise.3 This will create work-related risks for interventional cardiologists and electrophysiologists, as well as other health care professionals.

Interventional radiology imaging uses ionizing radiation, such as X-ray and fluoroscopy. Although these imaging procedures comprise only 12% of cardiology exams, they are responsible for 48% of total radiation exposure related to medical imaging, more than any other single source of medical radiation.4 The current core U.S. principle now governing the use of ionizing medical radiation is known as ALARA – As Low As Reasonably Achievable. Additionally, the U.S. Food and Drug Administration (FDA) is developing regulatory requirements specifically related to medically related radiation exposure.5

The Risks of Medical Radiation Exposure
While patients and providers are both exposed to radiation due to medical imaging procedures, medical personnel may be at the greatest risk because of the high number of procedures performed each year.6 Interventional cardiologists and electrophysiologists, in particular, are at the highest risk for radiation exposure.7 Invasive and interventional cardiologists often receive radiation through fluoroscopy,8 which can cumulatively cause a non-negligible lifetime attributable risk of cancer.9 Specifically, high radiation exposure, and associated increased risk for cancer, has been identified in clinicians who regularly perform interventional procedures involving fluoroscopy.10-13 Patient risk for radiation exposure is highest for individuals who require multiple imaging tests.1 Although exposure guidelines are in place for patients,14,15 individual patient differences may lead to differences in risk related to exposure. Specifically, the cumulative effective dose of radiation administered increases with age, and is higher in children, women and obese patients. However, safe exposure assumptions and regulations are based on a hypothetical patient (a 20- to 30-year-old man), and are therefore not representative of all patient types.16,17 Additionally, pediatric patients are more vulnerable to the effects of radiation, indicating that the current guidelines do not apply to all patients.18

Radiation Risks of Fluoroscopy Procedures
Fluoroscopic imaging is a fixture in modern electrophysiology and catheterization labs, and may expose both patients and practitioners to radiation due to scatter from the incident beam.5,19 These doses are rarely measured,20 and it is difficult to determine how much radiation internal organs absorb.21 Complex procedures generally require longer fluoroscopy times, resulting in increased radiation exposure.5,22,23 Besides cancer risks related to radiation exposure, other risks associated with fluoroscopic imaging include radiation-induced cataracts and skin burns.24
Medical Professionals at Risk From Radiation Exposure

Unlike many other mutagens, X-ray beams can access all internal organs, meaning that even a single electron set into motion by an X-ray photon may cause permanent molecular damage. This radiation causes DNA damage to human cells. Research shows that even low levels of radiation exposure from X-ray examinations can lead to chromosomal damage. Research supports the hypothesis that increased brain cancer in practitioners who perform fluoroscopic procedures may be linked to radiation exposure. Other radiation-associated conditions observed in interventional cardiologists also include lens opacity and posterior subcapsular cataract. These risks are compounded by the added risk of chronic orthopedic injury from traditional lead aprons, aggravated by conditions common to the EP lab (e.g., improper table height, fluoroscopy monitor height and position, and on-table control panel position). Traditional lead aprons weigh approximately 15 pounds, and can place up to 300 pounds of pressure per square inch on a physician’s intervertebral discs.

The Financial Impact of Medical Radiation

Medical radiation impacts a hospital’s bottom line in both the short- and long-term. In the short-term, once cardiologists reach the yearly limit of safe radiation exposure, they often must be “benched” for the remainder of the year. In this way, hospitals lose out on revenue generated by performing cardiac procedures, while continuing to pay cardiologists their annual salary. In the long-term, illness related to radiation exposure may jeopardize cardiologists’ ability to maintain a full workload, and the hospital may be responsible for treatment costs, as well as insurance or other liability associated with key staff developing radiation-induced illness.

An international survey conducted by the Society of Cardiovascular Angiography and Interventions (SCAI) revealed that nearly 1 in 5 cardiologists have purposely not worn a dosimeter to avoid exceeding a radiation limit. As cardiologists increasingly move from contract positions toward full-time hospital employment, hospitals will be responsible for their benefits and Workers’ Compensation claims. Efforts taken now to reduce radiation exposure and develop a radiation-safe hospital environment can help preserve both hospital revenue and the safety of staff members.

Regulatory Response: Reducing the Burden of Medical Radiation From Imaging Procedures

Regulatory measures have been proposed at the federal and state levels to help protect health care professionals and patients from excess medical radiation exposure. While the U.S. National Research Council (NRC) and the International Commission on Radiological Protection (ICRP) agree that radiation exposure from medical imaging is potentially dangerous and should be minimized, as of 2012 there are no U.S. federal regulatory requirements for recording or reporting these radiation doses.

However, the Centers for Medicare & Medicaid Services (CMS) has endorsed a clinical measure that would require physicians to adequately record fluoroscopy time in the patient’s record, which would become a payment determinant under applicable fee schedules. Additionally, a number of professional groups are working alongside the U.S. FDA to establish nationally recognized reference levels for many imaging procedures. The U.S. FDA has also announced plans to require increased education for providers on radiation exposure associated with fluoroscopy and computed tomography. Additionally, one influential U.S. state, California, has already instituted standardized reporting for exposure to medical radiation.

New technologies that reduce exposure to fluoroscopy for both patients and providers can aid radiation exposure mitigation efforts.

Conclusion

The use of medical imaging has increased substantially over the past 20 years, leading to concerns that physicians and patients are being exposed to increased and possibly excessive levels of radiation. Fluoroscopy, used for interventional radiology, is associated with the highest levels of radiation exposure. Current fluoroscopic navigational systems that interventional cardiology departments use can lead to substantial radiation exposure for physicians, patients and hospital staff.
<table>
<thead>
<tr>
<th>Did You Know?</th>
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<tbody>
<tr>
<td><strong>Burden of cardiovascular disease (CVD) and medical radiation</strong></td>
</tr>
<tr>
<td>▪ An estimated 82.6 million adults, or more than 1 in 3 Americans, have CVD.</td>
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<tr>
<td>▪ Interventional radiology used for CVD management is responsible for 48% of the total radiation exposure related to medical imaging.</td>
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<tr>
<td>▪ Ionizing medical radiation should be administered in doses As Low As Reasonably Achievable (known as the ALARA principle).</td>
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<tr>
<td><strong>Risks of medical radiation exposure</strong></td>
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<tr>
<td>▪ Medical personnel who perform a large number of medical imaging procedures may be exposed to high levels of radiation.</td>
</tr>
<tr>
<td>▪ Clinicians who perform fluoroscopic procedures are at risk for radiation exposure.</td>
</tr>
<tr>
<td>▪ Patient risk varies based on the number of procedures received, age, gender and body size.</td>
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<tr>
<td><strong>Radiation in fluoroscopy</strong></td>
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<tr>
<td>▪ Fluoroscopic imaging may expose both patients and practitioners to ionizing radiation (due to scatter from the incident beam).</td>
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<tr>
<td>▪ Complex procedures generally require longer fluoroscopy times, resulting in increased radiation exposure; these doses are rarely measured.</td>
</tr>
<tr>
<td>▪ Risks associated with fluoroscopic imaging include radiation-induced cataracts and burns.</td>
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<tr>
<td><strong>Medical personnel at risk from exposure</strong></td>
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<tr>
<td>▪ Radiation exposure in practitioners who perform fluoroscopic procedures has been linked to increased brain cancer, lens opacity and posterior subcapsular cataract.</td>
</tr>
<tr>
<td>▪ This type of ionizing radiation exposure can cause molecular damage to human DNA cells.</td>
</tr>
<tr>
<td>▪ Even low levels of radiation may lead to chromosomal damage.</td>
</tr>
<tr>
<td><strong>Hospital financial impact and risk profile of medical radiation</strong></td>
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<tr>
<td>▪ Cardiologists have a yearly limit for radiation exposure, after which they must be “benched” until the next year.</td>
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<tr>
<td>▪ When cardiologists are benched, they must still receive an annual salary, representing a profit loss for hospitals.</td>
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<tr>
<td>▪ Radiation exposure may lead to illnesses associated with costly treatment, such as cancer, that hospitals may be liable to cover.</td>
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<tr>
<td><strong>Regulatory response</strong></td>
</tr>
<tr>
<td>▪ No U.S. federal regulatory requirements currently exist to record or report radiation doses received from medical procedures.</td>
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<tr>
<td>▪ The U.S. FDA and numerous professional groups are working to establish nationally recognized reference levels for many imaging procedures.</td>
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<tr>
<td>▪ Many states are instituting their own radiation regulations.</td>
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<tr>
<td><strong>Conclusion</strong></td>
</tr>
<tr>
<td>▪ Current fluoroscopic navigational systems lead to substantial radiation exposure for patients, physicians and hospital staff.</td>
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References


2. The Burden and Total Cost of Cardiovascular Disease and Medical Radiation Exposure

In the United States, cardiovascular disease (CVD) exerts a substantial health and economic burden. An estimated 82.6 million adults, or more than one in three Americans, have CVD. The group of diseases comprising CVD includes: high blood pressure, coronary heart disease, myocardial infarction (heart attack), angina pectoris (chest pain), heart failure, stroke and congenital cardiovascular defects, many of which require emergent, interventional cardiac care. According to the American Heart Association (AHA) 2012 Statistical Update, in 2008 coronary heart disease caused approximately 1 of every 3 U.S. deaths.

The high prevalence of CVD has caused an increase in the number of image-assisted interventions used to treat it. For example, since the first generation of pacemakers became available to U.S. patients in the 1950s, health care professionals have commonly utilized ionizing radiation such as X-rays and fluoroscopic imaging to guide device positioning and placement.

The economic burden of CVD in the United States is substantial (Figure 1), and has been steadily increasing in significance; between 1999 and 2009, the National Heart, Lung, and Blood Institute reported a 22% increase in the total number of inpatient cardiovascular operations and procedures, from 6.0 million to 7.4 million (based on National Center for Health Statistics data).

- In 2010, direct and indirect costs totaled $444.2 billion.
- Direct costs included $272.5 billion in health expenditures for the utilization of medical services, including both individual costs and payments by insurers.
- Indirect costs represented $171.7 billion in lost future productivity attributed to CVD morbidity and premature mortality.

The extensive prevalence of CVD in the U.S. population is strongly attributed to risk factors such as genetics, family history, smoking or tobacco use; hyperlipidemia; physical inactivity; excess weight or obesity; and comorbid conditions such as diabetes, renal disease and metabolic syndrome.

- Because control of many of these risk factors remains a challenge, the AHA predicts that by 2030, 40.5% of the U.S. population will have some form of CVD. The burden of CVD can be expected to increase further as the U.S. population ages. Of the estimated 82.6 million American adults with CVD, approximately 40 million are aged 60 years or older.
- Based on anticipated increases in prevalence, the AHA projects that, between 2012 and 2030, total direct medical costs of CVD will triple, from $309 billion to $834 billion.
- Indirect costs (lost productivity) associated with CVD are expected to increase by 53%, from $185 to $284 billion.

As aging patients with CVD become refractory to medical therapy, and emerging technology offers new options, the need for interventional cardiac procedures is also likely to increase.
Concurrent with this increase in CVD, additional risk and societal burden associated with cancer treatment costs are likely to rise, due to an increase in the usage of medical imaging. Although imaging technologies provide substantial patient benefit, this benefit is obtained alongside risk, which few clinicians or hospital purchasers are fully aware. Specifically, the use of radiation for medical procedures and tests is now the largest man-made source of human radiation exposure.4,5

Cardiac therapies requiring medical imaging carry with them an added burden of increased exposure to radiation, resulting in a potential for increased societal burden relating to cancer treatments for affected patients and medical professionals.

- The cost of treating cancer in the United States exceeds $38 billion of conservatively estimated direct medical expenses; and another $59 billion spent on concurrent conditions affecting cancer patients.6 In addition to other issues related to the risk of cardiac medical imaging noted throughout this document, the indirect cost burden and profile of this additional financial risk area is summarized in Figure 2.

In 2011, a survey by Birnie and colleagues collected survey information from 58 Canadian interventional electrophysiologists alongside an age- and gender-matched sample of 36 noninterventional cardiologists.7

In 2004, the Interventional Committee of the Society for Cardiac Angiography and Interventions (SCAI) conducted an online survey of its Internet-registered members – a group primarily composed of invasive cardiologists.8

- The cost of treating neuromusculoskeletal conditions (primarily, back-related pain) rose to $194 billion in 2004. In 2012, this cost, adjusting for inflation, reached $238 billion for direct medical expenditures.9

- Indirect costs, including earnings losses and time lost from work were estimated at $22.4 billion per year (2000 – 2004), or $27 billion per year in 2012 in the U.S.9

Aside from orthopedic costs, a portion of which may be representative of cardiac imaging risk, the cost of treating cancer in the United States exceeds $38 billion of conservatively estimated direct medical expenses; and another $59 billion spent on concurrent conditions affecting cancer patients.6

Regarding a specific, indirect cost of modern cardiac medical imaging, the literature has been lacking visibility and focus on the question of our nation’s total potential risk associated with medical radiation exposure, for patients as well as for operators. The corresponding cost burden associated with an increase of these indirect risks in relation to the rise in CVD have similarly gone unanswered, including the societal burden of addressing orthopedic injuries and cancer treatments. Some percentage of these costs will be related to the corresponding radiation coming out of cardiovascular disease. However, it is not known at this time exactly how much these indirect costs will rise along with the increase in CVD-related treatment modalities currently being utilized. Noting the costliness of these areas of medicine, the intention of this brief is to highlight and place increased focus upon them, to identify opportunities where additional research may be conducted.

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**Figure 2: Economic Burden of Cancer Treatment in the United States (2005 Data)**

- Direct Costs: $45 Billion
- Indirect Costs: $72 Billion

Cancer TX costs from 2005 USD to 2012 USD
The Growth of Imaging Procedures Related to CVD

In the United States, the use of diagnostic or therapeutic imaging (and associated clinician and patient radiation exposure) has grown substantially. Over the past 20 years, the overall exposure level of the U.S. population to ionizing radiation has doubled. The total average effective radiation dose per-person in the United States is now 6.2 mSv per year.

During this time, radiation exposure from natural or background sources has not changed substantially. However, the proportion of total radiation exposure obtained from medical sources has increased from 15% in the 1980s to 48% today (Figure 3). A substantial proportion of this medical radiation exposure is obtained via diagnostic or therapeutic medical imaging.

A 2012 retrospective analysis of electronic medical records from 6 large integrated U.S. health centers (representing 30.9 million imaging examinations over 25.8 million person-years) found that radiation exposure due to diagnostic imaging alone increased as follows from 1996 to 2010:

- Patients experienced a doubling in mean per capita effective medical radiation dose received (1.2 mSv in 1996 vs. 2.3 mSv in 2010).
- By 2010, the proportion of patients who had high (> 20-50 mSv) or very high annual radiation exposure (> 50 mSv) was 6.8% and 3.9%, respectively.

To put these data in context, the International Commission on Radiological Protection (ICRP) recommends a maximum annual whole-body dose limit of 20 mSv, while the U.S. Occupational Safety and Health Administration stipulates a dose limit of 50 mSv per year. Data such as these have led to concerns that medically related radiation exposure is a serious public health problem in the making. Because of this, any risk-benefit assessment for conducting therapeutic or diagnostic imaging must consider the potential long-term risks of exposure to ionizing radiation.

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**Figure 3: U.S. Population Ionizing Radiation Exposure, Early 1980s vs. 2006**

<table>
<thead>
<tr>
<th></th>
<th>Early 1980s</th>
<th>2006</th>
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<tbody>
<tr>
<td>Collective effective dose (person-Sv)</td>
<td>835,000</td>
<td>1,870,000</td>
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<tr>
<td>Effective dose per individual in the U.S. population (mSv)</td>
<td>3.6</td>
<td>6.2</td>
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</table>
Patient Exposure to Medical Radiation During Cardiovascular Imaging

Just how much radiation are patients exposed to when they undergo cardiovascular imaging procedures? In a 2008 evaluation of 50 successive patients admitted over one month to the cardiology ward of an Italian hospital, investigators evaluated patients’ complete radiologic history and assessed their cumulative effective dose due to medical radiation from X-rays and other procedures. They found that:

- On average, each patient underwent 36 imaging examinations, associated with a median cumulative effective radiation dose received of 60.6 mSv.
- Fourteen out of 50 of these patients (28%) received doses exceeding 100 mSv.

The study authors adjusted the above data for patient gender and age based on morbidity and mortality data available from the ICRP, and from the Biological Effects of Ionising Radiation Committee VII (BIER VII).

- These results indicated that these patients’ median risk for future cancer was 1 in 200.

Last, the investigators looked into the primary source of patients’ radiation exposure. They found that although only 12% of the imaging procedures performed on patients were for arteriography and interventional cardiology, these procedures accounted for 48% of the overall radiation dose received per patient (Figure 4). This was a much larger proportion than was attributable to any other source of medical radiation.

![Figure 4: Interventional Radiology Is Responsible for Only 12% of Cardiology Exams, but Represents 48% of Total Radiation Exposure Due To Medical Imaging](image-url)
What is the difference between ionizing and non-ionizing radiation?

As shown in Figure 5, radiation is categorized as ionizing, and non-ionizing. Sources of radiation can be man-made, or may occur naturally in the environment. Naturally occurring (“background”) exposure generally creates little health risk. However, the higher levels of radiation used in medical imaging technologies have been shown to carry an increased risk of cancer and other negative outcomes.13

**Figure 5. Types of Radiation in the Electromagnetic Spectrum**[EPA.gov]

Non-ionizing radiation carries enough energy to move atoms and/or cause them to vibrate without freeing electrons.
- Examples of non-ionizing radiation include sound waves (non-thermal), microwaves (thermal) and visible light (optical effects).16
- The potential for negative health effects from low-frequency, non-ionizing (i.e., electromagnetic) energy, such as cell phone usage, remains controversial in the scientific community.5

Ionizing radiation particles carry sufficient energy to free electrons from molecules and create positive ions.
- Sources of ionizing radiation include ultraviolet light, gamma and X-rays, alpha and beta particles, neutrons and cosmic rays.16
- Ionizing radiation has been proven to produce biologic effects in the body. Low-dose radiation may impair or modify the genetic code (DNA) of cells. Elevated radiation levels are likely to kill cells.17

What is the difference between stochastic and deterministic radiation?

The biologic effects of radiation are categorized as stochastic (cancer-inducing), and deterministic (physically altering).18

Stochastic radiation injury occurs following ionizing radiation exposure, when the DNA of a single cell is incorrectly repaired.19 Ionizing radiation has both rapid and delayed stochastic effects. High exposure can lead to death within several months. Moderate exposure increases the likelihood of cancer over 10 or more years. Damage from low-level exposure (< 50 mSv) may not occur immediately, but cellular harm may manifest over longer periods due to undetected effects of the radiation on DNA.17,19
- No low-threshold dose exists at which an adverse effect due to stochastic radiation cannot occur; however, the probability of cancer or some genetic effect occurring increases with dosage.17
- Examples of the stochastic effects of radiation include: cancer, cataracts and genetic damage.22

Deterministic radiation injury is largely caused by the reproductive sterilization of cells. Deterministic injuries are often evident within hours or days, and typically result from very large dosages of radiation received over a short amount of time.
- A dose threshold, or level below which no biological response is observable, usually exists for deterministic injury, subject to biologic variation.17
- The most common deterministic radiation damage is skin injury, but damage can also be done to subcutaneous fat and muscles. Other examples of deterministic radiation injury include: hair loss, cataracts, sterility, and death.18
National (U.S.) Response to Increased Medical Radiation in Cardiovascular Imaging

Historically, the need for protection from medical radiation has not been addressed through the introduction of new imaging technologies and/or generational updates. Instead, government regulators and hospital executives and administrators have attempted to manage and mitigate such risk by instituting best practices, education, policies and radiation exposure calculators to provide guidance to at-risk populations.

In response to these concerns, there has also been a gradual, world-wide tightening of radiation protection standards, as well as increased awareness of the need to minimize unnecessary radiation exposure from medical radiation.

The core U.S. principle now governing the use of ionizing medical radiation is known as ALARA – As Low As Reasonably Achievable.

- The ALARA principle stresses that there is no magnitude of radiation exposure known to be completely safe. This finding is based on a comprehensive review of available biological and biophysical data by the National Academies of Science in support of a “linear-no-threshold” (LNT) risk model. This model states that cancer risk builds in a linear fashion at lower doses without a threshold, and that even the smallest dose has the potential to cause a small increase in human risk.

- This recognition of “no threshold” for radiation exposure confers a responsibility on all physicians to minimize unnecessary radiation injury hazards to their patients, their professional staff and themselves.

- ALARA also recognizes that incremental radiation exposure can have cumulative effects.

### Common Terms Used to Measure Radiation Exposure

<table>
<thead>
<tr>
<th>Radiation Exposure Measurement Principles</th>
<th>It is useful to understand the specific terminology used to describe the magnitude of radiation exposure or dosage received by an individual. The two categories of radiation measure are absorbed dose and biological dose.</th>
</tr>
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<tbody>
<tr>
<td>Absorbed radiation dose is expressed using a unit called the gray (Gy).</td>
<td>Human absorbed radiation exposure is generally measured in milligray (mGy) or 0.001 gray.</td>
</tr>
<tr>
<td>Biological radiation dose is expressed using a unit called the sievert (Sv).</td>
<td>The probability for human biological damage associated with radiation exposure is typically expressed in millisieverts (mSv) or 0.001 sievert.</td>
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For a more detailed summary of this information, see the Appendix to this document.
In 2010, the U.S. Food and Drug Administration (FDA) implemented its Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. Consistent with its mission to protect and promote the public health, the FDA strives to promote patient safety through two principles of radiation protection during medical imaging procedures:

- **Justification.** The imaging procedure should be judged to do more good than harm to the individual patient. Therefore, examinations that use ionizing radiation should be performed only when necessary to answer a medical question, help treat a disease or guide a procedure. Before referring a patient for any imaging examination, the clinical indication and patient medical history should be carefully considered.

- **Dose Optimization.** Medical imaging examinations should use techniques adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., as low as reasonably achievable). The approach should be selected based on the clinical indication, patient size and anatomical area scanned.

The FDA has indicated its intent to partner with industry, key professional organizations and other governmental agencies in the coming years to pursue regulatory requirements related to the following aspects of medically related radiation exposure:

- The appropriate use of imaging technologies (i.e., to promote only the use of exams that are appropriate for the patient).
- The development of equipment safety features that optimize/minimize radiation delivery and track patient dose received.
- Facility guidelines and/or personnel qualification accreditation requirements (to ensure that hospitals can demonstrate an understanding of safe radiation principles).
- Education and communications training for medical professionals regarding radiation exposure risk.
- The implementation of safety metrics designed to track radiation exposure (for example, lifetime patient dose registries).
Radiation exposure occurs naturally in the environment, but also occurs due to man-made sources, such as radiation obtained from medical imaging. The management of risks to human health from radioactivity are quantified and controlled through the use of dosage-limiting standards, detailed in this table.25

<table>
<thead>
<tr>
<th>Agency</th>
<th>Radiation Type</th>
<th>Standards/Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>International Atomic Energy Agency (IAEA) 1996 Basic Safety Standards</strong>26</td>
<td><strong>Exposed Workers (Aged &gt; 18 Years)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Effective dose</td>
<td>100 mSv in a consecutive 5-year period, subject to a maximum of 50 mSv during a single year</td>
</tr>
<tr>
<td></td>
<td>Annual equivalent dose to the lens of the eye</td>
<td>150 mSv</td>
</tr>
<tr>
<td></td>
<td>Annual equivalent dose to the skin, hands, forearms, feet, ankle</td>
<td>500 mSv</td>
</tr>
<tr>
<td></td>
<td><strong>Members of the Public</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual effective dose</td>
<td>1 mSv*</td>
</tr>
<tr>
<td></td>
<td>Annual equivalent dose for the lens of the eye</td>
<td>15 mSv</td>
</tr>
<tr>
<td></td>
<td>Annual equivalent dose for the skin, hands, forearms, feet, ankle</td>
<td>50 mSv</td>
</tr>
</tbody>
</table>

*In special cases, a higher value may be authorized in a single year, provided that the average over 5 consecutive years does not exceed 1 mSv/year.

| **The U.S. Nuclear Regulatory Commission (NRC) and U.S. Environmental Protection Agency (EPA)**27,28 | **Exposed Workers (Aged > 18 Years)** | |
| | **Annual limit of occupational dose to organs or tissue other than the ocular lens** | 500 millisievert (mSv) |
| | (i) Total effective dose equivalent, or (ii) Sum of external whole-body exposure (deep-dose equivalent ≥1 cm deep) and the committed dose | |
| | **Annual limits of occupational dose to ocular lens** | 150 mSv dose equivalent |
| | **Annual limits of occupational dose to skin of the whole body, including extremities** | 500 mSv shallow-dose equivalent (< 1 cm) |

| **Radiation Dose Limits for Individual Members of the Public** | **Total effective dose-equivalent, exclusive of dose contributions from background or voluntary participation in medical research** | |
| | (i) 1 mSv in 1 year** | |
| | (ii) 0.02 mSv in any 1 hour | |

**5 mSv in 1 year to NRC-preauthorized visitors with established need and limited duration**

3. Patients and Other Persons at Risk from Medical Radiation Exposure

Both patients and medical professionals alike are exposed to high radiation doses during medical imaging procedures. Physicians and other medical personnel involved with medical imaging may be at even greater risk, based on the length and consistency of their exposure over time. Key differences in patterns of exposure may be characterized as follows:

- Most patients who obtain medical imaging will experience a small number of comparatively high exposures over their lifetime.29
- Medical imaging professionals typically receive ongoing, long-term, low-level occupational radiation exposure.29

Although regulatory efforts have largely been directed at patient protection,21 evidence suggests that healthcare providers – in particular, cardiologists and electrophysiologists – are also at risk for negative outcomes and excess mortality.30-33

Interventional Cardiologists, Electrophysiologists and Other Medical Professionals

Among health care professionals, interventional cardiologists and electrophysiologists have the highest levels of occupational radiation exposure.17,34

- Research indicates that interventional cardiologists receive cranial radiation exposure that is two to three times higher than that received by radiologists.35
- This level of annual head radiation exposure received by interventional cardiologists is equivalent to approximately 250 chest X-rays.35
- A study documenting the radiation dose received by in-room personnel at three cardiac catheterization laboratories found that some staff sustained head dose radiation exposure of up to 60 mSv per year. Physicians were most likely to have this high exposure level.36

Invasive and interventional cardiologists receive frequent radiation exposure through fluoroscopy and cineangiography.37 In addition, cardiologists-in-training, nurses, laboratory technicians and support personnel who work in the cardiac laboratory setting are consistently exposed to radiation.37

- According to the National Research Council’s Biological Effects of Ionizing Radiation VII (BEIR VII) Report, among the most-highly exposed catheterization laboratory staff, cumulative professional radiation exposure is associated with a non-negligible lifetime attributable risk of cancer.23
- Clinicians who perform interventional procedures involving fluoroscopy have been found to have the highest occupational dose exposure among medical staff who perform X-ray procedures.30,36-40
- As shown in Figure 6, a 2009 evaluation of radiation exposure among medical staff from the Tuscany Health Physics Department showed that cardiac catheterization lab staff had the highest overall exposure levels.30
- In 2009, Venneri and colleagues found a 1 in 192 risk of fatal and non-fatal cancer among high-volume cardiac catheterization lab staff. For the most highly exposed personnel with 20+ years’ history in the lab, the estimated lifetime cancer (fatal or non-fatal) risk was 1 in 100.30

Figure 6: Proportion of Yearly Radiation Dose Exposure Among Medical Staff, by Area of Specialty30
Patient Risk

From a risk-benefit perspective, many patients who receive individual cardiac imaging procedures are exposed to an acceptable level of radiation. Bedetti and colleagues identified the estimated radiation doses associated with a number of invasive cardiac diagnostic and interventional procedures. This ranged from 1.4 mSv (for conventional cardiac rhythm device implantation) to 21 mSv (for radiofrequency catheter ablation, coronary angiography with ventriculography, and coronary predilation and stenting).15

However, patients’ risk accelerates when they receive substantial, repeated exposure due to multiple imaging tests (a situation that is not uncommon for patients with established cardiovascular disease).1 As noted previously, when Bedetti and colleagues evaluated the full radiologic history of 50 patients admitted to a cardiology ward, 14 (28%) had received cumulative doses higher than 100 mSv, while the median patient dose was 60.6 mSv. Figure 7 shows the frequency distribution for radiologic exposure associated with this study.15

In addition, there are also patients who are at higher risk due to their gender (female), relative obesity level and age (pediatric).

Risk in Specific Adult Populations

In general, cumulative effective doses of radiation from imaging procedures increase with advancing age and are higher in women than in men (because of women’s greater breast and thyroid sensitivity).22,41,42

- Compared with men, women are 37.5% to 52.0% more likely to develop cancer subsequent to receiving the same radiation dose.42
- In addition, the relative risk associated with past radiation exposure decreases substantially more slowly over time for women, compared with men.43
- Pregnant women and the developing fetus are particularly vulnerable to the effects of ionizing radiation.22,41,42

It has also been found that, during medical imaging procedures, obese patients receive more than twice the effective radiation dose received by normal-weight patients. This is an issue of concern, as obesity and CVD are closely related, and more than one-third of the U.S. population is obese.44

- Ector and colleagues evaluated normal-weight, overweight and obese patients who all received the same atrial fibrillation ablation procedure (which included a mean 83 minutes of fluoroscopy time). The corresponding effective radiation doses received by these groups were 15.2, 26.7, and 39.0 mSv, respectively.45

Figure 7: Frequency Distribution of Radiologic Exposure: Cumulative Lifetime Effective Radiation Dose of 50 Cardiology Patients15
“Reference Man” refers to a standard set of biological characteristics by which many radiation exposure safety limits are calculated. These characteristics have been applied to a Caucasian man of average height and weight. As such, the Reference Man standard does a poor job of defining radiation risk for other population groups such as women, children and obese individuals (Figure 8). Limitations of “Reference Man” does a poor job of defining radiation risk for other population groups such as women, children and obese individuals (Figure 8). Based on this evidence, and the ongoing use of Reference Man, there are reasonable grounds to doubt the generalizability of existing radiation exposure limits for individuals who do not match Reference Man’s characteristics.

Reference Man was implemented in 1975 in an attempt to provide a standard set of biologic characteristics that could be used to systematize the calculations needed to assess radiation protection. Reference Man is a hypothetical 20- to 30-year-old Caucasian male, weighing 154 pounds, and 5 feet 7 inches tall. The use of Reference Man in U.S. radiation protection regulations and guidelines, including those designed to protect the general public, is pervasive.

A 2008 report prepared by the Institute for Energy and Environmental Research (IEER) contends that the Reference Man standard has serious gaps for many individuals. The IEER considers the Reference Man approach to risk estimation as scientifically inappropriate because the vast majority of people, including women, children and patients who are overweight or obese, fall outside this definition. The IEER recommends ending the use of Reference Man in radiation protection regulations and guidance (to estimate cancer risk and dose conversion factors).

To more accurately assess patient risk, the IEER recommends that dose conversion tools be developed based on patient age and gender and for infants and developing fetuses.

In 2008, the Radiation Advisory Committee of the U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) reported that the use of Reference Man did not adequately represent the risk associated with radiation exposure in women or in children. The SAB recommended the use of a “Reference Family” that would be more representative of varying risks associated with radiation exposure to different individuals.

Following this report, President Barack Obama (then an Illinois state Senator) and California Representative Henry Waxman sent a letter to the EPA to question the scientific validity of the continued use of the Reference Man standard, and supported the use of the Reference Family approach.
Risk in Pediatric Patients

Research shows that, compared with adults, children overall are three to five times more susceptible to the negative effects of radiation. This is due to these patients’ rapid rate of development and associated cell division. According to the U.S. FDA, exposure to ionizing radiation is of particular concern in pediatric patients for three reasons:

- Younger patients are more vulnerable to the effects of radiation than adults (the cancer risk per unit dose of ionizing radiation is higher for younger patients).
- Younger patients have a longer expected lifetime for the effects of radiation exposure to manifest as cancer.
- The use of equipment and exposure settings designed for adult use can result in excessive radiation exposure for younger patients.

The potential for radiation-induced lifetime cancer risk increases the younger a child is at the time exposure occurs (Figure 9).

- Compared with middle-aged or older adults, newborns are estimated to be 10 to 30 times more sensitive to ionizing radiation.
- One estimate indicates, in the context of the same radiation dose, a one-year-old child is 10 to 15 times more likely to develop a malignancy compared with a 50-year-old adult.

In response to these very serious pediatric concerns, the U.S. FDA has proposed that, as part of 510(k) submission procedures, manufacturers of devices that deliver ionizing radiation should be required to describe available dose reduction features and provide technician training materials. The FDA has also proposed that manufacturers add labels warning against imaging equipment use on children, unless it has been shown that these devices are safe for pediatric use.
### Compared With Other Types of Radiation, What Are the Effects of Medical Radiation?

| The Face of Radiation Exposure | Most of what is known about the effects of radiation exposure on the human body comes from research on atomic bomb survivors.\(^5\) Because an atomic bomb releases all of its radiation at once, while radiation obtained from medical imaging is due to smaller doses accrued over time, this is not an ideal model for medical radiation exposure.\(^13\) However, the available evidence suggests that it is the intensity of overall radiation exposure that determines risk, regardless of whether this exposure accumulates occupationally over time or is due to a single event. |
| Single Exposure to Radiation | Survivors of the Hiroshima atomic bomb who were within 2,000 to 3,000 yards of ground zero received an immediate, effective radiation dose in the range of 5 to 100 mSv.\(^5,50\) A 40-year follow-up study (1958 to 1998) of nearly 28,000 Hiroshima and Nagasaki bomb survivors exposed to a single radiation dose in this range found a statistically significant increase in radiation-associated solid tumor risk.\(^5,23,50\) Eleven percent of all solid-tumor cancers identified in this group were assessed to be radiation exposure–related.\(^5,23,50\) This radiation-induced risk was found to persist throughout the individuals’ lives, regardless of age at exposure.\(^50\) |
| Intermittent Exposure To Occupational or Medical Radiation | In 2007, a large 15-country study of > 400,000 nuclear industry radiation workers (representing 5.2 million person-years of follow-up) was conducted to directly assess cancer risk following protracted, low doses of ionizing radiation. Workers were found to have received an average cumulative effective dose of 19.4 mSv; 90% of workers received cumulative doses that were less than 50 mSv.\(^51\) Investigators found a significant association between radiation dose and all-cause mortality, driven primarily by cancer mortality. The specific excess relative mortality risk was identified as 0.42 per Sv received (90% CI 0.07, 0.79).\(^51\) Another study compared lung cancer risk among atomic bomb survivors and U.S. uranium miners. It found no statistically significant difference between male bomb survivor and miner data in terms of relative risk based on time elapsed since exposure or age at exposure.\(^43\) In 1980, Land and colleagues conducted parallel analyses of cancer incidence data among Japanese atomic bomb survivors, tuberculosis patients in Massachusetts who received fluoroscopy, and New York women treated with radiation for mastitis. They found that absolute risk for breast cancer was comparable for the three cohorts.\(^23,52\) Similar findings were identified in a 1996 study conducted by Howe and colleagues.\(^23,53\) In 2009 Jacob and colleagues\(^54\) compared the effects of accumulated occupational exposure to low- or moderate-dose ionizing radiation against a matched population of atomic bomb survivors. Low- and moderate-dose occupational exposure data were obtained from 12 epidemiologic studies, as well as from the United Kingdom National Registry for Radiation Workers study. Bomb survivor data were obtained from publicly available datasets. The excess relative risk for the low- and moderate-dose studies was 1.21 (90% CI: 0.51 to 1.90); this was not statistically different from the atomic bomb population. This research provided strong evidence that cancer risk with occupational exposure is not lower than risk for atomic bomb survivors with similar exposure levels. Therefore, individual risk is similar regardless of whether radiation exposure is immediate or cumulative.\(^54\) |
4. **The Increasing Radiation Risk of Fluoroscopy Procedures**

Fluoroscopic imaging is a fixture in modern electrophysiology and catheterization labs. During fluoroscopic procedures, X-rays are passed through the patient’s body to capture real-time moving images and observe the movement of an object or substance in the body. The fluoroscopic X-ray tube is generally located under or alongside the operating table. Based on this proximity, the operator (typically, an interventional cardiologist or electrophysiologist) can be exposed to radiation due to scatter from the incident beam.

Fluoroscopy is a substantial source of X-ray exposure because, to enhance operator visualization, the X-ray beam typically stays on during procedures (i.e., the beam is not intermittent). However, doses administered to patients or clinicians are rarely measured and organ-specific doses are particularly difficult to calculate. In 2008, the President’s Cancer Panel noted that 12% of the U.S. population’s estimated collective effective radiation dose was due to observational and interventional fluoroscopy.

- As shown in Figure 10, the mean range of adult effective doses received with fluoroscopy is substantially higher than dosage received with computed tomography or nuclear medicine.

As shown in Figure 11, as clinicians gain experience performing specific fluoroscopic procedures (in this case, ablation for atrial fibrillation), less time is required to perform these interventions. Nonetheless, substantial levels of fluoroscopy exposure still persist, suggesting that enhanced clinician expertise alone cannot solve the problem of excess fluoroscopic radiation exposure. These data were obtained from a single hospital center and represent 1,504 ablation procedures performed on 1,215 patients.

Although improvements in radiologic technology and enhanced staff expertise can lead to improved image quality with reduced fluoroscopic X-ray exposure, fluoroscopy can still result in relatively high radiation doses compared with other X-ray procedures.
This is especially likely during complex procedures, when multiple cine acquisitions are required, and/or during interventional procedures (such as placing catheters or other devices inside the body) that require fluoroscopy administered for long periods of time.\textsuperscript{22,63,64}

Fluoroscopic duration may double, for simple compared with complex cardiac procedures. As shown in Figure 12, a review of several studies indicated that cardiac resynchronization therapy (CRT) required an average of 21 minutes of fluoroscopy for typical CRT procedures and 44 minutes for complicated CRT procedures, while more intricate procedures (i.e., complex ablation with mapping) required approximately 1 hour.\textsuperscript{65-71}

However, even the fluoroscopic time required for standard procedures such as CRT can vary substantially, as documented by Butter and colleagues. In this study, radiation exposure received by 104 consecutive patients during fluoroscopic CRT was measured using dosimeters placed on patients’ bodies.\textsuperscript{20}

- Mean patient fluoroscopy time was 20.3 minutes; however, as shown in Figure 13, a number of patients required fluoroscopy time exceeding 40 minutes. This was accompanied by attendant, higher rates of radiation exposure.\textsuperscript{20}

![Figure 12: Average Fluoroscopy Times: Cardiac Resynchronization Therapy and Ablation\textsuperscript{66-72}](image)

<table>
<thead>
<tr>
<th>Type of Case</th>
<th>Mean Fluoroscopy Times</th>
<th>Mean Procedure Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical CRT procedure (71%)</td>
<td>21 min</td>
<td>86 min</td>
</tr>
<tr>
<td>Complicated CRT procedure (29%)</td>
<td>44 min</td>
<td>133 min</td>
</tr>
<tr>
<td>Simple ablation (flutter, AVNR, Accessory, etc.) with mapping</td>
<td>15 min</td>
<td>101 min</td>
</tr>
<tr>
<td>Complex ablation (AF–PV isolation, VT, complex congenital disease) with mapping</td>
<td>59 min</td>
<td>178 min</td>
</tr>
</tbody>
</table>

![Figure 13: Many Cardiac Resynchronization Therapy Procedures Require More Than 40 Minutes of Fluoroscopy Exposure\textsuperscript{20,72}](image)
In addition, the risk of medical radiation–induced cataracts and skin burns are primarily associated with repeated or prolonged interventional fluoroscopy procedures. In this study, 2.9% of the patients evaluated were at risk for deterministic injury (cellular injury incurred by exceeding a threshold radiation dose) due to protracted fluoroscopy exposure.

In light of existing data, the Society of Interventional Radiology Safety and Health Committee has stated that any fluoroscopy procedure exceeding 60 minutes in duration provides an indirect indicator of significant radiation exposure.

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**Skin Injury Due to Fluoroscopic Procedures**

**Visible (and Legally Actionable) Skin Injuries from Fluoroscopy**

- Although the skin is only moderately radiosensitive, it is the organ at greatest risk of radiation-induced injury during medical imaging. Skin radiation exposure is generally acute during these procedures, as fluoroscopy requires direct skin exposure to radiation beams for a substantial length of time.
  - Skin injury is the most common deterministic effect caused by fluoroscopic procedures, and can result from doses of acute radiation ≥ 2 Gy.
  - Skin injury caused by radiation is easily recognizable because of the bodily location of the injury and the close temporal proximity of the injury to the fluoroscopic procedure performed. Signs of skin injury generally present within 2 to 3 weeks following patient exposure to radiation.

- Although the exact frequency of skin injury due to fluoroscopy is unknown, one study found a rate of less than 0.03% for cardiac interventions; however, this rate may be higher for complex interventions.
  - In 2011, a single-center retrospective chart review of 1310 procedures by Sawdy and colleagues showed that 15 patients experienced radiation burns (representing an incidence of 0.01%).
  - A U.S. FDA study indicated that the hospital-based fluoroscopic procedure with the highest rate of radiation-induced skin injuries to patients is a radiofrequency catheter cardiac ablation.
  - Other studies have reported high doses associated with the following fluoroscopic procedures: percutaneous transluminal coronary intervention (PTCA), transjugular intrahepatic portosystemic shunts (TIPS) procedures and embolization procedures in the brain.

- Due to the nature and location of the injury, skin damage due to radiation exposure is easily detectable, and is usually obvious. Many patients are motivated to take legal action for the external (i.e., visible) injuries sustained. One report has noted that a U.S. legal case is filed every 4 to 5 weeks by patients with skin injuries related to fluoroscopic procedures.
5. Specific Risks to Medical Professionals from Radiation Exposure

**Elevated Brain Cancer Risk**

Among interventional cardiologists and radiologists, the left side of the head is more exposed to radiation than the right. The possibility that physicians who are regularly exposed to radiation might have an elevated risk for left-side brain cancer was first suggested in 1975 by Matanoski and colleagues (Figure 14). These researchers evaluated predictors of mortality among a large cohort of physicians and observed that death rates from brain cancer among radiologists were nearly three times that of other specialists who did not use radiation.

In 1998, this was followed by a report from two Toronto cardiologists diagnosed with brain tumors. These physicians both performed occupational fluoroscopic procedures, and expressed concern that exposure to radiation during such procedures might have been the cause of their tumors. At the time, a connection between these tumors and occupational radiation exposure was considered biologically plausible. However, risk assessment suggested that it would be unlikely that this effect could be observable in the small population of Ontario cardiologists. Today, this argument for biologic plausibility still holds.

A comprehensive review of brain tumor epidemiology, presentation, diagnosis and treatment published in *The New England Journal of Medicine* noted that radiation is the only known, unequivocal cause of brain tumors. No other environmental exposure or individual behavior has been found to be a reliable risk factor for brain tumor development.

Available evidence indicates that even low-dose cranial irradiation can increase tumor incidence. In two studies, exposure was found to increase the incidence of meningiomas by a factor of 10, and of glial tumors by a factor of 3 to 7.

Other sources of cranial radiation, such as excessive dental X-ray exposure, have been associated with increased intracranial meningioma risk.

In addition, ongoing research on this topic continues to point to an association:

- A Swedish case control study (N = 233 patients with brain tumors) found that physicians working with fluoroscopy had a 600% increased risk of developing a brain tumor. However, this result did not achieve statistical significance because only three study participants worked with fluoroscopy.

- Another case-control study of 476 individuals diagnosed with glioma (and 462 control patients) found a 350% increased risk among physicians and surgeons.

These findings have provoked concern in the interventional cardiovascular community. In 2012, Roguin and colleagues reported on four interventional cardiologists, all with left-hemisphere brain malignancies. To supplement their analysis, the authors also identified five additional cases of brain malignancy in this population (including glioblastoma, meningioma and acoustic neurinoma) via a literature search. All the physicians evaluated had worked for prolonged periods (14 to 32 years) with exposure to ionizing radiation in the catheterization laboratory. The majority died shortly after diagnosis. The authors noted that these events could be a chance occurrence, but the cause might also be radiation exposure.
Lens Opacity and Posterior Subcapsular Cataract

Eye tissue is highly radiosensitive, making individuals exposed to ocular ionizing radiation vulnerable to dose-related opacification or clinical cataract development.87

- Posterior subcapsular (PSC) cataract is the least common of the three main forms of cataract (which also includes nuclear and cortical). However, PSC is the most common form of radiation-related cataract.88
- The effects of radiation on the eye tissue are not immediately apparent; radiation-induced cataracts are generally diagnosed at least 1 year following exposure to radiation.22

The threshold of radiation to prevent visual impairment in the form of cataract is estimated at 150 mSv/year.27,28,89

- Using this dose threshold, Hidajat and colleagues found that when radiologists perform 372 procedures annually over multiple years – or just over 1 procedure per day – they run the risk of exceeding the maximal exposure dose for cataract development (Figure 15).31
- Since some radiologists perform in excess of 500 procedures per year, an interventional radiologist with a heavy procedure load has a relatively high cataract risk.31

Although limited data exist on lens opacities associated with repeated interventional cardiologists’ exposure to fluoroscopic radiation, recent research has identified a significant increase in radiation-associated lens changes among interventional cardiologists. This indicates an urgent need to decrease exposure among these professionals.87 During two regional Sociedad Latinoamericana de Cardiología Intervencionista (SOLACI) Congresses, one in September 2008 and one in April 2009, 116 radiation-exposed and 93 non-exposed physicians and other health professionals of similar age were evaluated for cataracts using slit-lamp examination.87 Lens dose estimates were based on detailed, individual survey responses regarding yearly occupational workload and use of eye protection, combined with scatter radiation dose data (as many participants reported irregular use of personal dosimeters).87

- Among the exposed population, 38% of interventional cardiologists and 21% of nurses and technicians presented with PSC opacities typically associated with ionizing radiation exposure, compared with 12% of unexposed controls.
- The estimated, cumulative median values of lens dose received were 6.0 Sv for cardiologists and 1.5 Sv for associated medical personnel.87

In addition, participants at an April 2009 annual conference of the National Heart Association of Malaysia were recruited to undergo comprehensive dilated slit-lamp examinations to detect the presence of lens opacities.88

- Mean cumulative ocular doses, estimated by participant self-report of number of procedures per week and relevant exposure parameters per procedure, were 3.7 Gy for cardiologists and 1.8 Gy for nurses.88
- A strong dose-response relationship was observed between occupational exposure and the prevalence of radiation-associated posterior lens changes.
- The prevalence of radiation-associated PSC lens opacities was 52% for exposed interventional cardiologists, 45% for exposed nurses, and 9% for controls.88
To put these data in a national perspective, in the United States 17% of adults aged 40 years and older have cataracts of any form in one or both eyes. Of note, the prevalence of PSC cataract is so rare in the general population that the U.S. Centers for Disease Control and Prevention does not report on this subtype. Based on this, it is unlikely that the high rate of PSC lens opacities observed among these medical professionals could be explained by other biologic triggers.

Chromosomal/Genetic Damage

Unlike many other mutagens, X-ray beams can access all internal organs. This is why even a single electron set into motion by an X-ray photon may cause permanent molecular damage. This also explains why there is no stochastic radiation dose level that is considered risk-free or safe.

The primary way in which radiation injures human cells is via DNA damage. Chromosomal abnormalities represent the intermediate molecular damage that increases cancer risk, and chromosome aberration-based assays are considered the gold standard to assess individual radiation exposure.

- A number of studies show that, compared with non-exposed individuals, interventional cardiologists chronically exposed to low-dose radiation exhibit substantial chromosomal damage.

To evaluate whether chromosome damage, specifically chromosomal translocations, was increased after exposure to diagnostic X-rays (in particular, doses ≤ 50 mGy), Bhatti and colleagues analyzed data from three studies (N = 362). Subjects in the three studies were: 1) medical radiologic technologists, 2) airline pilots and, 3) university faculty members.

- Information on personal radiographic examinations was obtained from all study participants and computed as a cumulative red bone marrow (RBM) dose score (with 1 RBM unit approaching 1 mGy). Mean RBM dose scores were 49, 42 and 11 for studies 1, 2 and 3, respectively.

- The authors concluded that chromosomal damage was associated with low levels of radiation exposure from X-ray examinations, including doses ≤ 50 mGy. This suggested the possibility for negative, long-term health effects.

Andreassi and colleagues reported a case study comparing two 37-year-old, healthy male identical twins. One was a lawyer without any known exposure to carcinogenic/mutagenic agents; the other was an interventional cardiologist who worked in a high-volume cardiac catheterization laboratory and had been professionally exposed to radiation for the past 10 years.

- By evaluating a monozygotic twin pair, this study used a unique model to explore how genetically identical individuals can exhibit chromosomal variances due to environmental factors.

- In each twin, 500 metaphase (i.e., in the process of replication) chromosomes were blindly analyzed for structural aberrations. The cardiologist twin had a higher frequency of chromosomal abnormalities (3.2%) than the lawyer twin (1.2%).

Another multinational study compared the effects of low-dose radiation on chromosomal damage in two groups: interventional cardiologists (n = 37) and a matched control group of 37 clinical physicians with no history of ionizing radiation exposure.

- Compared with the control group, the frequency of aberrant cells (p < 0.05) and chromosome breaks (p < 0.01) were significantly higher in the interventional cardiologist group.

In addition, the risk of passing on radiation-induced damage to one’s offspring is an often-overlooked aspect of radiation exposure, but represents an additional risk above and beyond risk to the exposed individual.

- In a 2000 report, the United Nations estimated that radiation-induced damage passed on to offspring represents approximately one-fifth of all fatal cancer risk associated with radiation exposure.
Orthopedic Risks Due To Lead Shielding

Performing fluoroscopic procedures requires interventionalists to wear a lead apron for active radiation protection. Over the past 20 years, as interventional heart procedures have become more common and more complex, attending physicians have been required to spend increasing amounts of time encumbered by lead aprons. There are varying types and weights of lead aproning and shielding available to EP lab operators and staff, which are currently being studied and are commonly utilized in clinical inpatient and outpatient care settings for levels of thickness (e.g., 0.25 mm, 0.50 mm) and weight.

Traditional lead aprons weigh approximately 15 pounds, and can place up to 300 pounds of pressure per square inch on a physician’s intervertebral discs. This pressure can be aggravated by improper table height, fluoroscopy monitor height and position, and on-table control panel position. It has been noted anecdotally that this physical burden is orthopedically and ergonomically challenging for interventional cardiologists.

Clinical study has found that a traditional 15-lb apron can provide protection necessary for more complex, lengthy procedures that may take place in the EP lab; however, doing so is not without its consequence to the wearer. Additional study has found that a traditional lead apron places pressures of up to 300 pounds per square inch on intervertebral discs. However, conservative clinical practice would dictate use of a heavier-weight apron to counter the more complex, lengthy ablation procedures routinely performed in an EP lab. Therefore, increased risk is associated with these types of procedures, where operators may not have the benefit of newer, lighter-weight radiation shielding, which may be used in procedures expected to use less fluoroscopy time.

According to professor Ariel Roguin, chief of interventional cardiology at Israel’s Haifa Rambam Medical Center, many doctors, particularly those older than 35 years of age, “….suffer from orthopedic problems caused by the weight of the lead protectors worn while standing 6 to 8 hours daily.” Dr. Roguin notes that these doctors report aches and pains of varying severity in the neck, back, hips, knees, and ankles.

Research in this area suggests that lead aprons may be the cause of orthopedic problems for interventional cardiologists. A 2011 study by Birnie and colleagues collected survey information from 58 Canadian interventional electrophysiologists alongside an age- and gender-matched sample of 36 noninterventional cardiologists.

- Electrophysiologists reported a significantly higher prevalence of cervical spondylosis (20.7% compared to 5.5%, p = 0.033).
- There was a trend for increased prevalence of lumbar spondylosis (25.9% compared to 16.7%, p = 0.298).
- Importantly, none of the electrophysiologist respondents had a history of spondylosis before working in interventional electrophysiology.
- Electrophysiologists with cervical spondylosis were likely to be somewhat older (49 vs. 44 years) and to have worked in the specialty longer (20 vs. 13 years) compared with other physicians.
- Other variables evaluated (body mass index [BMI], type of lead used in apron, weekly average lead time, and percentage of time standing in electrophysiology lab) were not independent predictors of disease.

In 2004 the Interventional Committee of the Society for Cardiac Angiography and Interventions (SCAI) conducted an online survey of its Internet-registered members – a group primarily composed of invasive cardiologists.

- Of the 424 respondents, 42% reported spine problems. This rate is dramatically higher than the 27% general incidence of chronic back conditions among U.S. adults.
- Additionally, more than one-third of respondents reported missed work due to spine problems.
6. HOSPITAL FINANCIAL IMPACT AND RISK PROFILE OF MEDICAL RADIATION

When hospitals develop cost-benefit analyses, they rarely consider the impact of medical radiation. The short-term radiation concerns most likely to affect a hospital’s bottom line are the financial losses associated with needing to potentially “bench” catheterization lab staff to protect them from excessive exposure, as a means of protection in the workplace environment. The long-term risk and insurance or other liability of key staff developing radiation-induced illness, and the costs associated with treating these illnesses, must also be considered.

There is no standard practice to obtain patient informed consent for radiation-induced injury risk or to assess future economic liability associated with prior radiation exposure. Costs related to medical radiation exposure are increasingly incurred to hospitals, based on medicolegal theories of liability related to patients’ undue radiation exposure. Such lawsuits are becoming more common and highlight a need to implement proactive, institution-wide radiation protection measures.

Research documenting per-procedure radiation exposure patterns indicates that protective steps are necessary to ensure the occupational safety of cardiac lab staff.

- In 2010, Butter and colleagues evaluated the intensity of fluoroscopic radiation exposure received by interventional cardiologists during cardiac resynchronization therapy (CRT) over 104 consecutive procedures. To accomplish this, radiation dosimeters were placed on the surgeons’ forehead at eye level, and on the right hand.

- The maximum radiation dose measured at the physician-operator’s hand during a single implantation procedure was 9.2 mSv. Based on this, the authors recommended that surgeons limit themselves to a maximum of four such procedures per month.

- The goal of this limit was to avoid exposure exceeding the International Commission on Radiological Protection’s annual limit of 500 mSv to extremities (hands or feet).

- The authors also noted that, if the mean CRT procedure radiation dose could be reduced to 1.2 mSv, the number of procedures that could be safely performed by an individual practitioner would increase by sevenfold.

In theory, a system is already in place to protect physicians. Cardiologists who are occupationally exposed to radiation are typically required to wear electronic dosimeters (“radiation badges”) during procedures. These badges measure cumulative exposure and determine when annual and/or daily exposure thresholds have been reached.

To avoid exceeding recommended exposure levels as assessed by radiation dosimeter, however, cardiologists sometimes have to stop working altogether before the end of the year, which may lead to financial loss for the hospital.

- In a survey conducted among cardiologists by the Society for Cardiovascular Angiography and Interventions (SCAI) (N = 380), 6% of physicians reported having had to stop work at some point during the year because they exceeded their maximal radiation limit, as measured via radiation badge.

Based on this, hospitals are faced with a risk of financial loss from two perspectives: the direct procedural revenue loss, if they are unable to quickly find an adequate replacement electrophysiologist or interventional cardiologist as skilled as the “benched” clinician; as well as the potential expense of needing to continue paying salary for “benched” surgeons who have reached their annual radiation limit. As hospitals increasingly employ physicians, they must incorporate this added cost of salary payment for non-producing members of the catheterization lab into their risk assessments, and pro forma financial statements.

- A 2010 inpatient/outpatient survey of 114 hospital chief financial officers (CFOs) found that invasive cardiology departments generated the second-largest overall mean institutional revenue (following neurology), at $2.2 million annually.
• The same survey identified mean cardiologist salaries at $475,000.106

• A recent report indicates that, between 2007 and 2012, the percentage of cardiologists working directly for a hospital (as opposed to contracting their services) increased from 11% to 35%. Likewise, the percentage of cardiologists working in physician-owned practices has decreased from 59% to 36% over this same time period.107 The financial implications of having “benched” surgeons due to excess radiation exposure will become a more acute issue for hospitals as more cardiologists transition to being fully salaried employees (with associated benefits and Workers’ Compensation).

Avoiding the Issue Through Noncompliance

To avoid documentable over-exposure, many clinicians simply avoid wearing their radiation badges.

In a survey conducted among cardiologists by the Society for Cardiovascular Angiography and Interventions (SCAI; N = 380), 18% of the cardiologists surveyed reported not wearing a dosimeter at some time point due to concerns about exceeding a radiation limit.105

• In cases like this, hospitals open themselves to liability when surgeons willfully over-expose themselves to radiation, as work-related radiation exposure may lead to related illnesses that require costly treatments.

A radiation-safe hospital environment is a risk-averse institutional strategy, as well as a budget-effective approach for a facility supporting catheterization laboratory procedures. Invasive cardiology and electrophysiology is one of the most profitable service lines for U.S. hospitals,106 and any steps taken to maximize this line’s efficiency, as well as the health and well-being of affiliated cardiologists, can be expected to generate substantial returns.

Facing the Challenge of Occupational Radiation Exposure: An Electrophysiologist’s Story

Testimonial of Anonymous*

I have spent almost 7 years as an attending physician in a busy clinical electrophysiology laboratory. Prior to that, during my last several months of fellowship training, I was given the opportunity to get more hands-on experience and I performed many interventions as first operator. A large percentage of these were fluoroscopy procedures.

Just as I was completing my fellowship and preparing to assume the position of attending physician, the hospital informed me that my cumulative radiation dose had reached the maximum exposure limit for that year. To avoid further exposure, I was required to sit out for 6 months. This meant that I was suspended from performing EP laboratory procedures for the remainder of the year. In addition, I was instructed to enroll in radiation safety classes. Today, because of my years of experience, I am able to perform a high volume of procedures while maintaining a moderate level of radiation exposure. In addition to my clinical practice, I spend a fair amount of time training fellows in the EP lab. During these instructional sessions, I am always careful to position myself between the trainees and the radiation source.

In order to avoid the possibility of suspension due to excess radiation exposure, I take other steps to avoid reaching maximum dose limits. For instance, I often tape my dosimeter badge to the EP lab door so that it registers a lower total monthly radiation dose. This is a practice followed by many of my colleagues, and in fact, my senior partner was the person who originally suggested the idea. Although I realize this does not comply with safety guidelines, I don’t have major concerns about the risks involved.

I feel optimistic that some of the newer technologies currently under development will help to dramatically decrease radiation exposure. Examples include fluoroscopic cine loops and contact force-controlled zero-fluoroscopy catheter ablation. However, even though it is possible to use nonfluoroscopic navigation systems, fluoroscopy is still the only way to determine when you have hit tissue.

I believe that hospital administrators care about the issue of radiation safety, and want to find appropriate long-term solutions that will minimize the health risks to their patients and staff.

*Name and affiliation have been changed to protect the physician’s privacy.
A Financial Dilemma for CFOs and Clinicians

The regulatory and legal landscape for medical radiation exposure is in a period of rapid flux. In the next few years, it is expected that new, proactive federal regulations designed to monitor and track patient and physician radiation exposure due to medical imaging will be finalized. These will be implemented alongside educational programs designed to train physicians on the risks of medical radiation.21

Physicians do not want to sacrifice their own well being, but they also do not want to stop working midway through the year. Likewise, hospitals do not want to be exposed to the losses associated with unavailable staff.

- Figure 16 shows 2011 inpatient/outpatient utilization obtained from the Millennium Research Group. This represents a sampling of more than 5,000 U.S. hospitals’ treatment of Medicare and non-Medicare patients. It documents average allowable Medicare reimbursement rates associated with selected cardiac procedures, based on diagnosis-related groups (DRGs) and ambulatory payment classifications (APCs), as well as mean procedural volumes.

In the event that one electrophysiologist (in a laboratory where procedural volume is shared with another equivalent electrophysiologist) was unable to perform common procedures in the last quarter of a fiscal year, including ablations, ICD/CRT implantations, and EP tests, a typical facility with both inpatient and outpatient billing departments could stand to lose significant revenue in one quarter alone.

- As shown, hospitals that must reduce their EP lab performance capacity due to physician radiation overexposure stand to lose substantial annual income. In the case of ablation procedures, for example, the annual losses associated with just one physician being unable to perform during the final quarter of the year would exceed $200,000.

- At this point, cardiologists would be required to choose between their own personal safety and their ability to continue performing interventional procedures.

- Likewise, hospitals would be put in the difficult position of needing to substantially increase catheterization lab staffing, just to maintain existing performance levels.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Annual procedure revenue ($) inpatient/outpatient</th>
<th>Average quarterly number of inpatient procedures</th>
<th>Average quarterly number of outpatient procedures</th>
<th>Projected revenue loss: 1 of 2 EPs cannot perform in Q4</th>
<th>Projected revenue loss: 1 of 2 EPs cannot perform in Q3 and Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablations</td>
<td>$1,638,899</td>
<td>19</td>
<td>24</td>
<td>($204,862)</td>
<td>($409,725)</td>
</tr>
<tr>
<td>ICD / CRT</td>
<td>$5,399,664</td>
<td>35</td>
<td>47</td>
<td>($674,958)</td>
<td>($1,349,916)</td>
</tr>
<tr>
<td>EP test</td>
<td>$1,293,474</td>
<td>15</td>
<td>34</td>
<td>($161,684)</td>
<td>($323,369)</td>
</tr>
</tbody>
</table>

Data obtained from Millennium Research Group; proxy values using average Medicare DRG and APC payments

CRT + D = cardiac resynchronization therapy + defibrillator; EP = electrophysiologist; ICD = implantable cardiac defibrillator; Q3 = third quarter; Q4 = fourth quarter

Figure 16: Estimated Annual Inpatient/Outpatient Revenue Loss Due to One Electrophysiologist’s (Operating in a Lab of Two EPs) Inability to Perform Interventional Cardiac Procedures in a Fiscal Year
The substantial, occupational lifetime radiation exposure experienced by medical professionals in the electrophysiology lab is of concern because the performance of specialized cardiac imaging procedures is increasingly concentrated in a group of highly active practitioners whose careers span \( \geq 30 \) years. These professionals often work for hours every day in the catheterization laboratory, and in addition to their medical training, are required to complete a Fellowship program in clinical cardiac electrophysiology.\(^{29,33,108}\)

- Therefore, these physicians represent a substantial financial and time investment in terms of medical education, training and recruitment.

Aside from the clear financial impact and risk noted above, as U.S. regulatory and medicolegal environments continue to place pressure on facilities regarding radiation compliance and risk exposure, it will become increasingly important to ensure the adoption of institutional best practices, as well as the implementation of technologies that lower radiation exposure risk. Efforts taken now to reduce radiation exposure and develop a radiation-safe hospital environment can help preserve both hospital revenue and the safety of staff members.
A large number of regulatory measures have been proposed at the federal and state levels to help protect health care professionals and patients from excess medical radiation exposure.

The U.S. National Research Council\(^\text{23}\) reports that the widespread use of medical imaging procedures, alongside extended fluoroscopic exposure times for patients and operators, indicates a need for more focused radiation dose-recording, follow-up research, as well as strategies to substantially reduce procedure-related medical radiation exposure.

The International Commission on Radiological Protection (ICRP) has observed that “Medical exposure is the only [radiation exposure] category in which large reductions in average dose are possible.”\(^{109}\) Therefore, to protect physicians and patients, health care facilities must implement radiation-sparing strategies.\(^{95}\)

As of 2012, no U.S. federal regulatory requirements were in place to require the recording or reporting of radiation dose for interventional procedures.\(^{76}\) However, a number of professional groups, including the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) and the National Council on Radiation Protection and Measurements (NCRP) are working to establish nationally recognized reference levels for many imaging procedures. The U.S. FDA has been an active participant in these discussions.\(^{55}\)

- In 2010, the U.S. FDA announced plans to require manufacturers of fluoroscopy and computed tomography (CT) devices to incorporate features that provide clinicians with radiation exposure information.\(^{55}\)
- In 2011, the U.S. Joint Commission issued a Sentinel Event alert recommending new radiation-protective actions for hospitals. These include: ensuring that proper dosing protocols are in place; performing equipment safety evaluations; and establishing a culture of patient safety that provides education to physicians and technologists on radiation exposure and appropriate equipment usage.\(^{10,110}\)

- Simultaneously, it has been recognized that several common-sense measures can be put in place to keep radiation dose as low as reasonably achievable.\(^{111}\) These include: applying frame rate reductions to fluoroscopy and cine acquisition; using clinician shielding procedures; adjusting fluoroscopy monitor placement; and/or using modified imaging equipment to achieve patient/staff exposure reductions.\(^{77}\)

One of the first steps to achieving reduced medical radiation exposure is to increase the understanding of medical radiation risk at the physician and hospital levels. Available evidence indicates that awareness of medical radiation effects may be suboptimal in the medical community.\(^{35}\)

- Several studies demonstrate that cardiologists and other medical specialists – in particular, those who work regularly with radiation-emitting devices—tend to overlook radiation dose and/or underestimate the radiation-related risk associated with their work.\(^{96,112-116}\)
- Cardiologists may also be imperfectly aware of the radiologic dose range associated with the imaging procedures they provide.\(^{14}\)

To ensure the long-term safety and good health outcomes of clinicians and patients, more effort is needed to better quantify radiation exposure among these individuals. Unfortunately, electronic dosimeter safety features that alert wearers to doses exceeding diagnostic reference levels, or that surpass peak skin-dose thresholds for radiation-induced skin injury are not yet standardized.\(^{55}\)

However, the standardization of dosimeter safety will not solve the problem – high-risk medical professionals report that they often do not wear their dosimeters (Figure 17).

- In a survey conducted by the International Atomic Energy Agency (IAEA) during a training course involving interventional cardiologists from more than 56 countries, respondent physicians reported wearing their dosimeter badges only 33% to 77% of the time.\(^{109}\)
In a survey conducted among cardiologists by the Society for Cardiovascular Angiography and Interventions (SCAI; N = 380), 76% reported wearing their dosimeter almost all the time; however, 16% reported only occasional dosimeter wear and 8% reported never wearing a dosimeter badge.\textsuperscript{105}

Responding to rising concerns in the radiology community and the public, the U.S. FDA announced a new initiative in February 2010 aimed at reducing unnecessary radiation exposure due to medical imaging.\textsuperscript{21,117} The FDA intends to issue targeted requirements for fluoroscopic and computed tomography device manufacturers to incorporate new national dose registries. The FDA will also help to develop a patient medical imaging history card.\textsuperscript{21,117}

Other steps toward increased reporting standardization for medical radiation are already occurring at the U.S. state level:

- In 2012, California implemented a medical radiation protection law with several mandates, including a requirement that the radiation dose delivered with each scan be recorded in a patients’ radiology report.\textsuperscript{118}

- It also requires institutions to notify physicians within 5 days, and patients within 15 days post-exam if any of the following events occur: repeat exams pass specific stated radiation thresholds; a non-intended body part is irradiated; fetal dose exceeds 50 mSv; or if the total radiation dose delivered differs by more than 20% from the prescribed dose.\textsuperscript{118}

- Finally, the law will require imaging facilities to obtain accreditation by 2013 from an agency approved by the Centers for Medicare and Medicaid Services (CMS), the Medical Board of California or the State Department of Public Health.\textsuperscript{118,119}

This new mandate will likely serve as a framework for similar legislation to be crafted in other states.\textsuperscript{72,118,120}

Historically, the need for medical radiation protection has not been addressed by the introduction of new imaging technologies. However, the proliferation of imaging procedures has led CMS and the federal government to seek to lower costs related to the use of imaging. This will be accomplished through existing and planned rule-making mechanisms and health care reform measures implemented under the Patient Protection and Affordable Care Act (PPACA).

In 2011, the Physician Quality Reporting System (PQRS), an incentive program driving adoption of electronic health recordation by Medicare providers, included as a measurement: “Radiology: Exposure Time Reported for Procedures Using Fluoroscopy” among its broader listing of core measures. For physicians’ FY-2015 payment determination, the percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time will be used to assess up to a 1.5% payment penalty on fee schedule payments.\textsuperscript{121}

During the same time period, an expansion of regulation related to medical radiation exposure, as well as the efforts of consumer protection groups and nonprofit foundations, can be expected to generate sustained external pressure and emphasis on this issue.\textsuperscript{122}

All of the radiation exposure mitigation efforts discussed within this document are focused on tracking radiation received, and will not necessarily reduce exposure.
8. Conclusion

Over the past 20 years, the use of medical imaging procedures has grown substantially. The total average effective radiation dose per-person in the United States is now 6.2 mSv per year. During this time, radiation exposure from natural or background sources has not changed substantially. However, the proportion of total radiation exposure obtained from medical sources has increased from 15% in the 1980s to 50% today.

Of the medical imaging techniques used in cardiology, fluoroscopy is associated with the highest levels of radiation exposure. Although health risks due to medical radiation may be small at an individual level, when this risk is multiplied by millions of exams conducted each year, it is likely to yield significant, long-term population risk, with associated high costs.

Current conventional fluoroscopy navigation systems result in substantial radiation exposure to patients, physicians and hospital staff. Physicians and staff, in particular, are at risk in the EP lab due to the cumulative effects of repeated radiation exposure.

It is conceivable that, in the near future, purchasers of health technology such as medical imaging will need to compare cost, clinical utility and net health impact (on clinicians, patients and other users) as part of their value-based purchasing and comparative effectiveness goals.
Appendix

Common Terms Used To Measure Radiation Exposure

It is useful to understand the specific terminology used to describe the magnitude of radiation exposure or dosage received by an individual. Typically, values are expressed using International System Units (SI).\(^\text{19}\)

The two categories of radiation measure are **absorbed dose** and **biological dose**.\(^\text{19}\)

- **Absorbed radiation dose is expressed by the SI unit, the gray (Gy).** The absorbed dose quantifies the amount of physical energy by unit weight deposited in human tissue or organs. Prior to the use of SI units, absorbed dose was expressed in terms of rads or “rad;” 1 Gy = 100 rad.\(^\text{19}\)

- **Biological radiation dose is expressed in the SI system as sieverts (Sv).** Biological dose or dose equivalent is the rate and amount of total energy deposited into human tissues and organs. When absorbed dose is conveyed in terms of rad, the dose equivalent unit is the “radiation equivalent-man” or rem; 100 rem = 1 Sv.\(^\text{19}\)

Human absorbed radiation exposure is generally measured in milligray (mGy) or 0.001 gray. One Gy represents 1 J/kg or 100 rad (0.01 joules per kilogram of absorbed irradiated material).\(^\text{19}\)

- \(\leq 1\) Gy of absorbed radiation to organs or tissue is the acceptable mean dosage limit for an average adult.\(^\text{19}\)

- Radiation doses > 1 Gy cause nausea and blood changes, known as radiation sickness.\(^\text{19}\)

- Doses > 3 Gy can be fatal; at doses > 6 Gy, mortality is likely within several months.\(^\text{19}\)

The probability for human biological damage associated with radiation exposure is typically expressed in millisieverts (mSv) or 0.001 sievert.

A Sv represents the weighted average of equivalent dose, effective dose and collective dose of ionizing radiation when measured in grays. For gamma rays (X-rays) and electrons, 1 Gy = 1 Sv = 100 rem.\(^\text{19}\)

- A rem is equivalent to 3 years of average exposure to natural radiation.\(^\text{19}\)

- For doses < 1 Sv (100 rem), there is little likelihood of radiation sickness, and the main danger is increased cancer risk.\(^\text{19}\)

- For large exposures (> 0.2 Sv), there is a statistically significant increase in occurrence of solid cancer tumors and leukemia.\(^\text{19}\)

- Tissue type is also a factor in determining mean dose equivalents. To calculate dose equivalent, the weighted average is multiplied by the assigned tissues weighting factor (Q).

  - Electron-producing X-rays and gamma rays are assigned a weighting factor, or Q factor, of 1. Therefore, the biological dose of an X-ray would be calculated as the absorbed dose (D) in Gy, multiplied by the Q factor of 1 to get results measurements in Sv.

  - Alpha particles have a Q of 20. The dose equivalent is calculated as Sv \(\times\) 20.\(^\text{19}\)

Table 1 defines common terms used to describe biological effects of types of radiation exposure.
Table 1: Common Terms Describing Biological Effects of Radiation Exposure

<table>
<thead>
<tr>
<th>Dose Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head dose equivalent</td>
<td>The equivalent or effective dose multiplied by a weighting factor (Q) to yield the dose equivalent. In the case of head exposure to radiation by medical professionals, a Q factor of 0.03 is used to calculate the mean dose equivalent.³⁵,³⁶</td>
</tr>
<tr>
<td>Equivalent dose</td>
<td>Absorbed dose multiplied by the weighting factor; this represents the effectiveness of the radiation type.¹⁹,²⁰</td>
</tr>
<tr>
<td>Effective dose</td>
<td>Absorbed dose multiplied by the specific tissue-weighting factor. It represents sensitivity and other differences in tissue types of different parts of the body.¹⁹,²⁰</td>
</tr>
<tr>
<td>Collective effective dose</td>
<td>Estimate of total radiation exposure to a population (for example, gender- or age-specific) over a given period of time.²⁰,¹¹⁹</td>
</tr>
</tbody>
</table>
REFERENCES


