

**Radiologic Monitoring of Faculty and Staff in an Electrophysiology Lab Using
a Real-Time Dose Monitoring System**

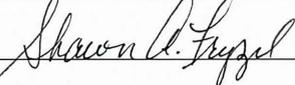
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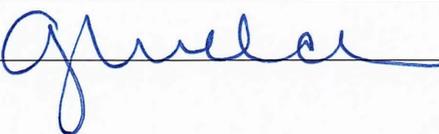
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TABLE OF CONTENTS

List of Tables	3
List of Figures	4-5
Acknowledgments.....	6-7
Abstract	8
Introduction.....	9-14
Review of Literature	15-50
Research Questions and Hypothesis	51-55
Methodology and Data Collection	56-71
Statistical Analysis.....	72-75
Results.....	76-83
Discussion.....	84-92
Conclusion/Recommendations	93-94
Authors.....	95
Appendices.....	96-101
References.....	102-114

LIST OF TABLES

TABLE 1: Radiation Safety Practices, Considerations and Recommendations for Distance, Time and Shielding	11
TABLE 2: Standard IARC Classification.....	18
TABLE 3: Radiation From Tests/Procedures	20
TABLE 4: Reports of Brain Cancer Incidence in Physicians, Radiologists, and Interventionists.....	41
TABLE 5: Unadjusted Descriptive Data of Total Case Parameters.....	80
TABLE 6: Adjusted Data Using Multivariate Linear Mixed Effect Model of Factors Associated With Radiation Dose to Electrophysiologist-Fellow, CRNA, and RN	81

LIST OF FIGURES

	Page
FIGURE 1: Illustration of the Electromagnetic Spectrum.....	22
FIGURE 2: Photoelectric Effect	24
FIGURE 3: Compton Effect	25
FIGURE 4: Radiation Risk Models	29
FIGURE 5: Radiation Exposure Among Various Specialists.....	36
FIGURE 6: Dose-Effect Relationship Between Radiation Exposure and Cancer Risk	37
FIGURE 7: Zero Gravity System	38
FIGURE 8: Dose Rate Chart.....	39
FIGURE 9: EP Lab 3 and Role Positions	52
FIGURE 10: RaySafe i2 Overview: RaySafe i2 System	58
FIGURE 11: RaySafe i2 Dosimeter.....	59
FIGURE 12: RaySafe Real-Time Display	60
FIGURE 13: RaySafe Docking Station	60
FIGURE 14: RaySafe Dose Manager Function.....	61
FIGURE 15: RaySafe Graph–One Day of Exposure– <u>D</u> ose, Peak, Mean	67
FIGURE 16: RaySafe Dose Table	68
FIGURE 17: Pivot Table Calculation of Individual Doses for CRNAs	69
FIGURE 18: Summary Report for Total Dose–Electrophysiologist and Fellow Team: Phase 1	78
FIGURE 19: Summary Report for Total Dose–Electrophysiologist and Fellow Team: Phase 2	79

FIGURE 20: The Relationship of DAP and Kerma.....	82
FIGURE 21: Beam Direction.....	88
FIGURE 22: Nomenclature for Radiographic Projections.	90

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ABSTRACT

Purpose: A real-time dose management system was used to determine if radiation exposure levels would decrease when providers were privy to their real-time radiation exposure levels. Six aggregate categories of providers were first blinded (phase 1) and subsequently made aware of their radiation exposure levels during electrophysiology procedures (phase 2).

Methods: A primary, quantitative crossover study of faculty and staff working in an electrophysiology lab at the University of Michigan Hospitals setting occurred. Participants in the control group was first blinded in phase 1 to their radiation exposure over an 10-week time period. The same group subsequently became the treatment group in phase 2 when over a second 10-week period real-time exposure levels were made available to them. Power analysis, using a 40% decrease in exposure, was calculated using a variance of radiation exposure equal to the mean radiation exposure with 80% power and $\alpha = .05$. Calculations revealed 102 subjects in each treatment and control group were necessary.

Results: Using the mixed effect linear model, a significant decrease in radiation levels occurred in phase 2 as compared to phase 1 for the operator role represented by the combined electrophysiologist-fellow role with a P value of .025. Exposure levels in all other provider groups for phase 1 or 2 failed to reach statistical significance. All dose values were low and well below the US maximum allowable yearly dose of 5,000 mrem per year.

Conclusion: A real-time radiation dose monitoring system during electrophysiology procedures may significantly lower occupational radiation exposure in health care workers.

Keywords: Anesthesia, electrophysiology, ionizing radiation, occupational exposure

INTRODUCTION

The use of ionizing radiation during medical procedures has increased dramatically over the past 25 years, putting health care workers potentially at risk for radiation-induced illness.¹ In 1982, the average yearly dose of ionizing radiation from medical exposures was approximately 0.5 mSv per person in the United States, but by 2006 it had reached 3.0 mSv, representing an increase of almost 600%.² One of the reasons for this rising trend is an increase in minimally invasive interventional procedures, defined as diagnostic or therapeutic procedures controlled and followed under continuous x-ray (fluoroscopy).³ Although it was originally mostly radiologists who performed fluoroscopically guided interventional procedures, today cardiologists perform many interventional procedures as well. Interventional cardiac procedures account for approximately 12% of *all* radiological examinations but may deliver substantially high radiation dose per procedure.⁴ “Most experienced (and most exposed) cardiac electrophysiologists have an exposure per annum of 5 mSv, 2 to 3 times higher than diagnostic radiologists, with a typical cumulative lifetime attributable risk on the order of magnitude of 1 cancer (fatal and nonfatal) per 100 exposed subjects. The excess cancer risk may involve more exposed and less protected organs, such as skin cancer, leukemia, breast cancer in females and brain cancer.”^{5(p79)} As a result of this trend, occupational radiation exposure may be a significant concern for cardiac electrophysiologists and support personnel.

Advantages of minimally invasive procedures over open surgical procedures are the use of a small incision, a substantial reduction in infection rate, and a shorter recovery period. In short, it is a better, safer, and more cost-effective way to practice medicine, and it is therefore predicted that the high demand for these procedures will continue.⁶ The disadvantage of interventional procedures is the potential for provider exposure to considerable levels of

radiation, depending on the laboratory workload and the complexity of the procedures performed.^{7,8} Radiation exposure to room staff occurs primarily as a result of scattered radiation produced from the interaction of the primary radiation beam with the patient and the operating table. Medical personnel standing next to a fluoroscopic unit may be exposed to scatter from all directions likely striking their upper and lower extremities. Throughout these procedures, electrophysiologists and other health care providers are present and delivering patient care. The anesthesia provider (AP) assigned to the room is positioned at the head of the bed, in close proximity to the radiation source, potentially being exposed to radiation throughout the day when providing sedation.

Radiation is an established level 1 carcinogen, which may target and damage DNA and induce cancer-causing mutations.¹ It can produce deterministic effects, which are predictable, dose related responses with a threshold below which the damage does not occur or stochastic effects that are statistically probable effects, not as predictable as deterministic effects. An absolute threshold does not exist with stochastic effects, but the incidence is postulated to increase with increasing dose. Occupational exposure is generally concerned with stochastic effects that result from the chronic and cumulative nature of this type of exposure.

Damaging effects of radiation can be substantially lessened by adhering to radiation safety practices, which are aimed at keeping exposure as low as possible. Minimizing radiation exposure is the goal of the radiation safety acronym, ALARA (*As Low As Reasonably Achievable*) that is defined in the Code of Federal Regulations, (NRC 10 CFR 20.1003).⁹ Suggested practices for achieving the ALARA goal include proper use of time, distance, and shielding (Table 1).

Table 1: Radiation Safety Practices, Considerations, and Recommendations for Distance, Time, and Shielding¹⁰

	Distance	Time	Shielding
Radiation Safety Practices	Inverse Square Law: The intensity of a beam is inversely proportionate to the square of it's distance from the radiation source. Example: Doubling distance from source results in 1/4 the dose.	Minimization as much as possible.	Lead aprons: .5 mm lead Thyroid collars: .25 mm lead Lead goggles: .5 mm lead Pregnant AP: 1.0 mm lead at level of the fetus Portable lead shields
Considerations	Challenging: Frequent radiation <1 foot due to needs of patient.	Challenging: Case scheduling not in control of AP	Attainable provided: 1) Tailored to fit each AP 2) Wrap around lead best because it protects from all angles 3) Use of Ultra-lite lead to avoid Orthopedic injuries/strains from older, heavier lead.
Recommendations	American College of Cardiology: 3-6 feet at all times	Minimization, but amount of time not defined.	National Council on Radiation Protection: Adult AP: 5,000mrem/year Pregnant AP: .5 mSv/month Fetus: 5 mSv for entire gestational period

mrem=millirem mSv=millisieverts AP= Anesthesia Provider

Although ALARA principles are good in theory and offer protective devices and precautions to reduce exposure, they are often difficult to fully implement because of the required proximity of the provider to the patient, examination complexity, need for maintenance of a sterile field, and cramped working conditions. Standard setting committees, such as the International Commission on Radiation Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP), ideally would like to accomplish zero exposure. However, realistically, this is not possible if society is to realize the enormous benefits from the use of radiation and radioactive materials. Therefore, it is advisable that facilities and equipment are designed to minimize patient and medical personnel's exposure rather than aiming for a

specific dose standard. However, the problem remains determining what is reasonable given the relative risks and benefits to be achieved.¹¹

Radiation at most institutions is measured by a dosimeter, which is a device worn as a badge by personnel during a case involving ionizing radiation, that quantifies exposure produced by scatter. Dosimeters currently worn at most institutions are categorized as passive, whole body monitors, utilizing optically stimulated luminescence technology. Most institutions use passive dosimeters because they are simple, accurate, durable, and reliable. However, they do not offer the provider feedback until many weeks/months later after being analyzed at an outside facility. At this institution, badges are worn for 3 months before being processed. An additional 7 to 14 days are necessary as the badges are sent out for evaluation.¹² Therefore, a provider at this institution will not have radiologic feedback if their badge is elevated for an approximate 3.5-month timeframe. Radiation safety services notify individual employees if their readings are elevated. This methodology does not allow the provider the ability to institute extra precautions or change behavior as a result of knowledge of his/her real-time exposure at the point of care. Immediately available radiologic information could be very beneficial to providers so they may take corrective actions to lessen their exposure during the procedure.

While patient radiologic exposure has been the subject of attention in the literature, personnel exposure is less well studied.¹³ It is well known that the use of passive personal dose meters is associated with noncompliance, which makes quantification of exposure difficult. “Failure to wear dosimeters is a problem throughout the world. Lack of compliance with radiation badge policies is a problem in many interventional cardiology services.”^{14(p77)} Additionally, passive dosimetry does not allow for optimization of radiation protection. One of the requirements of optimization is knowledge or awareness of occupational dose levels and how

different behaviors affect these levels.¹⁵ Therefore, efforts to aid in increasing compliance and improving knowledge regarding exposure are indicated. One of the solutions to the issue of noncompliance and the need for improvement of radiologic feedback is to increase awareness of exposure in real time. Several studies have supported improving awareness with the use of a real-time dose monitor.^{13,16,17}

A real-time dose monitoring system represents another option for monitoring radiologic scatter and provides immediate feedback regarding radiation exposure on a case-by-case basis. Currently, such dosimeters are not intended at present to replace for passive dosimeters, as they do not measure effective whole body dose. Real-time dose monitors use digital sensor technology, and at present there are no governmental regulations on how to use them. However, this may change in the future. Real-time dosimeters allow providers the ability to visualize their exposure rate (instantaneous) expressed as uSv per hour, as well as their dose per case or cumulative total, expressed as mSv and may increase awareness of their exposure.¹⁸ Racadio et al, in 2014, concluded that, “A radiation dose monitoring system that provides real-time feedback to the interventional staff can significantly reduce radiation exposure to the primary operator, most likely by increasing staff compliance with use of radiation protection equipment and dose reduction techniques.”^{19(p119)} It is hypothesized that if providers had real-time exposure data, they would take more precautions and total exposure levels would decrease. Therefore, the research question in this study is: Will the use of a real-time monitoring system result in decreased aggregate exposure among faculty and staff working in an electrophysiology lab (EPL)?

If personnel were aware of which tasks lead to elevated radiation exposure, they could conceivably avoid/minimize these practices to lower their exposure. Electrophysiologists and

fellows, who are at constant close proximity to the radiation source, may lower delivered doses by altering techniques that minimize elevated exposure associated with cine duration, projection angle, pulsed fluoroscopy, and collimation. This awareness could also decrease cumulative total radiation received by the patient during the case. Anesthesia providers, RNs, and technicians working in the electrophysiology (EP) suite may gauge when to approach the operative field by visual cues, maintaining optimal care without compromising the health of the provider.

Radiologic protective devices such as lead aprons, thyroid shields, and glasses help to attenuate exposure but do not provide optimal protection from radiation. Simultaneously minimizing work habits that lead to elevated exposure and maximizing compliance while maintaining excellence of patient care is mutually achievable. These goals may be facilitated by increased immediate awareness of exposure by the use of real-time radiation dose monitoring.

REVIEW OF THE LITERATURE

Historical Perspectives

Wilhelm Conrad Rontgen is credited with the discovery of x-rays in 1895. Through his experimentation with electric current flow using a gas discharge tube, he became aware that certain rays were emitted. Crystals of barium platinocyanide, which were scattered on the table, began to give off light when the gas discharge tube glowed. Further examination showed that wood, paper, aluminum, and some other materials were transparent to these rays. Lead glass was permeable to light but not to these rays. He utilized his wife's hand to look inside the human body for the first time. Dr Roentgen was uncertain of the nature of his findings, so he called this phenomenon "x-rays" with the "x" indicating the unknown. Doctors quickly learned to use these pictures as a diagnostic tool. Dr Rudolf Albert von Kolliker, a colleague, suggested that these pictures should be named after the discoverer and so, the Roentgen or x-ray is the name used today.²⁰

The first medical use of x-rays was described in *The Lancet* on January 23, 1896. The report indicated x-rays were utilized diagnostically to locate a piece of knife in the backbone of a drunken sailor who was paralyzed until it was surgically removed. This new technology spread quickly throughout Europe and the United States. The first therapeutic use of x-rays also occurred in 1896 when Leopold Freund, an Austrian surgeon, demonstrated before the Vienna Medical society, a hairy mole removal after treatment with x-ray.¹¹

The same year Antoine Henri Becquerel described radioactivity emitted by uranium compounds, and, in 1898, Pierre and Marie Curie isolated the radioactive elements polonium and radium.¹¹ The beneficial nature of radiation was realized a few years later when radium was used to treat cancer. Marie Curie received the Nobel Prize for her work in radioactivity in 1911.²¹

An awareness of the hazardous effects of radiation was also soon recognized in the early 20th century. Much of the knowledge of the damaging effects of radiation often came at great personal loss or death. The first recorded untoward biologic effect of radiation occurred when Becquerel described the effects of an accidental contact with radium. He inadvertently left a container of radium in his vest pocket. Two weeks later, he described the subsequent skin erythema that occurred as well as ulceration that required several weeks to heal.¹¹ It is understandable that scientists were unaware of the potential devastating effects of radiation due, in part, to the slow onset of symptoms from exposure. Who would suspect an invisible ray, similar to light, would be dangerous? Pierre Currie expressed the destructive potential of radiation when he theorized radiation could become dangerous in criminal hands and questioned whether mankind would benefit from unlocking this “Pandora’s box” of nature. He was particularly concerned about the destructive properties of radiation use in war.²¹ It is tragic that Pierre’s fears of the harmful nature of radiation were realized in his own family. His wife, Marie, and his daughter, Irene, are both thought to have died from leukemia, induced by prolonged exposure to radiation.¹¹ Ultimately the widespread use of radiation resulted in many more serious injuries. Therefore, the field of health physics, whose primary focus is the health and safety of people working with radioactive materials, was born.²¹

The Use of Radiation in Medicine

The existence of radiation has been known for a little over a century. Since its discovery, knowledge of its benefits to humans has been weighed against the risk of its potential negative effects. Beneficial effects of radiation are utilized in countless places in society; these include medicine, agriculture, academics, and industry. In medicine, the benefit of radiation’s physical

properties have been utilized in the diagnosis, monitoring, and treatment of a wide variety of metabolic processes and disease states. For example, radioactive iodine is used to treat thyroid and other cancers. Lives have been saved, life span lengthened, and the quality of life improved as a result of the careful application of radiation to the treatment of disease. But, the use of radiation is also associated with undesired consequences. These include the potential inducement of damage to cellular DNA. Radiation is categorized as a level 1 carcinogen as classified by the International Agency for Research of Cancer (IARC).²² The IARC categorizes cancer risk into 4 categories based on existing scientific evidence of carcinogenicity (Table 2).

Table 2: Standard International Agency for Research on Cancer (IARC) Classification²²

<p>Group 1: <i>"The agent (mixture) is carcinogenic to humans.</i> The exposure circumstance entails exposures that are carcinogenic to humans." "This category is used when there is sufficient evidence of carcinogenicity in humans. Exceptionally, an agent (mixture) may be placed in this category when evidence of carcinogenicity in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals, and strong evidence in exposed humans that the agent (mixture) acts through a relevant mechanism of carcinogenicity." Examples include asbestos, benzene and <i>ionizing radiation</i>.</p>
<p>Group 2A: <i>"The agent (mixture) is probably carcinogenic to humans."</i> "The exposure circumstance entails exposures that are probably carcinogenic to humans." "This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. In some cases, an agent (mixture) may be classified in this category when there is inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent, mixture or exposure circumstance may be classified in this category solely on the basis of limited evidence of carcinogenicity in humans." Examples include diesel engine exhaust, formaldehyde, and PCBs.</p>
<p>Group 2B: <i>"The agent (mixture) is possibly carcinogenic to humans."</i> "The exposure circumstance entails exposures that are possibly carcinogenic to humans. This category is used for agents, mixtures and exposure circumstances for which there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, an agent, mixture or exposure circumstance for which there is inadequate evidence of carcinogenicity in humans but limited evidence of carcinogenicity in experimental animals together with supporting evidence from other relevant data may be placed in this group." Examples include styrene and gasoline exhaust.</p>
<p>Group 3: <i>"The agent (mixture) is unclassifiable as to carcinogenicity in humans."</i> "This category is used most commonly for agents, mixtures and exposure circumstances for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals. Exceptionally, agents (mixtures) for which the evidence of carcinogenicity is inadequate in humans but sufficient in experimental animals may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans. Agents, mixtures and exposure circumstances that do not fall into any other group are also placed in this category." Examples include anthracene, caffeine and fluorescent lighting.</p>
<p>Group 4: <i>"The agent (mixture) is probably not carcinogenic to humans".</i> "This category is used for agents or mixtures for which there is evidence-suggesting lack of carcinogenicity in humans and in experimental animals. In some instances, agents or mixtures for which there is inadequate evidence of carcinogenicity in humans but evidence suggesting lack of carcinogenicity in experimental animals, consistently and strongly supported by a broad range of other relevant data, may be classified in this group." The only agent in that group is: caprolactam.</p>

Medical procedures using radiation commonly involve the use of x-rays.²³ An electrical device that accelerates electrons to a high energy and then stops them abruptly in a tungsten or gold target produces x-rays outside the molecular nucleus, artificially.¹¹ Some of the kinetic energy produced by the electrons is then converted to x-rays.¹¹ When exposed to x-rays, photographic film detects shadows that are produced from bones and other structures because they are denser than skin. Over time, technologic advances have yielded smaller, lighter, and more portable equipment in which higher quality images are produced, but the basic principle of capturing images with x-rays remains the same.²¹

The use of medical radiation has steadily increased since the 1980s such that it now nearly rivals background radiation. Much of the rapid growth in this trend has occurred from the increased use of computed tomography (CT) scans that deliver a great deal more radiation than ordinary x-rays.²⁴ Table 3 shows the variation in radiation from tests and procedures and indicates CT scans have an effective dose ranging from 10 to 23 mSv.²⁴ CT uses a pencil-thin x-ray to take multiple images, which are then transferred to a computer where the images are displayed in 3D and can be rotated and enlarged on screen. CT is excellent for looking at soft tissue, but the radiation exposure can be minimal to high depending on the part of the body being studied.²⁵ Many times, patients are excessively scanned because of financial incentives, fear of lawsuits, uninformed physicians, misinformed patients, patient demand, and lack of regulation.²⁵ Because of the high exposure levels produced by CT scans, it is suggested that patients inquire if the test is necessary, check the ordering physician's credentials, ask for the lowest effective dose for their size, and avoid unnecessary repeat scans.²⁵ Although CT scans do pose increased exposure risk for the patient, medical personnel receive minimal if any occupational radiation exposure because personnel are generally not directly involved or present in the suite when the

CT examination is being conducted.

Table 3: Radiation From Tests/Procedures²⁴

Sources: American College of Radiology, Health Physics Society, research and review articles

Test or procedure	Effective radiation dose in millisieverts (mSv)
Dental x-ray	0.005
Chest x-ray	0.02
Mammogram	0.7
Coronary calcium scan	1–3
Background radiation over a year	3
Abdominal CT	10
Cardiac CT	
64-slice	7-23
320-slice	10–18
Angioplasty	7–57
Technetium stress test	6–15
Thallium stress test	17
Dual isotope stress test	18–38
Angiogram	2–23
Echocardiography	
Magnetic resonance imaging (MRI)	
The sievert reflects the biological effects of radiation on tissues.	

Most radiation exposure to medical personnel occurs as a result of commonly utilized x-ray procedures. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2008 report indicated fluoroscopic procedures represent the largest source of occupational exposure in medicine.⁴ “Interventional fluoroscopy procedures are medical procedures in which potentially high dose rate x-ray fluoroscopy with high temporal resolution may be used to guide navigation, placement or manipulation of medical devices inside the human body.”^{26(p339)} Under fluoroscopy, the patient is imaged to guide diagnostic and therapeutic procedures, which require medical and technical staff to directly participate.⁴ So, unlike CT procedures, fluoroscopic procedures, which are utilized in the EPL, require that staff is present in the room during the entirety of the exam. Therefore, “electrophysiologists and support personnel may be exposed to considerable levels of radiation, depending on the laboratory workload and complexity of the procedures.”^{7(p644)}

Radiation Overview

Radiation is defined as the emission and propagation of energy through matter or space either by means of subatomic particles or by electromagnetic disturbances.¹¹ The nucleus of a given atom is composed of a certain number of positively charged protons and neutrally charged neutrons. This nucleus is surrounded by a rotating cloud of negatively charged electrons, identical in number to the protons in this nucleus. As a result, the charges of the electrons and protons cancel each other out, producing a neutrally charged atom. Common forms of particle radiation include alpha radiation (consisting of a packet of 2 protons and 2 neutrons ejected from a nucleus) and beta radiation (consisting of an electron ejected from an atom).¹¹

Electromagnetic radiation is pure energy, which can be described alternatively as either a massless photon with a particular energy or a wave of a particular frequency traveling at the

speed of light. ¹¹Radiation can also be classified as ionizing or nonionizing. Ionizing radiation is defined as radiation that has the potential to strip electrons from an atom, therefore producing a positively charged, chemically reactive ion from the original atom. Particle radiation can be ionizing or nonionizing, depending on whether the particle is traveling fast enough to deliver sufficient energy to an atom to cause an electron to exit. Low frequency (and therefore low energy electromagnetic radiation) such as electric and magnetic fields, radio waves, microwaves, infrared, visible light, and ultraviolet light are examples of non-ionizing radiation. High frequency (and therefore high-energy electromagnetic radiation) such as shortwave ultraviolet light, x-ray and gamma radiation are examples of ionizing electromagnetic radiation. The electromagnetic spectrum is represented in Figure 1.¹¹

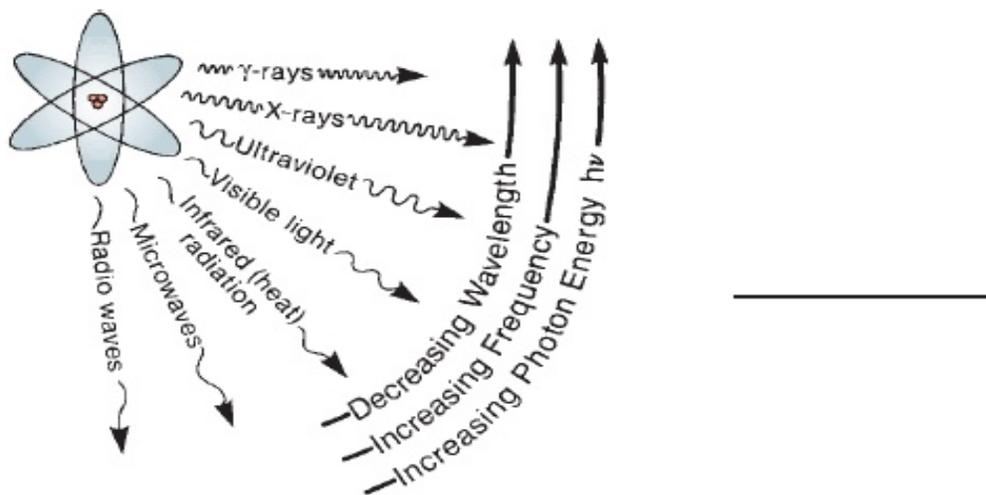


Figure 1: Illustration of the Electromagnetic Spectrum. X-rays and gamma rays have the same nature as visible light, radiant heat, and radio waves; however, they have shorter wavelengths, and consequently, larger photon energy. As a result, x-rays and gamma rays can break chemical bonds and produce biologic effects.^{11(p5)}

On average, a US resident receives an annual radiation exposure from natural sources of about 310 mrem.²⁷ According to a lecture on risk assessment (Donna Livant, PhD, University of Michigan, October 17, 2013), natural radiation is always present in the environment and includes

cosmic radiation, ingested radioactivity, and radiation from the earth's crust. Cosmic ray radiation originates from outside the solar system and from charged particles emanating from the sun. It accounts for approximately 26 to 50 mrem per person per year. Ingested radioactivity occurs when small traces of radioactive materials are ingested either in food or are inhaled as airborne particles. Radioactive thorium, radium, and lead in small quantities can be detected in most people. Radioactive potassium-40 represents the largest contributor in food with a dose rate of 20 mrem per year. Inhaled radioactivity, primarily radon gas, emanates via seepage through the basement of a house from rocks underground. It accounts for approximately 200 mrem per year and is the largest contributor to background radiation. Finally, naturally occurring radioactive materials in the earth's crust are widely distributed across the country, and humans are exposed to varying gamma rays from them. Quantities vary with the Colorado plateau containing more radioactive thorium and uranium registering the highest level at 75 to 140 mrem per year. The Northwest, Central and West is intermediate with values of 36 to 75 mrem per year and the Atlantic/Gulf Coasts are the lowest at 15 to 35 mrem per year.

In addition to natural background radiation, the human population is exposed to various sources of radiation that result from human activities. Medical radiation is the largest contributor to this category. Diagnostic and therapeutic medical procedures such as CT scans, x-rays, and nuclear medicine contribute, as previously referenced, an additional 300 mrem per year.²

Occupational exposures from ionizing radiation represent the final source of annual radiation exposure. Scatter radiation represents the primary form of occupational exposure to faculty and staff.¹⁰ The energy from x-rays is distributed in 3 possible directions upon striking internal structures. First, all the energy can be absorbed by a process called the photoelectric effect (Figure 2).¹¹ Second, some energy travels directly through the patient to the image

detector, which produces an image. Third, emitted photons interact with a “free” electron giving it a portion of it for kinetic energy. The remaining energy contained in the photons is deflected and changed in direction, producing scatter. The Compton effect describes scatter radiation that produces hazardous occupational exposure for personnel.^(11,28) For most individuals in this country, occupational exposure represents <0.1% of the total radiologic exposure.¹¹ But, for those individuals whose jobs are defined by a consistent daily or weekly exposure to x-rays, this value can be considerably higher.

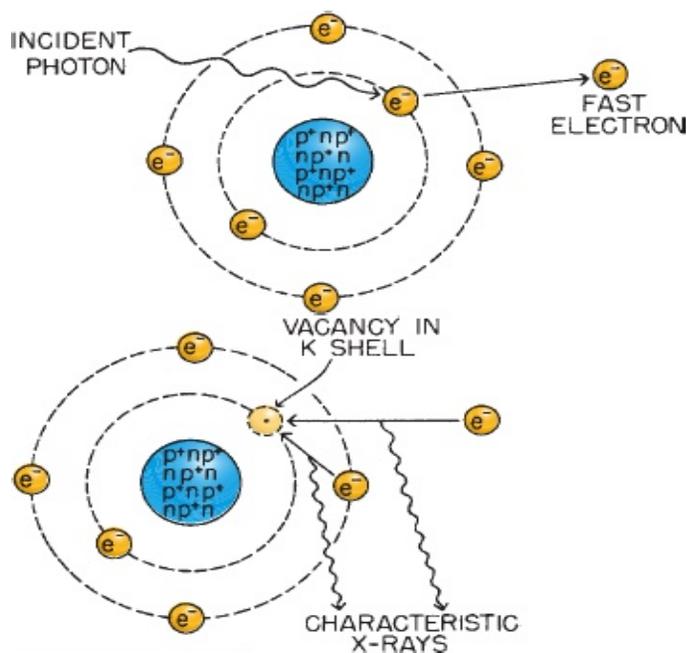


Figure 2: Photoelectric Effect: The complete absorption of a photon of x-ray energy by an orbital electron. The electron is ejected with a kinetic energy equal to the energy of the incoming photon less the binding energy that previously held the electron in orbit. The vacancy is either filled with an electron from an outer orbit or by a free electron from outside the atom.¹¹

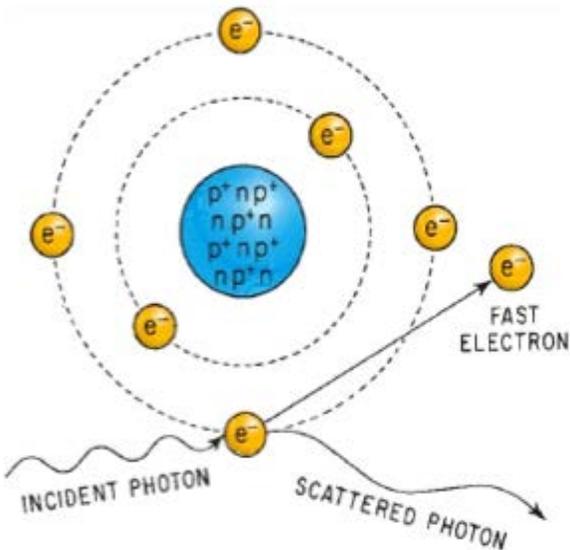


Figure 3: Compton Effect. A photon interacts with a loosely bound electron of an orbital electron of the absorbing material. A portion of the photon energy is transferred to the orbital electron as kinetic energy. The rest of the energy is reduced in the remaining original photon, which is deflected from its original path and proceeds with a longer wavelength due to its reduced energy.¹¹

Radiobiology

Radiobiology is defined as the study of the effect of ionizing radiations on living organisms.¹¹ Central to understanding the effects of radiation is DNA, a macromolecule that carries the genetic material of most organisms and is composed of a sugar phosphate backbone and a nitrogenous base.¹¹ It exists as a double stranded helix held together by hydrogen bonds between complimentary base pairs. DNA is affected by ionizing radiation resulting in the loss or gain of electrons. This reactive process may produce the biological effects of ionization either directly or indirectly. The direct effect of radiation is absorption by a target (DNA), which comprises approximately one-third of all damage.¹¹ The indirect effect occurs when radiation energy is absorbed in nontarget molecules, which then become reactive and subsequently attack the target (DNA). The indirect effect is responsible for two-thirds of all damage.¹¹ One of the primary nontarget molecules is the water molecule. Water interacts with radiation to form

hydroxyl radicals, which are capable of producing damage to DNA. Damage to DNA can involve single and double strand breaks, base damage, or interstrand cross-link damage. It may also result in damage to molecules that regulate vital cellular processes (RNA, proteins, and DNA).¹¹

Damage to DNA may result in 1 of 3 endpoints: (1) enzymes may be unable to repair the damage and the cell dies; (2) enzymes may be able to repair the damaged DNA with no adverse effects; or (3) enzymes may inaccurately repair the damaged DNA, resulting in chromosomal aberrations, which may result in genetic alterations leading to the production of cancerous cells.¹⁰

Radiation damage is described in terms of its deterministic and stochastic effects. Most organs and tissues of the body are unaffected by the loss of a few cells. However, if there is loss of a significant portion of cells, observable harm and loss of function may result. Deterministic effects are acute in nature, and the severity of the effect in affected individuals varies with the threshold dose of exposure. That is, *the severity of the effect is dose related*.¹¹ An example of a deterministic effect is the development of a cataract in irradiated eyes. Most of the information regarding deterministic effects of radiation comes from (a) medically exposed groups, (b) the survivors of the atomic bombings of Hiroshima and Nagasaki, (c) radiation accidents, and (d) animal experiments.²⁹ Stochastic effects describe, “*The likelihood or probability of an effect, rather than its severity, varies with dose. Disease incidence increases proportionally with dose, but there is no dose threshold.*”^{10(p259)} Radiation induced carcinogenesis or inherited mutations are examples of stochastic effects.

Radiation Risk Models: Low Dose Exposure

There is little disagreement regarding the carcinogenic effects of ionizing radiation at high doses.^{1,30} However, the characterization of health effects (cancer and noncancerous) of chronic low-dose radiation is controversial. Several studies indicate the adverse effects of occupational radiation exposure may, over time, be associated with an increased incidence of cataracts, cancers, and possibly other diseases.³¹ Chronic low-dose exposure occurs in the EP area, as almost all procedures require radiation over several hours during any single day. For this study, the electrophysiologist and fellow are positioned to the right of the patient, and therefore are consistently closest to the radiation source. The anesthesia provider's workspace is at the head of the patient's bed and the nursing staff is generally situated to the left of the patient.

Recent case reports of interventionists with left hemisphere brain malignancies support continued safety concerns, since operators typically receive higher levels of ionizing radiation exposure to the left side of their bodies.³⁰ Other reports suggest the evidence implicating occupational radiation-induced cancer caused by fluoroscopy remains circumstantial and inconclusive.³¹ It's argued that such studies cannot exclude other biologic agents and chemicals unrelated to radiation as being causative.³¹ For example, a study showed an increased risk for brain tumors associated with ionizing radiation, chemical industry, and laboratory work. The use of cell phones increased the risk in the most exposed portion of the brain.³² Other case specific control studies failed to identify a significant risk of brain tumors caused by exposure to medical ionizing radiation.³¹

Our understanding of these effects primarily resulted from atomic bomb survivor studies.³³ Japanese survivors are the single most important group studied because of the large population exposed, the closeness by which the subjects were followed, and the fact that people

of all ages and both sexes received a wide variety of radiation exposures. Approximately 120,000 people were followed with due vigilance. Fifty thousand incurred doses in excess of 0.005 Sv (500 mrem). By 1998, there were more than 17,000 cases of cancer, 853 thought to be caused by radiation exposure.¹¹

Opponents challenge the Japanese survivor data and indicate that this type of exposure cannot be compared with medical exposures for several reasons. First, extrapolating health effects in the Japanese population to the consequences of low-level exposure to radiation is very challenging. The natural incidence of certain types of cancers is very different in the Japanese population compared with the United States. For example, breast cancer is approximately 3 times higher in the United States, and stomach cancer is 10 times higher in Japan. Second, exposures from medical imaging are from x-rays and gamma rays of relatively low energy, many times administered intermittently as a consequence of multiple procedures. The atomic blasts exposed Japanese residents instantaneously to high-energy gamma rays, neutrons, and charged particles. Third, Japanese survivors were exposed to whole-body radiation and to radioactive fallout, whereas medical exposures are external irradiation to specified regions of the body. Fourth, it is argued that food in Hiroshima and Nagasaki was limited, and much of the population was malnourished, which compromised health status. This may have amplified the effects of the radiation. Third, the bombs created hazards for this population in addition to the radiation. These included high heat and pressure, fire, flying debris, and psychological terror. Because of the bomb blasts, the ability to treat the population was hindered, and many people died of injuries and exposures that arguably might have survived under better conditions.³⁴

Four radiation risk models have been proposed to assess health risk of exposure to low dose ionizing radiation. These are the linear-non-threshold (LNT) model, the threshold model,

the hypersensitivity model, and the hormesis model (Figure 4). Low dose is defined as 1 to 100 mSv (100-10,000 mrem) or less than 0.1 mGy per minute over months or a lifetime.³⁵ Of these 4 models, the LNT is the risk model used internationally by most health agencies and nuclear regulators to set dose limits for workers and members of the public.³³

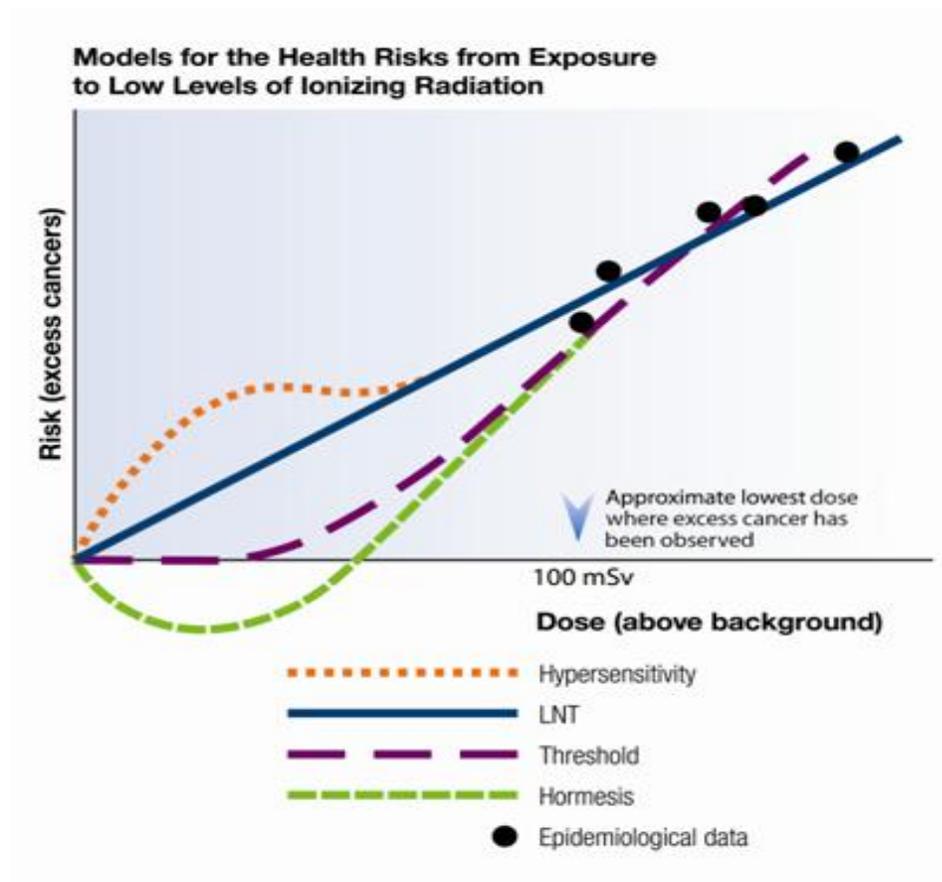


Figure 4: Radiation Risk Models

The hypersensitivity model suggests a greater risk at lower doses.

The LNT model is the straight line that is extrapolated to zero, meaning that cancer risk will rise with increasing dose.

The threshold model implies that below a certain dose, there is no risk.

The hormesis model suggests that low radiation doses may even be protective and beneficial.³³

The *linear-non-threshold hypothesis* (LNT) model was introduced by the National

Academy of Sciences Biological Effects of Ionizing Radiation (NAS BEIR) VII as a radiation protection risk and is considered the gold standard today, although it is under considerable debate. It is the most conservative of the 4 models and says, “Any radiation dose carries with it an associated risk of cancer induction, and the risk increases linearly with increasing dose.”^{31(p279),36} The LNT model indicates a straight line that extrapolates to zero, indicating that with increasing radiation dose, cancer risk will rise. In absolute terms, interpretation of this theory indicates that no amount of radiation should be considered safe, and even the smallest dose (1 electron hitting a cell) may initiate carcinogenesis. Biochemical evidence indicates, “DNA damage resulting from a single ionizing radiation traversal of a cell is expected to be potentially different from the biochemical damage resulting from normal oxidative processes.”^{35(p2)} LNT postulates that, “It is unlikely that there is a threshold below which cancers are not induced, but at low doses, the number of radiation-induced cancers is small.”³⁶ The LNT theory evolved after plotting known dose data and incidence of disease using the Japanese bomb survivor data. Where data were available, a linear relationship was seen indicating that as radiation dose increased so did the incidence of disease. The BEIR VII revealed that the balance of evidence from epidemiologic, animal, and mechanistic studies supports a simple, proportionate relationship at low doses between radiation dose and cancer risk.³⁵

As indicated, the LNT model is controversial. Opponents argue this conservative approach *assumes* that cancer incidence, as it relates to radiation dose, behaves in the same way as at higher doses; that is, in a linear manner. The theory’s weakness, however, admittedly suffers from substantial indeterminateness in the low dose range. That is, there is little epidemiological evidence to substantiate cancer incidence below 100 mSv. For the reasons previously stated, it is argued that the Japanese bomb survivor data should not be referenced for

chronic low dose exposure. Scientists have recommended a large-scale study of chronic low dose exposure for many years. Currently, a large-scale retrospective epidemiologic study is being conducted to support or refute cancer incidence linked to low dose exposure to be discussed later in this paper. Proponents argue that extensive efforts were made to compose a highly expert committee to avoid conflicts of interest and that the LNT model is based on a comprehensive review of the world literature on radiation and epidemiology.

The *threshold model* asserts that not all radiation doses are associated with cancer induction. In fact, below a certain dose, there is no risk.³³ However, after a certain level of exposure, cancer risk begins to accumulate. This theory was proposed after cancer incidence and mortality data from the atomic bomb survivors were reanalyzed to allow for the possibility of a threshold dose. The same dose response models as used in the original papers were used to fit the data. The fitted models over predicted the incidence of cancers in the lowest exposure groups. This was deemed evidence that a nonlinear rather than a linear threshold model is more appropriate.³⁷

The *hypersensitivity model* describes a phenomenon in which cells are excessively sensitive to low dose radiation. This model suggests a greater risk of cancer at lower doses of radiation and that low dose radiation is more harmful than the LNT because of increased sensitivity at a specific point in the cell cycle. A strong association has been shown between low dose hyper-radiosensitivity and the survival response of the cells in the G2 phase of the cell cycle.³⁸ G2 represents a sensitive phase between DNA syntheses, preceding prophase in mitosis.¹¹

Lastly, the *hormesis model* proposes a biphasic dose response pattern where low doses stimulate a beneficial or protective response and higher doses exhibit a negative or toxic effect.

This model suggests that the risks for cancer risk are smaller than proposed by the LNT model. An adaptive response, which produces moderate amounts of stress, can enable the organism to perform better. Exposure of individuals to low-dose radiation may elevate the immune response thereby protecting individuals from cancer.^{34(p316)} In other words, the view of this model is exposure to low dose radiation may promote health.

Radiation Measurement and Risk

Dosimeters are radiation detection devices worn by medical providers, which measure scatter from ionizing radiation. Dosimeters report effective doses in health care institutions for medical workers. The effective dose conveys the fact that some types of radiation are more damaging than others, and some parts of the body are more sensitive to radiation than others.¹¹ Donna Livant, PhD, October 17, 2013, University of Michigan, delivered a lecture on risk assessment and conveyed the following key concepts. Effective dose necessitates the comprehension of 4 concepts, which are absorbed dose, radiation weighting (W_R) factor, equivalent dose, and tissue weighting factor (W_T). The formula for calculating effective dose is expressed as the summation of the absorbed dose times the product of the W_R and W_T , expressed as the following:

$$\text{Effective dose} = \Sigma \text{ absorbed dose} \times W_R \times W_T \text{ }^{11(p256)}$$

Absorbed dose may be defined as the energy absorbed per unit mass, but absorbed dose simply expresses a physical quantity and does not convey the risk of biologic effect. Some radiation types are more effective at a certain dose than others. A more appropriate tabulation was devised to determine the biological effect of an absorbed dose. It is expressed as: absorbed dose $\times W_R$, which defines the equivalent dose. Radiation-weighting factor defines a

dimensionless multiplier used to assign risks from exposure to different types of radiation on a common scale. In essence, it defines the quality of the radiation. For example, the W_R for x-rays and gamma rays is 1. But the W_R for neutrons is 5 to 20, thereby creating the potential for a great deal more biologic damage with neutron radiation. The problem with equivalent dosing is that it assumes uniformity. If the body was uniformly radiated, the probability of the occurrence of stochastic effect is proportional to the equivalent dose, and risk would then be proportional to equivalent dose. But, equivalent doses of radiation to different tissues vary substantially, and different tissues vary in their sensitivities to radiation-induced stochastic effects.

A third more appropriate calculation was devised to account for the tissue-weighting factor, W_T , which represents the relative contribution of each tissue to the total risk and defines effective dose. For example, gonadal tissue and hematopoietic bone marrow have the highest W_T values at 0.2 and 0.12, respectively, whereas breast, liver, esophagus, bladder, and thyroid have W_T values of 0.05. Effective dose expresses the sum of all the weighted equivalent doses in all the tissues or organs that are irradiated. It is critical because it is proportional to the risk of stochastic effects. It measures cancer risk to a whole organism caused by the radiation delivered nonuniformly to parts of the body. It best represents risk because it takes into account both the type of radiation and the nature of each organ being irradiated. Sieverts (Sv) and rems are the units of both equivalent and effective dose.

Equivalent dose and effective dose cannot be measured directly. Instead, the dose must be calculated indirectly from other quantities, which are measured by a personal dosimeter. A typical dosimeter contains 2 values denoted personal dose equivalent (H_p) signified $H_p(0.07)$ and $H_p(10)$. These values represent the personal dose equivalent in soft tissue at 0.07 and 10 mm below the surface of the body, respectively, at the location of the dosimeter. $H_p(0.07)$,

worn at the collar and over protective garments, provides a reasonable estimate of the dose equivalent in soft tissue delivered to the surface of the unshielded skin and to the lens of the eye. In Europe, Hp (10) represents a dosimeter worn on the anterior chest inside leaded garments and is an estimate of the operator's effective dose. However, a single under the lead dosimeter does not provide any information regarding eye dose. The formula used to estimate E (effective dose) from dosimeter data may be specified by national regulations or by local hospital policy. Therefore, in the United States, when a protective apron is worn during procedures using fluoroscopy, the NCRP recommends combining the Hp (10) values from both body and collar dosimeters to estimate effective dose by the following formula

$$E \text{ (estimate)} = 0.5H_w + 0.025H_N^{39}$$

where H_N is the reading from the dosimeter at the neck, outside the protective apron, and H_w is the reading from the dosimeter at the waist or on the chest, under the protective apron.³⁹

Personal Dosimeter and Compliance

According to the Michigan Department of Licensing and Regulatory Affairs (LARA), radiation safety section rule 222 states: "UM must require the use of assigned dosimetry by individuals who are subject to occupational monitoring."⁴⁰ As indicated previously, dosimeters at many institutions are categorized as passive whole body monitors, utilizing optically stimulated luminescence technology. Further, rule 348 states: "Dosimetry must be worn in controlled areas by each individual occupationally exposed to ionizing radiation from therapeutic or diagnostic x-ray equipment. "Occupationally exposed" means present in a procedure room (controlled area) while the radiation producing machine (x-ray or fluoroscopy) is operating."⁴⁰

Compliance regarding appropriate wear of dosimeter badges is frequently suboptimal. The rate of personal dosimeter use has been reported as less than 50% in the literature.⁴¹ Proposed reasons for lack of compliance are: (1) lack of awareness or immediate feedback from the passive dosimeter, (2) improper wearing (placement) of radiation badge, and (3) wearing radiation badge inconsistently. Because of the lack of compliance, measurement of radiation exposure using a passive dosimeter may be inaccurately reported for any given provider.

Interventionist Data

Cardiology involves several specialties, 2 of which target minimally invasive interventions involving different functionalities of the heart. An electrophysiologist is a physician who targets therapy to the electrical conduction system of the heart such as atrial and ventricular ablation procedures for arrhythmias. An Interventional cardiologist focus upon structural issues of the heart, which cannot be corrected through traditional surgical approaches, and alternatively performs procedures such as the stenting of blocked vessels. For the purpose of radiation exposure, electrophysiology will be inclusive of considerations for the cardiac interventionist. This is because much of the information, which is stated directly regarding interventional cardiology, is also true for the electrophysiologist.

It is known that “Interventional cardiologists have among the highest radiation exposures of all health professionals” (Figure 5).^{30(p225),42}

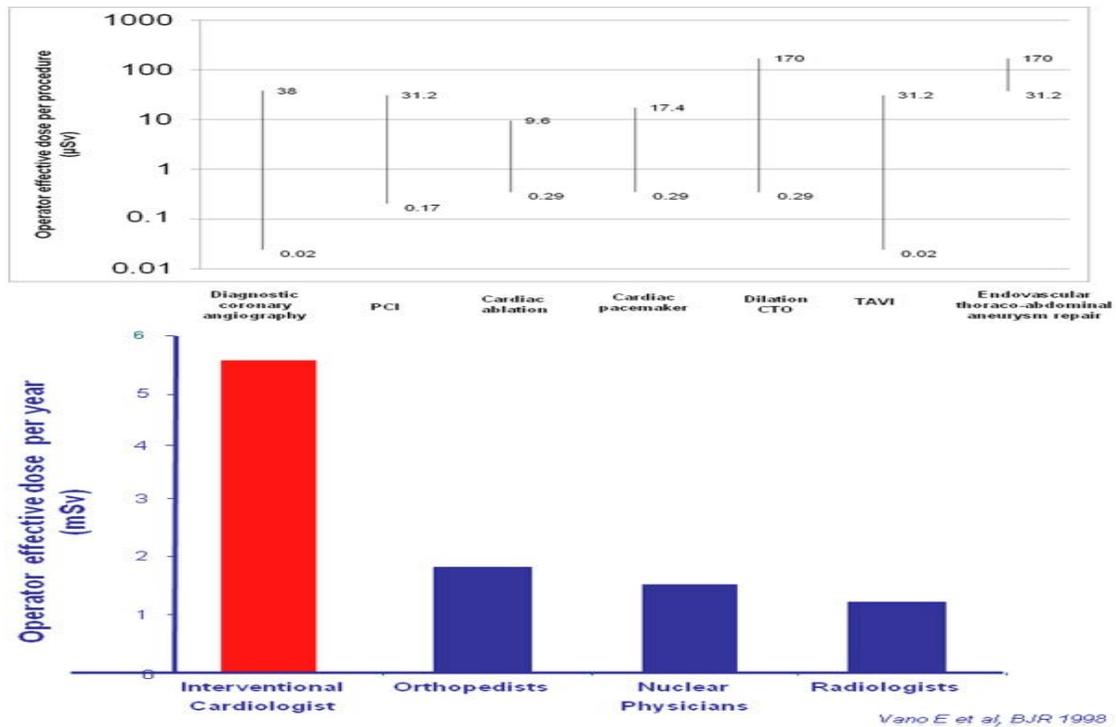


Figure 5: Radiation Exposure Among Various Specialists. The annual radiation exposure of different specialists. Interventional cardiologists are by far the most exposed. There is great deal of variability between and within procedures. Interventional cardiac procedures include diagnostic coronary angiography, percutaneous coronary angioplasty, cardiac ablations, cardiac pacemaker, dilation of chronic coronary total occlusion, and endovascular thoracoabdominal aneurysm repair.⁴²

There are several reasons for elevated exposure levels among interventional cardiologists. First, the interventionist's position during the procedure is very close to the x-ray source. Second, the interventionist is in close proximity to the patient, which is the scatter source for radiation exposure. Third, the intensity of the beam used in this setting lies between radiation intensities used in nuclear medicine and radiotherapy.¹⁴

Shielding also plays a significant role in mitigating radiation exposure but is variable because of the duration of the procedure, caseload in the lab, and the relative position of the operator, patient, and x-ray source.¹⁴ While working in the EP suite, the electrophysiologist may alternate their position with the cardiac fellow at the patient's bedside and in the control room. This is significant because the radiation intensity in the control room may be tens of thousands of

times less than that at the operator's position.¹⁴ When location with respect to shielding is considered in addition to the workload of the lab, exposure factors for the interventionist are 1,000 times higher than those of staff working in the control room.¹⁴

A variety of personal protective equipment (PPE) and shielding devices are available to the electrophysiologist PPE includes a custom fitted lead apron and thyroid shield. Leaded moveable shields are also used, but exposure may still be problematic. Other areas of body, the head, arms, and legs, remain exposed for prolonged periods (Figure 6).⁴²

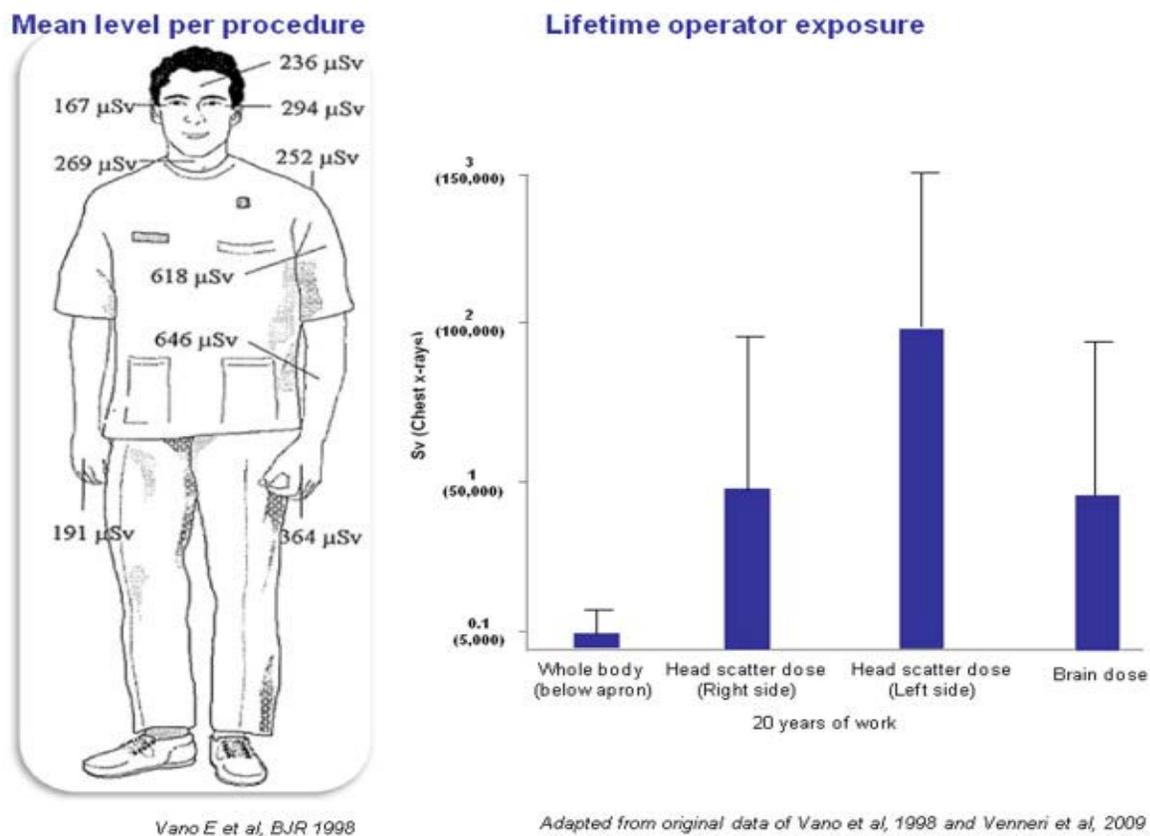


Figure 6: Dose-Effect Relationship Between Radiation Exposure and Cancer Risk The *left side* of the interventionist is more exposed than the right side in most cases due to the layout of the interventional room where the interventionist operates on the right side of the patient. Scattered radiation originates from the patient and is more intense when the x-ray tube is on the patient's left.⁴²

Additional radiation-mitigating devices are increasingly being used for protection, which include custom fitted goggles, which help to deter cataract formation. The zero gravity system, a recent addition to the available PPE, is being used in many EP suites as well. (Figure 7).⁴³



Figure 7: Zero Gravity System. The system is a flexible, single, continuous lead barrier, suspended from rails and attached to a wheelbase during use. It includes a suit, which allows for a greater degree of protection by integrating a body shield with 1-mm lead equivalence and a clear acrylic head shield with 0.5-mm lead equivalence.⁴³

The system offers greater radiation protection as well as improved comfort when compared with traditional shielding. Figure 8 illustrates the zero gravity system has the lowest dose rate when compared with traditional shielding.⁴⁴

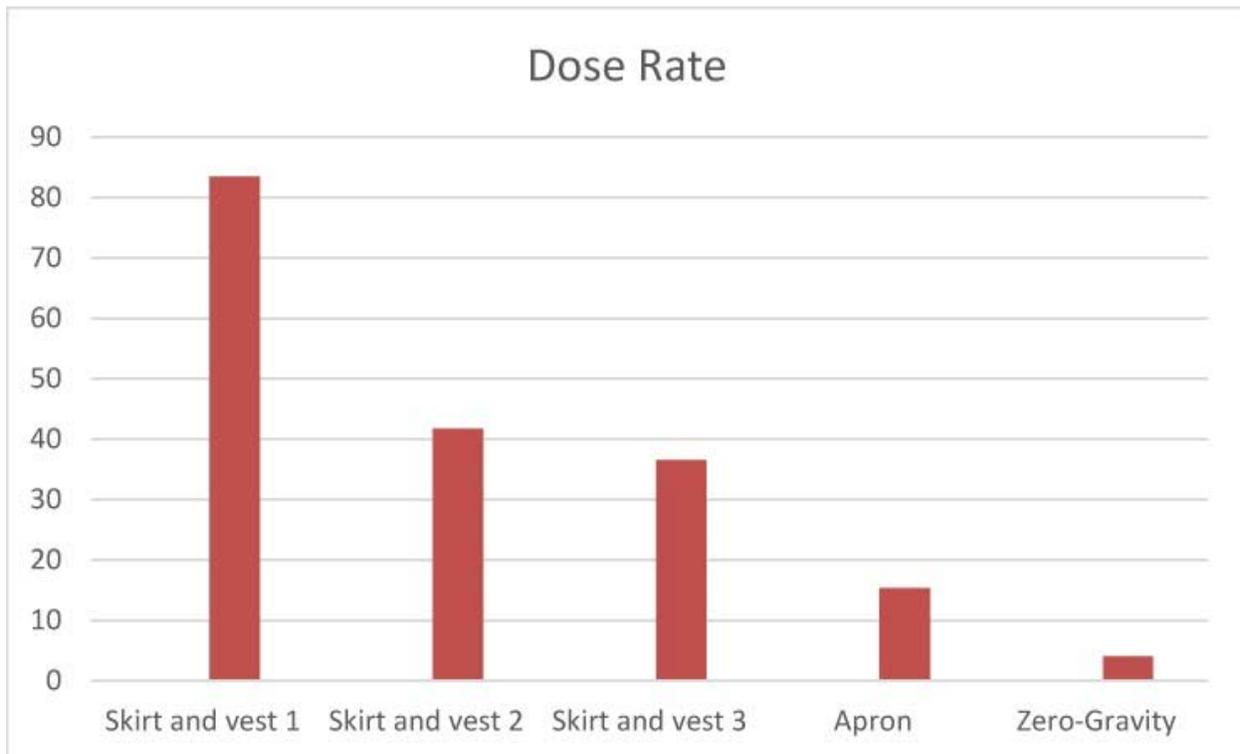


Figure 8: Dose Rate Chart: The exposures to the operator are highly variable depending on the radiation protection garments worn. Both the apron and the zero gravity system showed lower exposures than the skirt and vest wrap around presumably due to their higher lead equivalencies and attenuating properties.⁴⁴

The zero gravity system provides the best protection, presumably because of its higher lead equivalencies and attenuating properties.⁴³ Lead equivalent refers to the thickness of lead required to achieve the same shielding against radiation under specified conditions as that provided by a given material.⁴⁵ In this case, the zero gravity system has 1.0 lead equivalencies in the front of the apron compared with the other modes of protection with lead equivalencies

ranging from .35 to .5.⁴⁴ The choice of shielding is governed by personal preference, comfort, availability, and cost. In the PI's work environment, 2 zero gravity systems exist for 5 EP suites.

The 2 most well-known and documented health risks to the interventionists and staff are the formation of cataracts and elevated stochastic cancer risk.⁴⁶ Cataract formation, or opacification of the lens, is classified into 3 main categories, nuclear, cortical, and posterior subcapsular, according to their anatomic location.⁴² Posterior subcapsular is the least common type but is most frequently associated with ionizing radiation exposure.⁴² The Retrospective Evaluation of Lens Injuries and Dose study (RELID) found that interventionists developed posterior subcapsular lens opacities at a 3-fold higher rate than a control group, which didn't use fluoroscopy.³⁰ A French multicenter study also reported a significant increase of posterior subcapsular cataract development among interventionists, as did studies in Finland and Malaysia.³⁰ Until recently, the dose threshold for radiation-induced cataracts was considered 2 Gy (200,000 mrem) for a single dose and 5 Gy (500,000 mrem) for fractioned dose.⁴² However, recent epidemiologic findings indicate the dose threshold for cataract formation is 0.5 Gy (50,000 mrem).⁴² After years of exposure without proper protection, occupational exposure can potentially exceed 0.5 Gy (50,000 mrem) and is therefore suggested to be a stochastic effect exposure.⁴² It is estimated that cataract formation can be found in up to 50% of interventional cardiologists.⁴²

Radiation induced malignancy may also be a risk for interventional cardiologists. At the molecular level, changes in DNA have shown "interventional cardiologist develop somatic DNA damage and chromosomal abnormalities, as measured in vitro by micronuclei frequencies in diving peripheral blood cells, at a higher rate than clinical cardiologists."^{30 (p225)} Several studies have suggested a correlation between interventional worker exposure and cancer (Table 4).

Table 4: Reports of Brain Cancer Incidence in Physicians, Radiologists, and Interventionists

Study	Methods	Findings
Matanoski et al, 1975 ⁴⁷	Cohort study of mortality in 6,500 US male radiologists (years first worked, 1920-1969) over a 50-year period	Excess cancer risk among radiologists compared with other physicians
Wang et al, 1990 ⁴⁸	Cohort study of Chinese diagnostic x-ray workers (1950-1985)	Trend of excess cancer risk (standardized incidence ratio 1.2 for employment duration 10-14 years; 2.3 for 15-19 years) compared with nonradiation medical workers, not available for brain cancer
Andersson et al, 1991 ⁴⁹	Cohort study of Danish radiation therapy workers	Trend of excess cancer risk (standardized incidence ratio 1.09 with measured radiation dose < 5 mSv, and 2.23 with dose 5-50 mSv), not available for brain cancer
Carozza et al, 2000 ⁵⁰	Case-control study of occupation and glioma	Physicians at increased, albeit imprecise, risk of glioma (OR 3.5, CI 0.7- 17)
Andersen et al, 1999 ⁵¹	Population-based study of occupation and cancer incidence (from the 1990s to 1980s)	Brain cancer increased among physicians in general; no breakdown by specialty
Hardell et al, 2001 ³²	Case control study of 233 gliomas	Excess cancer risk of 6.0 in fluoroscopists
Blettner et al, 2007 ⁵²	Case control study of German patients (age 30-59 years at diagnosis) with brain cancer in 2001-2003	Occupational exposure (physicians, nurses, radiographers) with OR 2.49 (0.74-8.38) for neurinoma, OR close to 1 for glioma and meningioma
Finkelstein, 1998 ⁵³	Report of a case cluster (1990s)	Brain cancer in 2 interventionalists
Roquin et al, 2012 ⁵⁴	Report of 31 brain and neck cancers	Tumors included 17 cases (55%) of glioblastoma multiforme, 2 astrocytomas (7%), and 5 meningiomas (16%). The malignancy was left sided in 22 (85%), midline in 1, and right sided in 3 operators.

OR= Odds ratio

CI=Confidence interval

Over the past century, the trend in radiologic exposure and disease has changed. Epidemiological studies of occupational radiation exposure in medicine before 1950 demonstrated an excess risk of cancer, with increased rates of leukemia, and skin and breast malignancies. For example, Matanoski et al conducted a study of mortality in radiologists over a 50-year period, which showed elevated cancer risk among radiologists compared with other physicians (especially for leukemia and lymphoma). The study suggested a possible relationship between these finding and immunologic changes induced by radiation.⁴⁷ Since the mid-20th century, average annual occupational radiation dose estimates have decreased dramatically.^{30(p225)} Yet “radiation-induced malignancy remains one of the most feared long-term occupational risks of fluoroscopy, despite the limited data validating these concerns.”^{30(p225)}

Studies focused on brain cancer have emerged. The myth that the brain is radioresistant has led many electrophysiologists in past years to fail to protect their heads from ionizing radiation. This myth began with the 1906 law of Bergonié and Tribondeau, which states that the brain is a highly differentiated organ with low mitotic activity and is therefore radioresistant.⁴² However, it is now known that “Ionizing radiation is one of the few established causes of neural tumors.”^{42(p4)} A 1991 review of cohort mortality studies among 140,000 white male workers exposed to ionizing radiation in the US nuclear programs was studied. The report indicated, “The increased risk of brain tumor was highly consistent, persistent and stable, on the order of magnitude of 15% to 30%. As a consequence of these data, policy makers have identified brain cancer as a “specified” cancer potentially related to occupational exposures under the Energy Employees Occupational Illness Compensation Program Act.”^{42(p4)}

Cardiologists’ annual head exposure (ranging from 20-30 mSv/y) was shown to be nearly 10 times greater than their whole body exposure,⁵⁵ and the left side of the head

experienced twice the exposure levels of the right side.⁵⁶ Physical position of the provider to the radiation source is important because the electrophysiologist stands on the right side of the patient, but the left side of the cardiologist's head is closest to the radiation source. A 2013 report documented brain and neck tumors in 31 physicians from around the world showing that 23 interventional cardiologists, 2 electrophysiologists, and 6 interventional radiologists were effected. These malignancies were left sided in 22 (85%) of the cases.⁵⁴ These findings of disproportionate left sided tumors suggest the possibility of a causal relationship between brain cancer and occupational radiation exposure.⁵⁴ However, "Epidemiologic evidence of radiation induced brain cancer in fluoroscopists is suggestive but by no means conclusive. Essentially, no data are available on the contemporary population of invasive fluoroscopists, whose level and pattern of head exposure is unprecedented, although some anecdotal clusters of brain cancer have been recently described."^{42(p4)}

Anesthesia Provider

The Anesthesia provider (AP) delivering sedation or general anesthesia during EP procedures may be at risk for increased radiation exposure for several reasons. Ideally, the AP remains behind a rolling leaded shield utilizing all radiation protective equipment throughout these procedures, but this practice isn't always possible. He/she frequently may stand very close to the patient and the radiologic source, generally 1 to 2 feet away and does not have the increased protection at this institution of the leaded skirt at the head of the bed. In many radiologic suites a leaded skirt exists attached to the operating room table that partially wraps around the bed. Many times it exists only for position of the interventionist to the right of the table. If the patient's airway obstructs under sedation or a problem develops with the

endotracheal tube, the AP must immediately attend to the airway potentially stepping closer to the radiation source, increasing exposure. The surgeon may also require an AP to participate or intervene during the procedure, placing equipment such as an esophageal stethoscope.

Anesthetists may also experience increased exposure by association with pharmacologic interventions. When a drug is administered, many times the anesthetist steps closer to the radiologic source using a port in the IV to administer the medication thereby increasing exposure. The interventionist, concentrating on the patient and the procedure at hand, may neglect to discontinue use of fluoroscopy while the AP is in harm's way. Depending on the radiation requirements used during this time (cine or projection angle), the AP may experience exposure to scatter radiation at high levels.

Second, the AP's daily work habits may increase exposure. Cramped work environments are a common occurrence in radiation suites. Since the AP's primary position is near the head of the bed and the workspace is tight, delivering direct patient care while maintaining a safe distance from the radiologic source is often impossible. Radiologic emitting devices are large, movable pieces of equipment, as is some anesthesia equipment and protective devices such as mobile lead screens. Other room staff, such as registered nurses and technicians may also experience radiologic exposure because of the need to manage equipment and administer drugs, which requires close proximity to the radiation source. However, these providers have the ability to use a rolling leaded shield and or retreat to the safety of the control room.

Very little literature exists on ionizing radiation exposure in APs. Anastasian et al compared the forehead radiation exposure of both the anesthesiologist and radiologist during 31 adult neuroradiology procedures involving head and neck angiography or interventional radiology (IR) to approximate eye lens exposure. Radiologists in this study wore radiation

goggles as part of their standardized safety equipment. Anesthesiologists did not. The study demonstrated that the scattered radiation exposure to the anesthesiologist's face could be up to 3 times that of the radiologist.⁵⁷ It was not surprising that the radiation level was higher for the anesthesiologist than the radiologist, because at the time of this study, the standard of practice for radiologists and interventionists was use of leaded eyewear and ceiling-mounted leaded shields to protect the face. No such radiologic standard existed for anesthesiologists. It was hypothesized that the radiation exposure to the unprotected eye of the anesthesiologists might be in the same range as the radiologist. "Exposure to radiologists from scatter radiation during angiography and interventional radiologic procedures has been measured and may exceed the threshold for long-term injury."^{57(p513)} Multiple linear regression showed that total exposure of the anesthesiologist correlated with the number of pharmacologic interventions he was required to make during the procedure as well as the total exposure of the radiologist. That is, the total exposure of the anesthesiologist was positively correlated with and exceeded the exposure of the radiologist. Additionally, giving boluses through the IV also brought the AP closer to the patient's head and therefore closer to the radiation source thereby elevating exposure. Therefore, it was suggested anesthesiologists should wear protective eyewear to mitigate eye exposure and ensure parity of radiologic protection.

A prospective study that investigated the level of radiation exposure of anesthesiologists during IR procedures over a 6-month time period in the endoscopic retrograde cholangiopancreatography (ERCP) and cardiac catheterization (CC) lab compared the data obtained with the current radiation safety guidelines. A total of 1,344 procedures were performed. Anesthesia was required for 39/645 in ERCP suite and 86/699 in the CC lab. The combined net exposure of anesthesiologists was 0.28 mSv (28 mrem) for ERCP and 2.32 mSv (232

mrem) for cardiac catheterization. The study, conducted in Pakistan, concluded that anesthetists' exposure rates in this setting were below the allowable maximum level of 20 mSv per year.⁵⁸

Radiation exposure of trainee anesthetists working in urology, orthopedics, and radiology suites found radiology procedures produced had the highest radiation exposure, followed by orthopedics, and then urology. Exposure levels were examined in 732 procedures, 96 (33%) orthopedic procedures, 91 (30%) urology procedures, and 50 (39%) radiology procedures. Combined net exposure over a 6-month period in urology was 0.2177 mSv (21.77 mrem), orthopedics 0.4265 mSv (42.65 mrem), and radiology 3.8457 mSv (384.57 mrem). When extrapolated to 1 year, the radiation exposure in this setting was well below the 20 mSv per year allowed. The authors suggested that because exposure is low, routine dosimetric monitoring for anesthetists is unwarranted.⁵⁹

Katz examined radiation exposure of members of a small department of anesthesiology (30 anesthesia care providers) by comparing radiation exposure before and after the establishment of an EPL. The study was designed to examine the change in radiation exposure to the AP after the establishment of an EPL. This was attributed to the proportion of radiation cases, which were conducted pre-EPL vs post-EPL. That is, there were 6,337 anesthetic cases with zero EP cases before the opening of the EPL. A total of 6,820 anesthetic cases, including 212 EP cases post-EPL or after the opening of the EPL, were conducted. The total radiation exposure was 503 mrem pre-EPL and 1,006 mrem post-EPL. This data indicated that not only did the volume of cases increase in the 6 months postEPL but also with it the opportunity for radiation exposure. Even when ALARA principles were practiced, pre-EPL exposure levels were half of those seen after the EPL opened. However, in this study, exposure rates were below the US yearly maximum allowable levels of 5,000 mrem per year.⁶⁰

Current Studies

Critics argue that it is essentially impossible to accurately predict cancer incidence and death in a population of individuals exposed to ionizing radiation at doses below about 100 mSv. “No prospective epidemiologic study with non-irradiated control subjects has quantitatively demonstrated adverse effects of radiation at doses less than about 100 mSv^{34(p319)} Suspected cancer incidence and death from medical imaging procedures lack supporting data and are only speculative. A greater ability to accurately predict cancer induction caused by low doses of ionizing radiation may be achieved as understanding of the cellular mechanism of cancer improve, better criteria for identifying cancer precursors at the cellular and molecular levels are developed, and more relevant epidemiologic data on cancer risk of patients exposed to medical radiation accumulated in large registries are determined.³⁴

Efforts have begun both internationally and nationally to investigate large subpopulations of individuals exposed to ionizing radiation. “In 2006, the National Academy of Sciences (BEIR) VII committee identified “future occupational radiation studies” as one of the top 10 research needs which should include highly exposed populations with a full record of exposure. This population is well suited to assessing the effects of long-term, low-level radiation exposure in humans.”^{42(p1)}

The International Nuclear WORKers Study (INWORKS) study was published in *Lancet Haematology*, July 2015.¹ The study was designed to strengthen the scientific basis for protecting people from low-dose protracted or intermittent radiation exposure. A cohort of 308,297 radiation-monitored workers employed for at least 1 year in the United States, the United Kingdom, and France were monitored by personal dosimeters for external exposure and followed for up to 60 years (8.22 million person years).¹ Subjects were employed by the Atomic

Energy Commission, AREVA nuclear cycle, National Electricity Company in France, Departments of Energy and Defense in the United States, and nuclear industry employers included in the National Registry for Radiation Workers in the United Kingdom. Doses were accrued at very low rates (mean 1.1 mGy [110 mrem, SD 2.6]). The excess relative risk of leukemia mortality in these workers (excluding chronic lymphocytic leukemia) was 2.96 per Gy (90% CI 1.17-5.21; lagged 2 years), most likely because of an association between radiation dose and mortality from chronic myeloid leukemia (relative risk per Gy 10.45, 90% CI 4.48-19.65).¹ The summary stated, “Our results provide direct estimates of risk per unit of protracted dose in ranges typical of environmental, diagnostic medical, and occupational exposure.”^(p280) The final interpretation indicated, “It provides “*strong evidence* of an association between protracted low-dose radiation exposure and leukemia mortality.”^(p276)

Legislative support for an additional study was garnered when the House of Representatives passed Bill HR 5544 on September 18, 2014, which is referred to as the Low Dose Radiation Research Act of 2014. HR 5544 mandates: “The Director of the Department of Energy shall carry out a research program on low dose radiation. The purpose of the program is to enhance the scientific understanding and reduce uncertainties associated with the effects of exposure to low dose radiation in order to inform improved risk management methods.”⁶¹ The bill mandated study coordination with federal agencies. It also imposed an 18-month completion time for the study after the date of adoption of the Act.⁶¹

In response to this mandate, the One Million U.S. Radiation Workers and Veterans Study is currently in progress. It is an expansive epidemiologic effort coordinated by the NCRP. The primary goal of this study is to provide scientifically valid information on the level of radiation risk when exposures occurred gradually over time as opposed to seconds as with the Japanese

bomb survivors.⁶² The primary outcome variable of the study is cancer mortality and is tied to the validity of dose reconstruction approaches using a dosimeter badge from Landauer. The Million Workers Radiation Study includes a diverse population, 115,000 atomic veterans, 360,000 US Department of Energy workers, 430,000 nuclear power plant workers, 130,000 industrial radiographers, and 240,000 medical workers. In assessing medical workers' exposure, an estimated 4 million film-badges and thermoluminescent dosimeter are being examined. It is expected the report will be completed in 2016.⁶²

Changing Regulations

In January 2015, the NCRP announced it is revising radiation regulations. This effort would update Report No. 116 and the CC-1 committee was created to aid in this effort.⁶³ The CC-1 committee is charged with updating and expanding Report No. 116 on limitation of exposure to ionizing radiation.⁶³ New knowledge exists on radiation effects lower than those that were apparent in 1993, when the report was published.

ICRP Report 103, published in 2007, recommended the acceptable effective dose to the lens of the eye decrease from 150 mSv (15,000 mrem) to 20 mSV (2,000 mrem) averaged over 5 years, with no more than 50 mSv (5,000 mrem) in any 1 year.⁶⁴ The NCRP maintains that the *goals* of radiation protection in the United States are the same as the international community but that the degree and approach to obtaining these goals differs. One way the United States differs is the allowable maximum of 50 mSv (5,000 mrem) per year limit, which is not in accordance with many international limits. According to Scott Pollack, MD, cardiologist at Central Florida Cardiology Group, Orlando, Florida, "It is the responsibility of hospitals to protect their employees by leveraging available solutions for the enhancement of safety within the

interventional suites. This action, in conjunction with the possible regulatory changes mandating radiation protection, will ensure the safety of physicians and staff.”⁶⁵ It is therefore suggested that ethical and regulatory changes may promote real-time dose monitoring in the future.

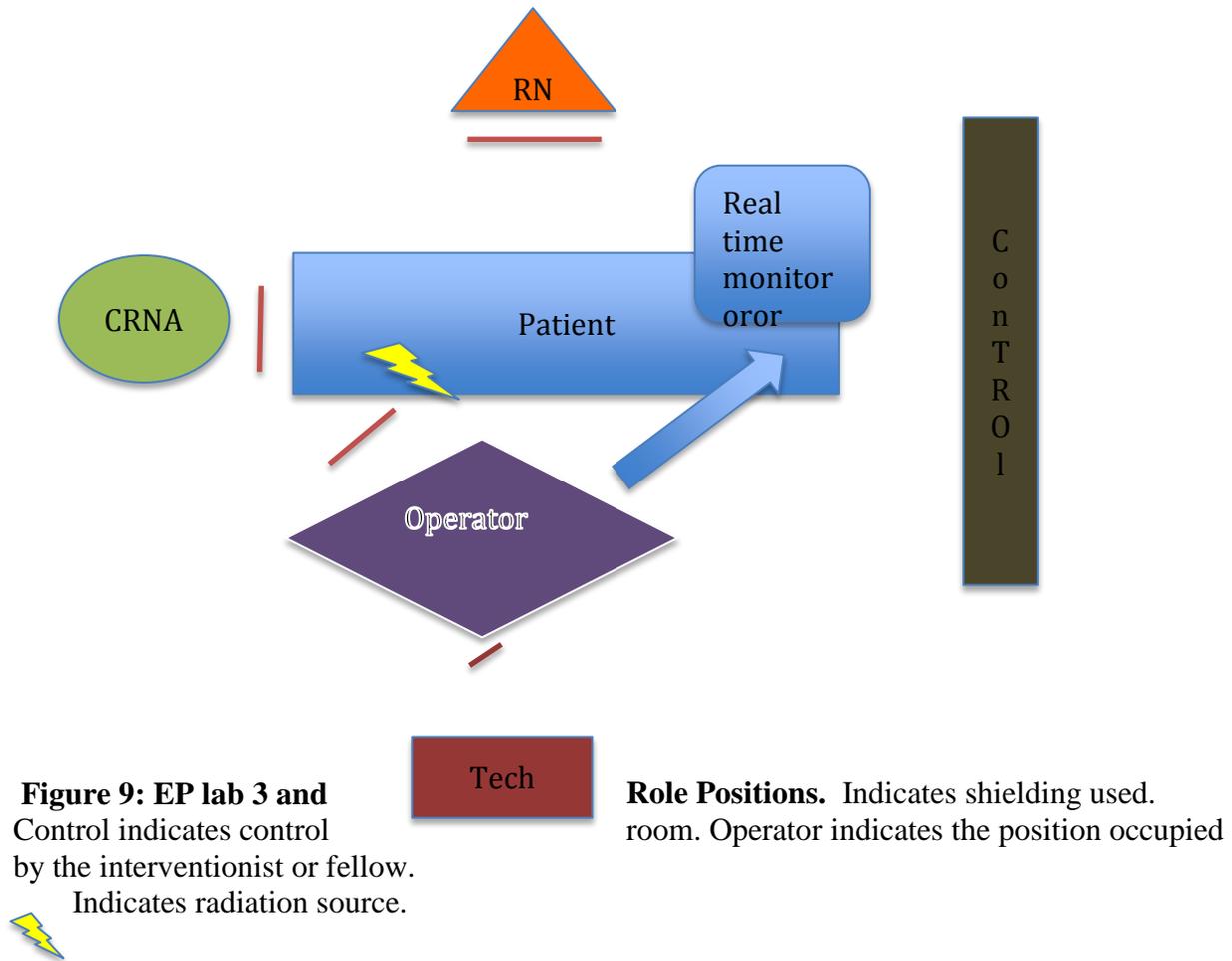
It is clear that a knowledge deficit exists in the measurement of low dose ionizing radiation and the stochastic health effects that may be associated with it. The goal of this research is to determine if the use of a real-time monitoring system will result in decreased aggregate exposure among faculty and staff working in an EPL. This may be accomplished by presumed behavior modification including increased use of Personal Protective devices (PPD)’s and incorporation of avoidance behaviors but will not be observed as this is beyond the technical feasibility of the Primary Investigator (PI) for this study. Evidence-based recommendations from this study will be made regarding the ability of this device to improve awareness thereby lowering exposure.

RESEARCH QUESTIONS AND HYPOTHESIS

1. What is the effect of implementation of real-time dose monitoring on electrophysiologist aggregate radiation exposure?

Hypothesis: It was predicted that aggregate radiation exposure dosage would decrease significantly when electrophysiologists were aware of their real-time exposure levels. The RaySafe Company touts up to a 40% reduction in physician and staff exposure levels when real-time dose monitoring is used.⁶⁶ Several studies using real-time dose monitoring systems have demonstrated a significant decrease in operator dose.^{19,67,68,69} The University of Rochester Medical Center experienced a 50% reduction in staff exposure within the first year of implementation of the RaySafe i2 real-time monitoring system.⁴⁶

The position of the dose-monitoring screen (base station) is important for replication of prior study results. For this study, the base station was positioned in the direct line of vision of the operator, where the electrophysiologist or fellow stand. This allowed for visualization of the screen for awareness of exposure values (Figure 9). It was predicted that when exposure levels were evident, the electrophysiologist would alter his behavior, either by taking dose reduction strategies or increasing use of personal protection equipment, although observation of these behaviors was not inclusive of this study. One electrophysiologist uses a zero gravity system almost exclusively during these procedures. It was expected that this reduction would be reflected on the study badge by decreased dose in phase 2.



2. What is the effect of implementation of real-time dose monitoring on cardiac fellow aggregate radiation exposure?

Hypothesis: It was predicted that aggregate cardiac fellow radiation exposure levels would decrease significantly in phase 2 after implementation of real-time dose monitoring system. The fellow occupies the same physical position as the electrophysiologist during a case, but the fellow's total time in that position varies during a case. The fellow was provided the same ability to view the base station and be informed of his/her real-time exposure values. It was expected that this knowledge would result in behavioral modification to reduce exposure.

3. What is the effect of implementation of real-time dose monitoring on aggregate electrophysiologist and cardiac fellow's combined radiation exposure levels?

Hypothesis: It was predicted that knowledge of real-time radiation exposure levels would result in significantly lower radiation exposure levels for the operator role in phase 2 represented by the combined electrophysiologist and fellow's dose. Generally, one of these practitioners stands in the operator's position throughout the procedure. The other alternates between the operator's position and the control room. Combining data from both providers' badges was expected to demonstrate a significant reduction in total exposure after visualizing exposure with the real-time monitoring system.

4. What is the effect of implementation of a real-time dose monitoring system on aggregate Certified Registered Nurse Anesthetist (CRNA) radiation exposure levels?

Hypothesis: It was predicted that there would be no significant difference in aggregate CRNA radiation exposure levels after implementation of a real-time radiation exposure monitoring system in phase 2 resulting from the configuration of the room, which does not allow the CRNA to easily see the base station. The base station is positioned at approximately a 90° angle from the CRNA, which does not allow for unobstructed viewing. The electrophysiologist or cardiac fellow could alert the CRNA of elevated readings and when to avoid approaching the patient when periods of high emissions occur during the procedure. Prior studies have indicated elevated CRNA exposure. In Mohapatra et al, which used a real-time dose monitor in the setting of endovascular procedures, "Findings suggest that anesthesiologists received more radiation than necessary to perform required patient care activities."^{13(p706)}

5. What is the effect of implementation of a real-time dose monitoring system on aggregate registered nurses circulating in EP lab 3 during cardiac interventional procedures?

Hypothesis: It was predicted that total exposure levels experienced by registered nurse circulators in phase 2 would not change after implementation of real-time dose monitoring. The RN workspace is located 180° behind the base station, allowing virtually no opportunity for circulating RNs to view the base station.

6. What is the effect of implementation of a real-time dose monitoring system on EP technician radiation exposure levels?

Hypothesis: It was predicted that aggregate exposure levels for EP technicians would not change in phase 2 with implementation of real-time dose monitoring. Technicians are afforded the opportunity to occupy the protective nature of the control room during a procedure, and therefore it was expected their radiation dose would be minimal.

7. What conclusions may be drawn regarding the ability to reduce provider radiation exposure levels by increasing knowledge of their exposure levels in real time?

Hypothesis: If the aggregate dose for any provider type was lower in phase 2 than in phase 1, it is suggestive but not conclusive that as providers are made aware of their exposure, they were motivated to take protective measures to reduce it. Scott Pollack, MD, cardiologist at Central Florida Cardiology Group, Orlando, Florida, stated, “The biggest benefit regarding real-time dose monitoring is awareness. Once physicians and staff see their individual exposure levels, it becomes personal. Radiation loses its cloak as the silent killer with a visual cue that reminds them of the ever-present danger.”⁶⁵ Miles Carver, manager of

invasive cardiology services at Good Samaritan Hospital in Lebanon, Pennsylvania, agreed. Carver stated, “When physicians and staff are more aware of their personal doses, they are more apt to change their behavior.”⁶⁵

8. What is the difference in aggregate dose of all providers per procedure type between before and after implementation of real-time exposure monitoring?

Hypothesis: It was expected that there would be a significant difference in total exposure per procedure after implementation of a real-time dose monitoring system. Certain procedures are associated with considerably more radiation dose than others, most notably ventricular tachycardia (V-tach) ablations. The difference was expected to be most notable where radiation levels are elevated during V-tach ablation procedures.

METHODOLOGY AND DATA COLLECTION

University of Michigan IRB approval and consent from the Anesthesia Clinical Resource Committee were obtained to conduct a quantitative, crossover research study where all subjects were assigned to both the treatment and control groups (Appendix 1 and 2). A convenience sample of 88 voluntary participants included electrophysiologists, cardiac fellows, nurse anesthetists, registered nurses, and technicians who provide care to patients receiving interventional EP procedures.

All subjects were asked to utilize their usual radiation protective equipment. At minimum, protective equipment included a leaded apron and thyroid shield (0.05-mm lead equivalent). Protective leaded eyewear was also available. A ceiling mounted transparent shield and operating room table mounted skirt were available for electrophysiologist and EP fellows. The zero gravity system was also available to the electrophysiologist and utilized more frequently by a single electrophysiologist. A movable rolling shield was also available, primarily used by the nurse anesthetists and registered nurses.

The study occurred at a University of Michigan hospital in an EPL over a 20-week time period and consisted of 2 phases. Six labs exist in the EP area. The director of EP operates primarily from EP lab 3 and gave his consent to implement the study in this location. Procedures included cardiac ablations, pacemaker implantations, internal cardiac defibrillator insertions, and myocardial lead extractions. The real-time display unit remained in a constant fixed position attached to the gantry. The gantry is the arm on which all of the monitor screens are mounted for viewing radiologic examination data during the procedure. The real-time display was primarily directed toward the electrophysiologist and fellow for the duration of the study because of its position on the gantry and was installed by the Unfors RaySafe company representative.

Inclusion criteria consisted of faculty and staff assigned to work in the designated EPL during the study period and limited to only those who work solely with adult patients. Eligible personnel included Electrophysiologists (n=10), cardiology fellows (n=10), anesthesiologists (n=95), registered nurses (n=20), and technicians (n=15). Providers who do not work in the EPL with the adult population and those who declined to participate were excluded. The PI and research assistants were not assigned to EP lab 3 for the duration of the study due to the potential for bias. No incentives were utilized and providers were asked to sign consent forms to participate in the study as part of a standard, nonexempt research project within IRBMED.

The study utilized the RaySafe i2 system to measure radiation exposure in real time. The RaySafe i2 system, shown in Figure 10, contains the following components:

1. Dosimeter
2. Real-time display (base station)
3. Dose viewer (computer software)
4. Dose manager (computer software)
5. Dock station (used to connect dosimeters and computer)
6. Dosimeter rack (dosimeter storage)

RaySafe i2 Overview

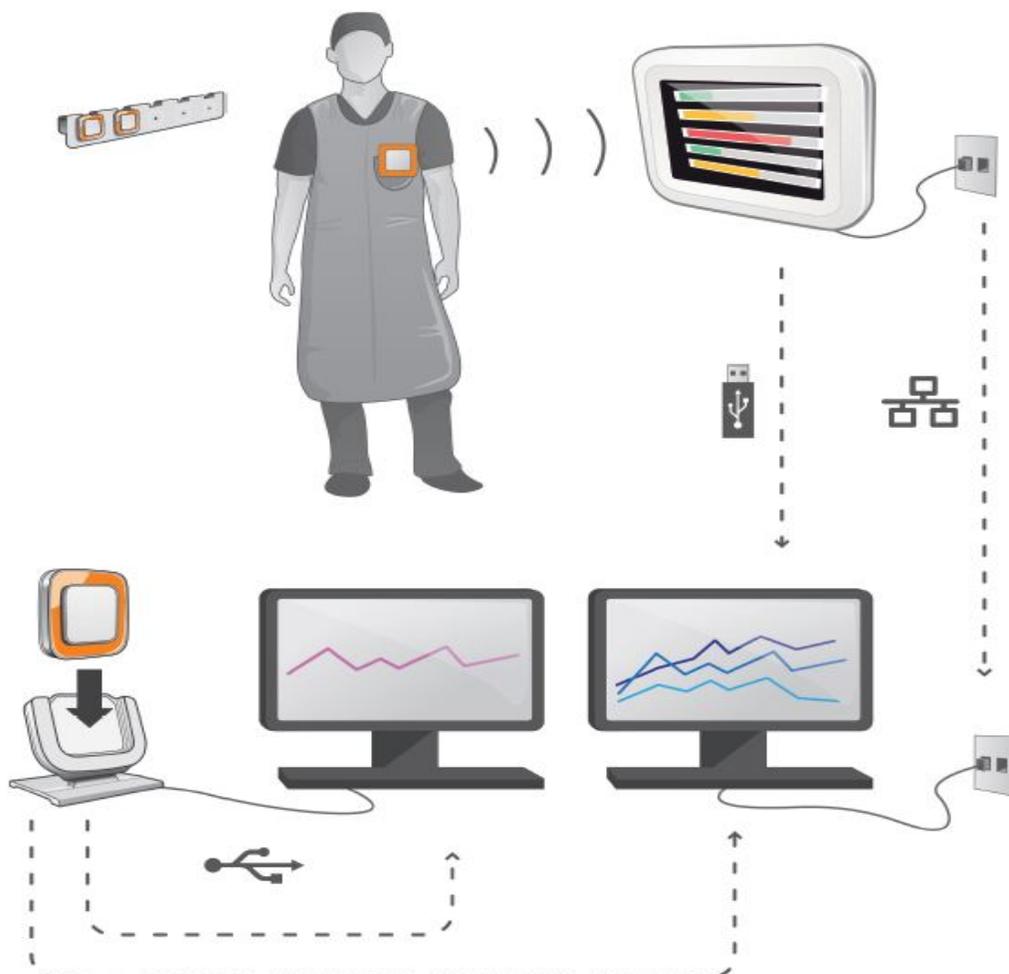


Figure 10: RaySafe i2 Overview: RaySafe i2 System. Dosimeter communicates wirelessly to real-time display. Radiation exposure is immediately visualized in real time by logarithmic scales in red, yellow and green. Numeric values indicating both instantaneous and accumulated values are also visible.⁶⁶

Dosimeters are worn at the level of the chest on the outside of the lead apron. The device measures and records x-ray exposure every second and transfers the data wirelessly to a real-time display (base station), which is attached to the gantry (boom) in the EP suite (Figure 11).⁶⁶



Figure 11: RaySafe i2 Dosimeter. A real time dosimeter worn at the chest level and communicates wirelessly to a base station. It provides immediate feedback, shows dose levels and enables a provider to avoid dose in real time.⁶⁶

The real-time display reveals radiation exposure immediately by color indicator bars, which may be viewed by all participants in the room (Figure 12). The color indication bars signal the intensity of varying levels of exposure in real time. Red signals high exposure (2-20 mSv/h or .2-2 rem/h.), yellow signals intermediate (.2-2 mSv/h or .02-.2 rem/h), and green signals low level of exposure (<.2 mSv/h or <.02 rem/h).⁶⁶ Absence of color is ideal and represents zero exposure. The accumulated dose is located next to the color indicator bars. By tapping on an individual badge, historical information may also be obtained. Up to 8 badges may be viewed simultaneously on the monitor. Data may be stored for up to 5 years in the base station.⁶⁶



Figure 12: RaySafe Real-Time Display. It shows real time dose exposure from up to 8 dosimeters in range at a time. Color indication bars (green, yellow and red) represent the intensity of the currently received exposure. The accumulated dose per individual is displayed next to the color indication bars. By tapping a dosimeter name the user can look at historical data in separate views.⁶⁶

More detailed historical data can be obtained by using the dock station (cradle), which is connected to a computer, and viewed using dose viewer and dose manager computer software.

(Figure 13)⁶⁶



Figure 13: Raysafe Docking Station. The cradle (white outer portion) is a dock station that connects a dosimeter to a computer for data read out as well as dosimeter options writing into the dosimeter.⁶⁶

The dose viewer is used to assign dosimeters, alter dosimeters names, set colors or reset dose history. The dose manager is more complex, involving advanced software and is used to analyze and report dose information. It will store and manage dose history from multiple dosimeters, collect dose history from real time displays in the hospital network, and analyze dose data. Additionally, it will view dose history as a graph or table, export dose data for further analysis with other software tools such as excel and create and print report of dose history (Figure 14).⁶⁶

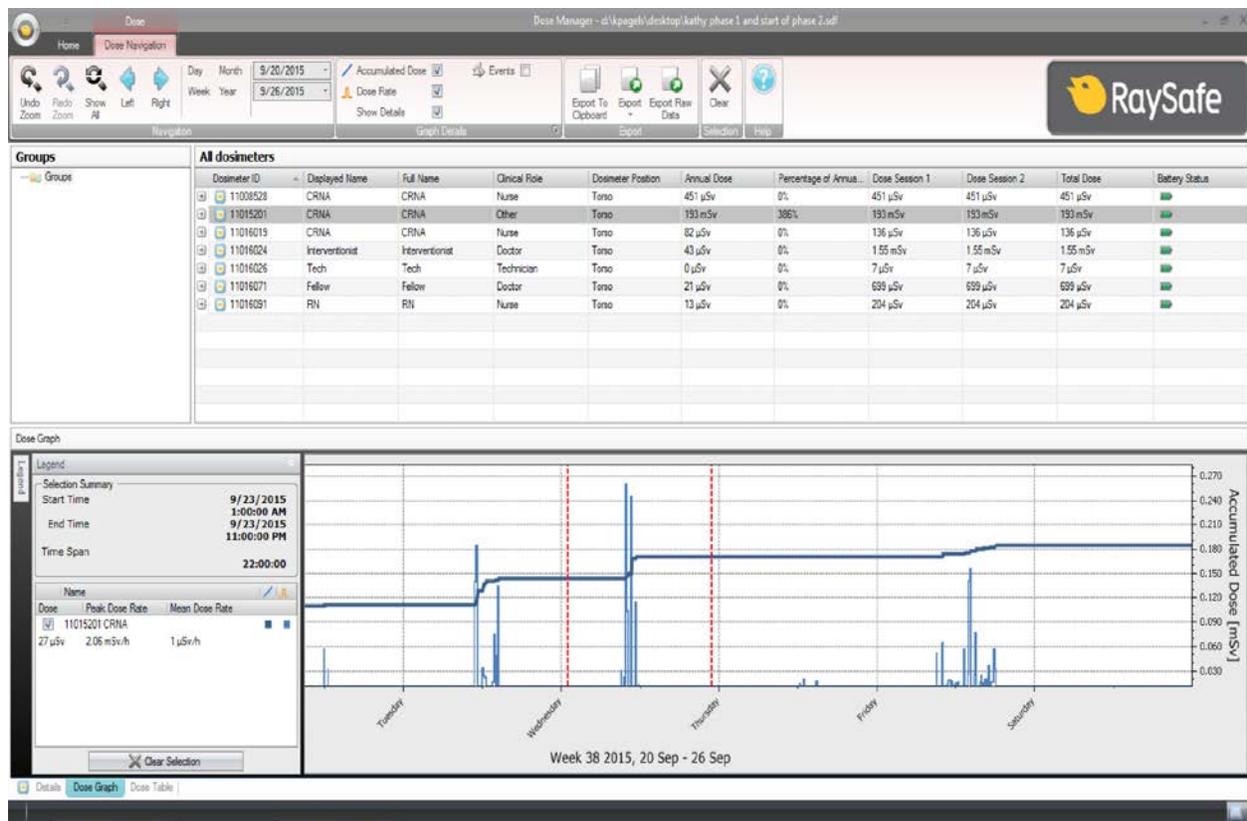


Figure 14: RaySafe Dose Manager Function. It is advanced software for analyzing, reporting and archiving dose information. It handles multiple dosimeters and can retrieve the dose information from multiple real time displays through the hospital network or via USB storage.⁶⁶

Participants were also instructed to wear a passive dosimeter that measures cumulative exposure over a 3-month period of time. Passive dosimetry is managed by Radiation Safety Services and is a requirement for working in any radiologic area at this hospital.⁴⁰ Data obtained from passive dosimeters was not utilized, as these values were not the focus of this study. Both dosimeters (passive and real time) measure radiation exposure. However, the passive dosimeters measure deep and shallow tissue levels along with lens exposure, reflecting whole body exposure. The RaySafe device measures targeted radiation and does not measure whole body exposure. These badges are worn at the level of the chest. The RaySafe device is intended to be used as an additional piece of equipment to monitor exposure in potentially high dose offsite areas such as interventional radiology and EP. It does not, at this time, replace the government mandated passive dosimeters.⁶⁶ In review, real-time monitors are not regulated by the government and therefore at present cannot replace passive dosimeters, but this may change in the future. Therefore, no attempt was made to *measure or estimate* either whole body dose or any other dose for any individual or group of individuals. Those issues are beyond the technical feasibility and scope of the study. This is a study of *relative exposures* as recorded by the system that is sponsoring the investigation.

In phase 1, which occurred over 10 weeks, the control group, which was blinded, could not visualize their radiation exposure readout via their RaySafe dosimeter. The real-time display mode was set to the “hide” option in which the dosimeter readings were not shown on the base station. During this time, the dosimeter will continue to collect exposure information but were not visible to the participants. The dosimeter continued to signal the base station and record accumulated dose during this time. During phase 2, the hidden mode was removed, and the same subjects visualized their exposure values on the base station for the subsequent 10 weeks.

Radiation measurement may be expressed in different units. As with distance, weight, and temperature, radiation units may be expressed as either SI units (sieverts) or US customary units (rem). US scientists and engineers in most fields had converted to the metric system by 1964 when the National Bureau of Standards officially adopted the International System of Units. However, nuclear physicists never officially made this change because even a small error in conversion between metric and customary units can be very dangerous. This, in fact, occurred with the Mars Climate Orbiter when there was a mistake made in converting these units. Because of this concern, the US Nuclear Regulatory Commission still requires plants to report radiation releases in rem, while the rest of the world reports in sieverts (Sv).⁷⁰ The RaySafe device is manufactured outside of the United States and therefore reports in sieverts. Measurements in this study were reported as millisievert (mSv) and microsievert (uSv). For reference, 1 mSv=100 mrem=1,000 uSv.

The independent variable in this study is the provider's awareness of radiation exposure reflected in the factors of phase, generalized procedures, and kerma. The dependent variable is dose measured as scatter radiation exposure. Randomization of participants was not utilized because there is a specified order of treatment effects. If real-time dose monitoring readouts were introduced first, measurements of the blinded control group could have been confounded, and a carryover effect could underestimate results during the second phase.

The RaySafe dosimeter is intended to be a personal dose meter or PDM. That is, each badge is identified by a unique code on the back of the badge and is to be linked to 1 person and ideally not shared. However, for this study, the RaySafe Company provided 5 badges; for cost purposes, all badges were shared in all categories of providers: electrophysiologists, fellows, anesthesia providers, scrub technicians, and RNs.

Several practices were utilized to encourage correct usage and compliance with wearing the RaySafe badges properly. The night before each data collection day, the PI sent a personal email to the CRNA assigned to EP lab 3 for the following day. The study protocol was attached, which included instructions on correct placement of the RaySafe badge. The cardiac fellow received a text by pager thanking him for participating in the study, as a reminder of having consented to participate in the study.

The RaySafe badge was worn outside the lead apron, attached to the chest pocket with the company logo facing outward. At the start of the case, as part of the time-out procedure, the CRNA leading the timeout made a statement that both the passive dosimeter as well as the RaySafe badges were being worn and appropriately placed for all categories of participants and in the correct position on the outside of the lead. The PI, along with research assistants, discussed correct badge wear at the time of provider consent. A video illustrating badge wear as well as the real-time dose monitoring system was also available at the time consent was obtained (<https://www.youtube.com/watch?v=KYRVT8GiCQc>).⁷¹ The PDM was both labeled (electrophysiologist, fellow, RN, technician, and anesthetist) and color coded to ensure the correct category of participant was wearing each badge daily. For example, the electrophysiologist always wore a green PDM; anesthetist, blue; RN, yellow, etc.

A handoff procedure for badge wear was conveyed to all participants. Handoffs were necessary when a relief person arrived during the day. This process was necessary to ensure accurate and consistent recording of scatter for each provider group. When handing off a badge, anesthetists used a script incorporated into their electronic documentation indicating the following: “*Sign out/debrief initiated: Please give digital dosimeter for radiation study to relief person.*” Nursing (RN) and technicians followed the same handoff procedure during transfer of

their badges, but the handoff was not documented in the computer when they vacated the room. The electrophysiologist and fellow rarely left the EP suite and therefore did not hand off badges in a given day. Those choosing not to participate in the study were either assigned to the room or were giving breaks in the room and did not wear the badge or their accumulated values were not included in the study tabulations. The group primarily affected were the CRNAs, as they had the most fluctuation in personnel assigned to the room for breaks and lunches. Thirty-five CRNAs were present during the study but not participating as evidenced by Centricity (electronic medical record system for anesthesia) sign in and sign out times in the room. Most were primarily break personnel and not primary CRNAs assigned to the room for the day. Signs were posted on the exit doors and around the EP floor as a reminder to each participant to please hand off their badges before exiting the EP suite, and to return the badge at the end of the day. The next day began a new collection period. The date changed on the base station and the RaySafe dosimeters. A written protocol was also available in all associated providers' work areas.

Multiple variables were examined using several electronic systems to obtain the data. Variables included were: procedure, total case time/per case and per day, total fluoroscopy time/day, total runs/day, total air kerma (mGy)/day, total dose area product (uGym²)/day, number of cases/day, aggregate dose/day, individual dose/day, mean dose rate/day, peak dose rate/day, number of days of the study, total participants as well as role data (electrophysiologist, fellow, anesthetist, RN, and technician) linked to each of these categories. The PI received daily automated EP and fellow schedules delivered by Outlook. Outlook is a personal information manager from Microsoft utilized by the University for hospital email communication.⁷² This information conveyed the procedure(s) performed, interventionist involved, fellow assigned, and a small amount of patient demographic data. By identifying these participants and procedures

each day, the PI was able to tabulate total cases and link individual role identity to the data collected.

The study was designed to measure aggregate data for all roles and only individual values where possible because of the limited number of RaySafe badges. Case time data were obtained through Centricity, an electronic medical record system used by the anesthesia department. Centricity data records events, such as provider in and out times on a second-by-second basis. Since radiation is generally not emitted in the room until the procedure begins, the provider in and out time interval was utilized as total case time. Total case time also represented the aggregate time for the electrophysiologist, fellow, RN, and technician because data were reported primarily by group. Since there is 1 interventionist and 1 fellow at the start and end of a case, this time period reflected their individual times in the case as well. However, the RN and technician were replaced by coworkers for relief periods. These provider substitutions are not recorded in the electronic charting system. Therefore, since individual case time could not be determined for RNs and technicians, evaluation of their corresponding radiation exposure was not possible. Therefore, total aggregate time was determined for all categories collectively between phase 1 and 2. Additionally, aggregate data were determined for each of the 6 categories along with individual data where possible.

The CRNA badge also revealed aggregate data like the other badges. However, Raysafe did not have a method of determining multiple user radiation readings on a single shared badge. Since in this case the PI did have incremental CRNA times for all who entered or exited a case, measurement of individual exposure was possible. Additional calculations were necessary to determine individual exposure amounts. The CRNA individual case time data were linked to the corresponding time stamped radiologic exposure intervals using the RaySafe software programs

and pivot tables. For example, if CRNA A was present according to Centricity from 9:15:18 to 09:31:29, the time period was matched to the exact time frame for radiologic exposure on the CRNA dosimeter (Figures 15-17). Using these methods, aggregate and individual (CRNAs only) exposure data were obtained for faculty and staff. Faculty are defined as the electrophysiologist and staff are defined as all other roles.

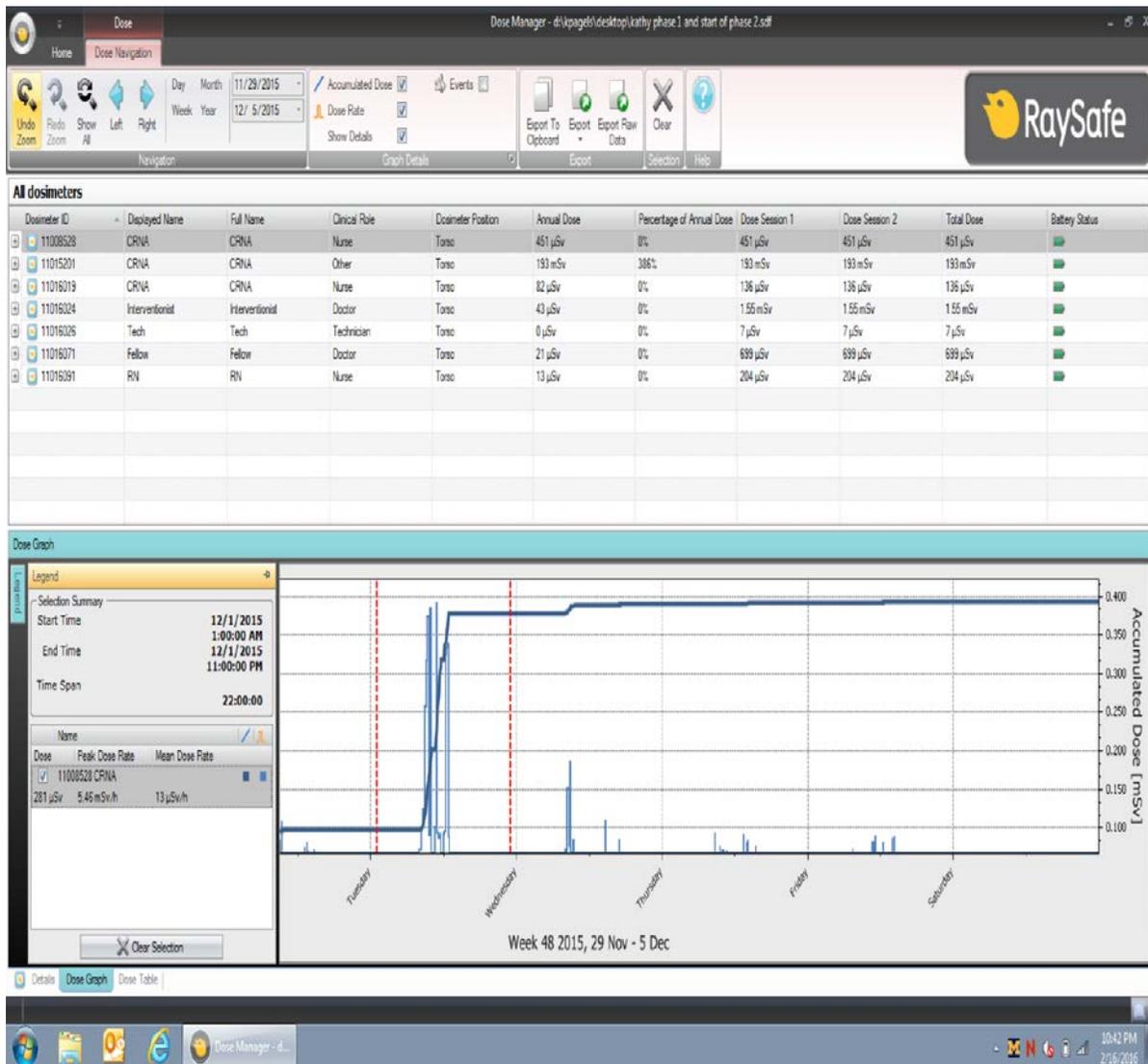


Figure 15: RaySafe Graph-One Day of Exposure–Dose, Peak, and Mean. Highlighted area of exposure day of interest. Left side of graph indicates the day's dose, peak, and mean values for the CRNA provider.

December 1 2015.xls [Compatibility Mode]

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
3			Acc. Dose [mSv]	Dose [mSv]	Dose Rate [mSv/h]	Name									
4	00:00	00:00:00	0.10	0.00	0.00										
5	01:00	01:00:00	0.10	0.00	0.00										
6	02:00	02:00:00	0.10	0.00	0.00										
7	03:00	03:00:00	0.10	0.00	0.00										
8	04:00	04:00:00	0.10	0.00	0.00										
9	05:00	05:00:00	0.10	0.00	0.00										
10	06:00	06:00:00	0.10	0.00	0.00	Steve B									
11	07:00	07:00:00	0.10	0.00	0.00	Steve B									
12	08:00	08:00:00	0.10	0.00	0.01	Steve B									
13		08:32:24	0.10	0.00	0.03	Steve B									
14		08:32:25	0.10	0.00	0.01	Steve B									
15		08:32:26	0.10	0.00	0.01	Steve B									
16		08:33:37	0.10	0.00	0.02	Steve B									
17		08:33:38	0.10	0.00	0.04	Steve B									
18		08:33:39	0.10	0.00	0.01	Steve B									
19		08:33:40	0.10	0.00	0.01	Steve B									
20		08:33:41	0.10	0.00	0.03	Steve B									
21		08:33:42	0.10	0.00	0.02	Steve B									
22		08:33:43	0.10	0.00	0.02	Steve B									
23		08:33:44	0.10	0.00	0.01	Steve B									
24		08:33:45	0.10	0.00	0.03	Steve B									
25		08:33:46	0.10	0.00	0.02	Steve B									
26		08:33:47	0.10	0.00	0.01	Steve B									
27		08:33:48	0.10	0.00	0.02	Steve B									
28		08:33:49	0.10	0.00	0.02	Steve B									
29		08:33:50	0.10	0.00	0.03	Steve B									
30		08:33:51	0.10	0.00	0.18	Steve B									
31		08:33:52	0.10	0.00	0.50	Steve B									

Figure 16: RaySafe Dose Table in Dose Manager Application. CRNA daily aggregate data further categorized by individual by using Centricity data and typing the name next to the time frame.

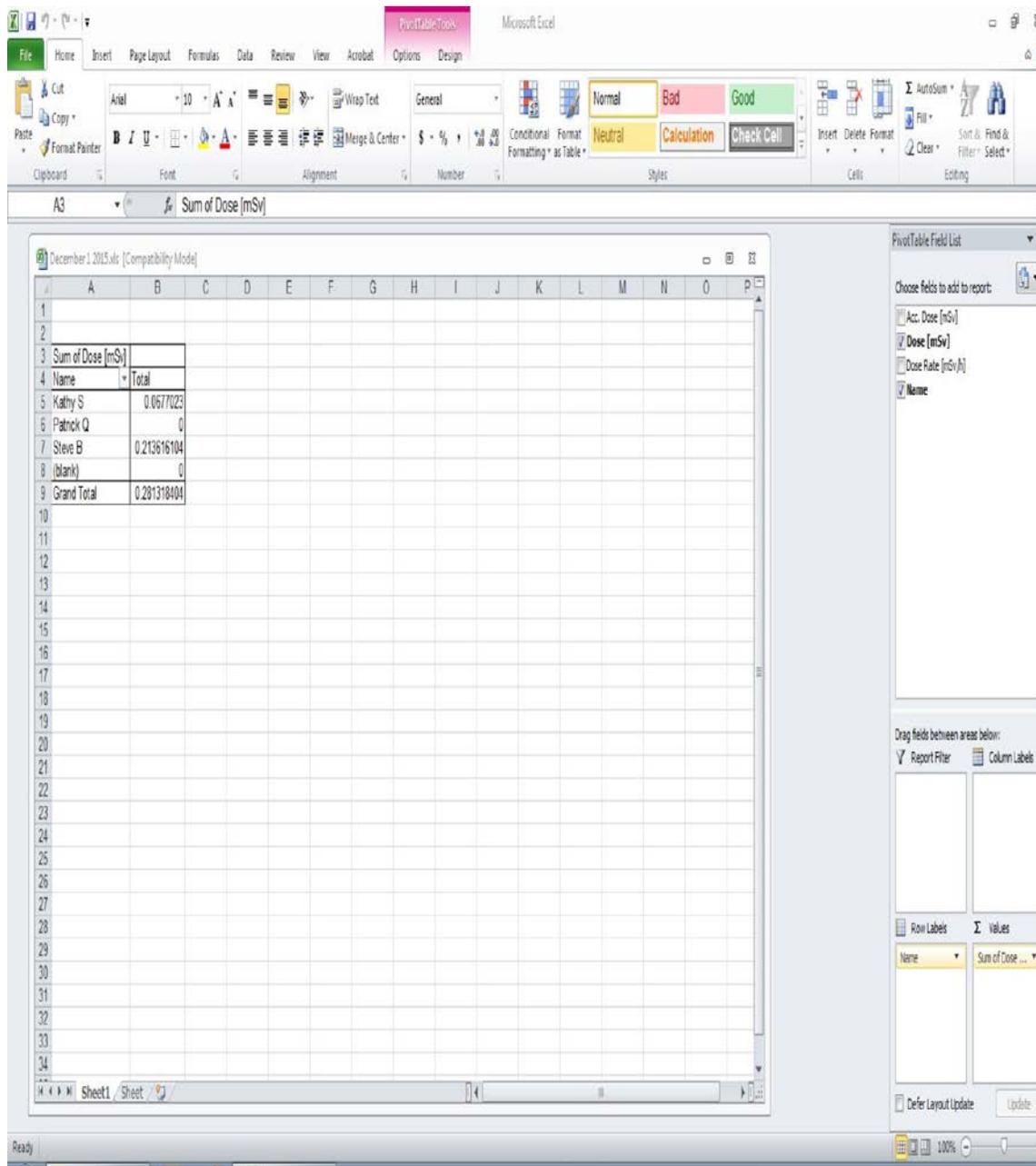


Figure 17: Pivot Table Calculations of Individual Doses for CRNAs. Pivot table calculation indicates that of the 281 uSv accumulated on this day, 213 were identified with Steve B and 68 uSv to Kathy S.

Radiologic data emanating from the x-ray machines were retrieved from the Siemens Artis system as well as the EP recording system (EPRS). This allowed for the retrieval of total fluoroscopy time, runs, kerma, and DAP per day. Data were stored in Excel on an encrypted password protected university owned laptop. The laptop was only used by the PI and only for the purposes of this study.

Staff (RNs, technicians and CRNAs) were assigned to the EPL at the discretion of the electrophysiology and anesthesia weekly schedulers. A mirror image of the approximated first 10-week assignment (control portion) of the study was used for the approximated second 10-week assignments for the (treatment group) as much as possible. To ensure that everyone who volunteered to participate in the study was allowed an opportunity to participate, every effort was made by the schedulers to place personnel in EP lab 3 at least twice during the study (1 control group and 1 treatment group). The EP float CRNA, who coordinates CRNA breaks and lunches to EP lab 3, attempted to assign study participants as much as was feasible. No attempt was made to match the procedures each CRNA was assigned to between the 2 phases of the study. This would have been technically difficult and could have been misleading because it is not the type of procedure, but the complexity of the procedure in an individual patient that determines the length of the case and the radiation exposure.

The recruitment of subjects occurred via a defined protocol. An email, with an IRB approved attachment, was sent to potential study participants describing the study and requesting voluntary participation (Appendix 3). One follow-up reminder email was sent within 2 weeks of the first email announcing locations, dates, and times of the consenting process. Volunteers, who wished to participate in the study, were asked to sign consent as part of a standard, nonexempt research project. Consent was obtained with the assistance of 2 trained nurse research assistants.

Consent information was obtained by securing a room at the hospital for the process of discussing the project. Individually or by group, time as needed was taken to answer all questions and to fully explain the study. If participants wished to meet privately, time would have been arranged to meet and discuss the study as well. No inquiries were made for additional questioning. Two University of Michigan medical physicists were also available either in person, by email, or on call to answer questions regarding the study or other radiation safety related questions that potential participants may have at the time of recruitment and consent into the study. These individuals were also available to assist with the write up of the study upon completion of the data collection to ensure correct interpretation and presentation of radiologic parameters. Additionally, a partial waiver of informed consent was requested for the project as well. The waiver was necessary for recruitment purposes. The PI assessed patient information regarding the procedure in each EPL, which was necessary for recruitment and not for purposes of patient care. The PI accessed patient records to determine procedures in each lab to assess radiation exposure. Therefore, the PI partially assessed patient information. That is, by IRB definition, the PI assessed patient information regarding the procedure in each EPL and radiation data, which was necessary for recruitment of cases included in the study but not for purposes of patient care.

STATISTICAL ANALYSIS

Statistical analysis was conducted in collaboration with Consulting for Statistics, Computing and Analytics Research (CSCAR), at the University of Michigan. Data were analyzed using IBM SPSS Statistics V 23.0, and significance was determined at P values $<.05$. The Anderson-Darling was used to assess normality indicated by a P value $>.05$.⁷³ In this study, all parameters of interest had P values $<.05$, indicating the data were not normally distributed. Therefore, the data were reported as medians with lower and upper quartiles (interquartile range or IQR).

Statistical comparisons used the linear mixed effect model, which is an extension of the linear regression model for data and is appropriate for data collected and summarized in groups.⁷⁴ It consists of 2 parts, fixed effects, and random effects. Fixed effects are constant across individuals and random effects vary. Fixed effects consist of the conventional linear regression portion, which describe the relationship between the dependent variable and one of more explanatory independent variables. The dependent variable is the outcome or the effect being explained. In this case, the dependent variable, Y , was the dose for each of the 5 categories. The independent variable is the cause or explanation of the variation associated with the dependent variable. For this study, the independent (fixed) factors were phase 1 (blinded) or phase 2 (unblinded), generalized procedure, and kerma. Generalized procedures were categorized into 1 of 3 procedures, which were atrial fibrillation/atrial flutter ablations, ventricular ablations, and device insertions. Kerma was classified as both a fixed effect and a covariate as it is a continuous, observed variable. Kerma is the acronym for kinetic energy relaxed per unit mass and is reflective of the radiologic output from the equipment used during the procedure expressed in m(Gy). Random effects are associated with individual experimental

units drawn at random from a population and, in this case, within subject repeated measurement occurred. The random variable was participant names associated with each role. Multiple dose readings occurred from the same subjects within each group as the EPL is the primary surgical setting for cardiac fellows, registered nurses, and technicians with each group representing no more than 12 participants. We did observe 1 electrophysiologist who accounts for a large proportion of the repeated measurements. Anesthetists didn't incur as many repeated measurements because they represented a larger pool of participants (56) and have a more diverse work assignment outside of the EPL. To ensure equitable comparisons between the dependent and independent variables, normalization of these parameters was included in the formula of the linear mixed effect model as determined by SPSS calculations.

Several considerations regarding interpretation of values should be noted regarding the linear mixed effect model. The model reports an estimate of fixed effects table for each independent variable. The estimate raw or unstandardized regression coefficient is referred to as B. It represents the slope or value for the regression equation for predicting the dependent variable from the independent variable. When 2 or more correlated predictors exist in the model, the B coefficient is known as a partial regression coefficient, and it represents the predicted change in the dependent variable when the predictor is increased by 1 unit while holding all other predictors constant.⁷⁵ In this case, the partial regression coefficients were the 3 independent fixed factors of phase, generalized procedure, and kerma. For example, a 1-unit increase in kerma is predicted to increase dose by 8.68EX.05 for electrophysiologist-fellow with all other independent variables held constant (see Table 6, legend). It is important to know that SPSS will automatically choose the category with the highest numerical value (or the lowest alphabetical letter) as the reference category for categorical variables.⁷⁶ Phase and generalized procedures are

categorical variables and as noted, kerma is a continuous variable. For kerma, the reference or starting point for radiation machine output is zero. The reference category is set to zero, and all parameters in a category are then compared with the reference of zero. For example, for the fixed effect of generalized procedures, V-tach ablations had the highest value and therefore was set to zero as the reference value. The other 2 types of procedures of atrial fibrillation/flutter ablations and device insertion/revision were then compared with V-tach ablations and values noted.

The linear mixed effect model used the log total dose as the dependent variable. Kerby Shedden, PhD, director of Consulting for Statistics, Computers and Analytics Research (CSCAR), in an email on April 24, 2016, indicated that by taking the log of the outcome variable, the effect of the predictor variable is expressed in proportional terms. A treatment effect may be multiplicative or additive, but it was expected that the effect would be multiplicative in this case. Second, the data are quite skewed, and the inferences (P values, etc) for the mixed model will be more accurate if the distribution of the dependent variable is roughly symmetric.

The primary analysis compared preexposure and postexposure, as measured by PDM by job title and not by individual. That is, the daily exposures of each of the 5 job titles (groups): cardiac electrophysiologist, cardiac fellow, circulator RN, scrub nurse/technician, and CRNA, regardless of the individuals working particular days or parts of days was an appropriate fit for the linear mixed effect model. In addition, a sixth category was assessed of a combined electrophysiologist-fellow role representing the operator position. As indicated previously, at this large teaching institution, it is practice that the electrophysiologist and the fellow alternate positions between the operator position and the adjacent control room. Both the fellow and the electrophysiologist rarely stood in the operator position for any extended time period together. To capture all of the radiation that occurred in the operator position, the electrophysiologist and

fellow's doses on their PDMs were summed representing the radiation received in total for the operator position. Similarly, kerma could not be assigned proportionately to the electrophysiologist or fellow, as the time each person occupied the position was not recorded. Therefore, kerma was assigned to the combined electrophysiologist-fellow group.

RESULTS

A total of 154 procedures were performed during the 4.5-month period from September 1, 2015 to January 15, 2016. As indicated, the total dose for each participant category was not normally distributed as indicated by all P values < 0.05 . An example of this data is provided for the operator role (electrophysiologist + fellow doses) in Figures 18 and 19. The entirety of the unadjusted descriptive data are summarized in Table 5. Statistically, the values represented in Table 5 could not be examined independently. Rather, the fixed and random factors with repeated measurement were correlated and could only be assessed by way of the linear mixed effect model as represented in Table 6. The results for the electrophysiologist-fellow data indicated a significant decrease in exposure with P value = .025 between phase 1 and 2 (Table 6). This is in agreement with the median phase exposure which decreased in phase 1 from 32 uSv (IQR 3.0-64.0 uSv, 95% CI, 12.504-48.448) to 7.0 uSv (IQR 1.0-15.0 uSv, 95% CI, 1.0-13.552.) in phase 2 (Table 5).

The other participant categories did not achieve significance for phase. For the CRNA data, the primary CRNA in each case was chosen as the main reporting value because that provider received the majority of the exposure during the case. Relief CRNAs' median exposure value was 0.0. The primary CRNAs' median dose in phase 1 was 2.0 uSv (IQR 0-9.5, CI 0-3.16). A median of 1.0 mSv (IQR 0.0-5.750, 95% CI 1.0-2.0) was recorded in phase 2. Although the CRNA doses were generally low, elevated values were observed in some cases with a maximum value of 214.00 uSv for 1 case. RN exposure data showed a median phase 1 value of 1.0 (IQR 0.00-3.0, CI 0.00-2.0). Phase 2 median value was 1.0 (IQR 0.0-2.0, 95% CI 0.0-2.0).

Significance was also obtained for the other 2 variables associated with dose. For the CRNA and RN, kerma was significantly associated with dose ($P=.00$). This is to be expected

since as energy per unit mass increases, dose may be expected to increase as well. This positive association between kerma and dose was not observed in the electrophysiologist-fellow group in which the real-time dose monitor was optimally positioned. A closely related term is the dose area product (DAP) that indicates the dose times the exposed area and describes biological effect.¹¹ DAP was also collected for each case in this study but could not be included in the linear regression due to multicollinearity. A scatterplot of both kerma and DAP are listed in Figure 20 indicating kerma and DAP are highly correlated ($R=.99$; Figure 20).

Lastly, generalized procedures achieved significance for the CRNA group with $P=.027$. The implants/revision category within this group had the greatest significance with $P=.018$. However, it did not affect the procedures significantly to detect a significant difference in overall phase.

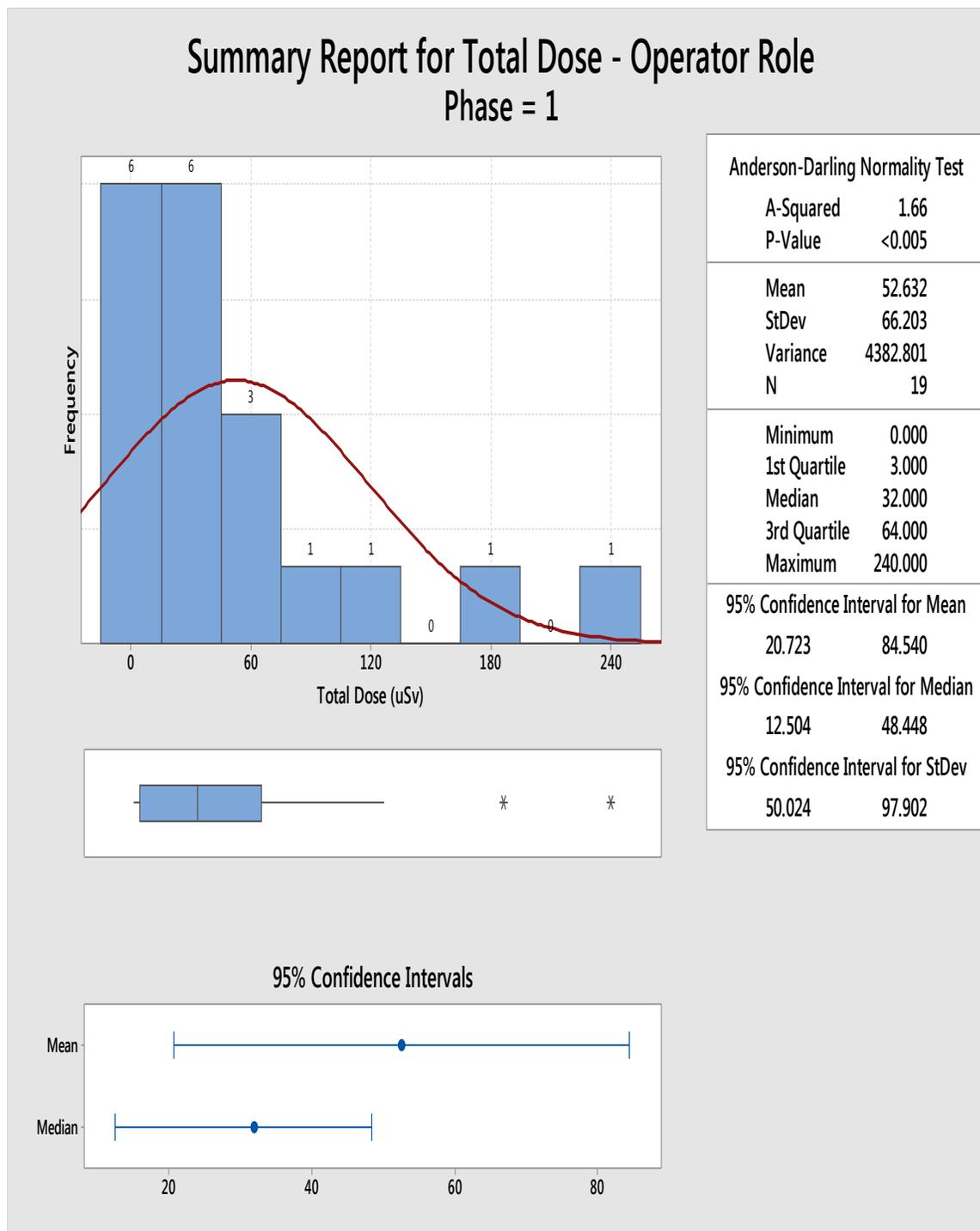


Figure 18: Summary Report for Total Dose-Electrophysiologist and Fellow Team: Phase 1. The electrophysiologist-fellow team (operator role) data did not follow a normal distribution in phase 1. The median values for the 19 procedures in which both the electrophysiologist and fellow were participating were 32 uSv.

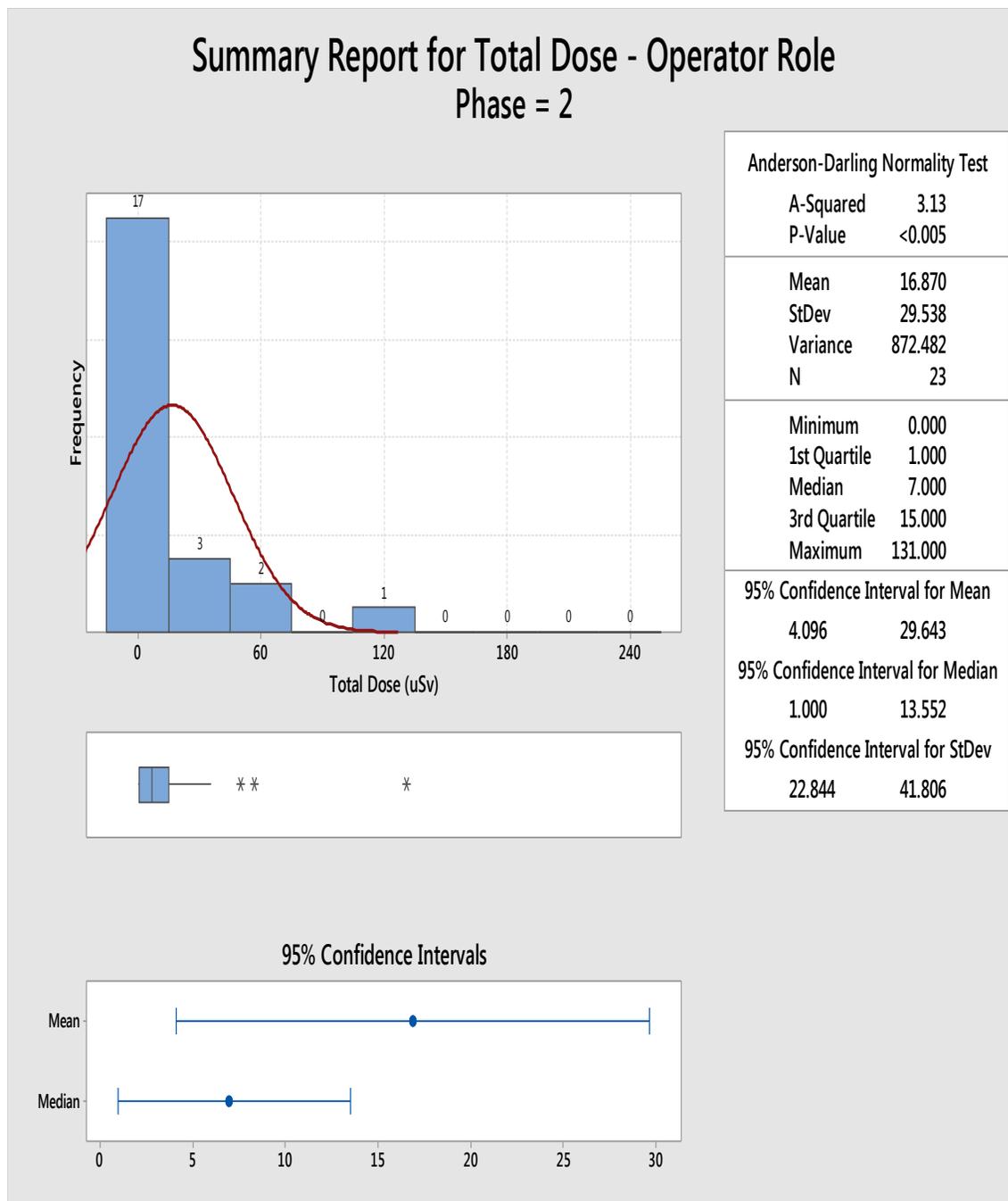


Figure 19: Summary Report for Total Dose-Electrophysiologist and Fellow Team: Phase 2. The electrophysiologist-fellow team (operator role) data did not follow a normal distribution in phase 2. The median values for the 23 procedures in which both the electrophysiologist and fellow were participating were 7.

Table 5: Unadjusted Descriptive Data of Total Case Parameters

Participant data	Phase 1	Phase 2
Operator (Electrophysiologist + fellow)		
Total dose (uSv)	1000	388
Number of procedures	19	23
Dose mean (uSv)	52.63	16.87
Dose median (uSv)	32	7
Dose minimum (uSv)	0	0
Dose maximum (mSv)	240	131
CRNA (primary)		
Total dose(uSv)	329	456
Number of procedures	46	68
Dose mean (uSv)	7.15	6.7
Dose median(uSv)	2	1
Dose minimum (uSv)	0	0
Dose maximum (mSv)	47	214
RN		
Total dose(uSv)	107	95
Number of procedures	50	57
Dose mean (uSv)	2.14	1.66
Dose median(uSv)	1	1
Dose minimum (uSv)	0	0
Dose maximum (mSv)	19	15
Total case parameters		
Total procedures	63	91
Mean kerma (mGY)	519.03	377.71
Median kerma (mGy)	247	186.5
Kerma minimum (mGy)	0.1	0
Kerma maximum (mGy)	3771	2505
Time in case mean (minutes)	297.51	290.34
Time in case median (minutes)	229.45	256.75
Time in case minimum (minutes)	106.92	96.39
Time in case maximum (minutes)	631.5	645.49

Table 6: Adjusted Data Using Multivariate Linear Mixed Effect Model of Factors Associated With Radiation Dose to Electrophysiologist-Fellow, CRNA, and RN

Parameter	Estimate	CI	P value
Operator role (Electrophysiologist + fellow)			
Phase 1	0.53	(.07, .98)	0.025
Phase 2	0		
Kerma	0	(-.0003, .0005)	0.665
Generalized procedure (all)			0.359
<i>A-fib/flutter</i>	-.28	(-.96, .40)	0.413
<i>Implant/revision</i>	-.57	(-1.39, .24)	0.162
<i>Ventricular tachycardia ablation</i>	0		
CRNA			
Phase 1	-.01	(-.09, .07)	0.762
Phase 2	0		
Kerma (primary CRNA)	0	(.0008, .0012)	0
Generalized procedure (all)			0.027
<i>A-fibrillation/flutter</i>	-.05	(-.17, .07)	0.407
<i>Implant/revision</i>	-.16	(-.30, -.03)	0.018
<i>Ventricular tachycardia ablation</i>	0		
RN			
Phase 1	0.05	(-.05, .15)	0.336
Phase 2	0		
Kerma	0	(.0002, .0004)	0
Generalized procedure (all)			0.506
<i>A-fibrillation/flutter</i>	-.01	(-.19, .17)	0.919
<i>Implant/revision</i>	-.08	(-.27, .12)	0.444
<i>Ventricular tachycardia ablation</i>	0		

Statistics per IBM SPSS V23.0. Significance determined at $P < .05$. Phase 2 and ventricular tachycardia are the reference categorical variables. Kerma is a continuous variable with reference point beginning at 0. Significance noted for phase of the Operator role (electrophysiologist-fellow) category. The estimate indicates if kerma and generalized procedures are held constant, the increase in the outcome variable of dose in phase 1 is .53 more than phase 2. Significance was also noted for kerma for RN and CRNA categories and generalized procedures for CRNA.

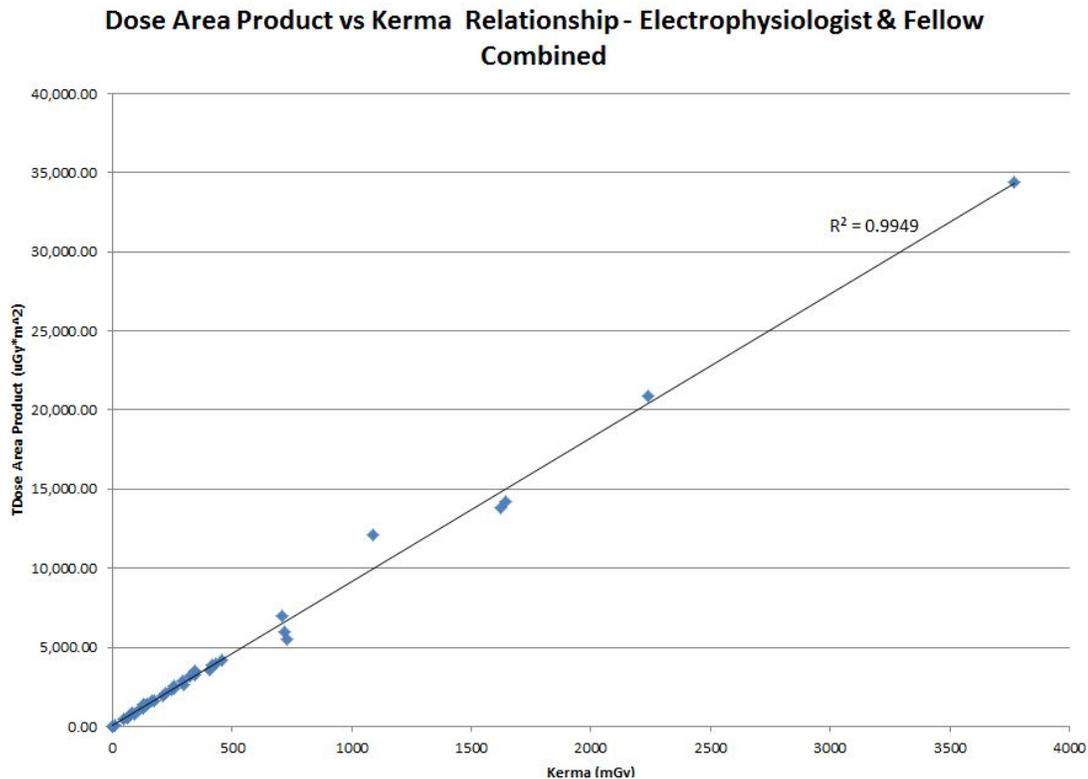


Figure 20: The Relationship of DAP and Kerma. Kerma and DAP are highly correlated with $R^2=0.9949$. To prevent multicollinearity, kerma was the chosen variable in the linear mixed effect model.

Several exclusions were made. The data provided evidence that the number of technicians wearing their badges was not sufficient to calculate their exposures and therefore technician data were excluded. Participants were excluded if they had not signed a consent but were assigned to the room and may or may not have worn the study badge.

Participants were also excluded from consideration for the day if all 3 values of dose, peak, and mean on their PDM indicated radiation exposure was zero. It is possible but unlikely that in an 8-hour to 16-hour work day ALARA practices may be excellent, or radiation exposure may be very low to achieve a zero reading on a badge in all 3 of these categories. It was not possible to observe participants during the case to see who was wearing their badge. The PI relied solely on feedback retrieved off the badge. Therefore, it was assumed that absence of data

for all 3 categories for an entire working day for all cases was considered evidence of noncompliance of badge wear among participants. All badges were reviewed for daily use and any aggregate badge reading greater than zero in any of the 3 categories was considered to have been worn in compliance of the study protocol, as verified by RaySafe representative Chintan Shah in phone conversation on April 21, 2016.

Three cases were excluded due to lack of radiologic examination information pertaining to kerma, DAP, runs, and fluoroscopy time. For the CRNAs, 7 days were excluded due to issues associated with the malfunction of the badge that twice required replacement by Unfors RaySafe.

DISCUSSION

In this study, a significant decrease in radiation levels occurred in phase 2 as compared to phase 1 for the operator role represented by the combined electrophysiologist/fellow role with $P=.025$. The linear mixed effect model indicates that when generalized procedures and kerma are controlled or held constant, there is still a difference between phase 1 and phase 2. It is suggestive that this reduction occurred because these participants could directly visualize their exposure in real time on the base station in front of them. Because they had continuous and immediate feedback, the people in this role likely took more precautions and corrective actions during the case, possibly leading to no significance associated with either kerma or generalized procedure. Other study participants could not visualize their real-time exposure values as easily, and no significant dose reduction occurred associated with phase. It was hoped that those parties who could see the exposure monitor would share exposure values with the other providers in the room. This instruction was not given as part of the study protocol and did not happen. The nurse anesthetist and RN groups did not demonstrate exposure reduction during phase 2.

The 2 other fixed variables of generalized procedure and kerma had mixed results. Significance was obtained for the CRNA groups for kerma with $P=0.00$. Generalized procedures overall were found not significant for either of these groups. However, the CRNA group did show partial significance for one of the procedures with $P=.018$ for implants/revisions although overall $P=.027$ for generalized procedures. As there was no observation of the procedures, the rationale for why implants/revisions were significant is unknown at this time. As found in this study, certain procedures such as V-tach ablations are associated with greater kerma and thereby dose. The higher the output from the radiologic equipment, the higher the dose may be if unaware of exposure status. The RNs also had significance of 0.0 for kerma, but generalized

procedure was also not significant. So, even though kerma was significant, it was not enough to be reflected in dose as a difference between phase 1 and 2 for either role. One explanation is the relative position of these providers to the radiation sources, which are the equipment and the patient. Figure 9 indicates the relative positions of each provider in the EPL. The RN is further away than the CRNA and therefore should not experience as much dose associated with procedure. This is because of the inverse square law, which indicates the intensity of the beam is inversely related to the square of its distance from the radiation source. So, for example, doubling the distance from the source results in one-fourth of the dose.¹⁰ Therefore, significance for implants/revision procedures amongst the CRNAs was not enough overall to achieve significance in dose and reflected as a difference between phase 1 and phase 2.

The blinded median phase exposure of the interventionist-fellow role of 32 uSv per procedure was in keeping with prior demonstrated ranges of .02 to 38.0 uSv per procedure by ICRP.¹⁴ The wide range in dose was attributed to a wide variation in procedure complexity as well as inconsistency in the use of the shield and other personal protective devices.¹⁴ The results of this study appear to be consistent with these prior observations.

The results of this study are also consistent with recent studies, which found significantly lower operator dose when using a real-time dose monitor. Heilmaier et al found that kerma air product (KAP) declined considerably in 15 of 19 types of fluoroscopically guided interventions (FGIs) when real-time exposure data were available. They concluded that combined use of a patient dose monitoring system and a real-time occupational dose monitoring system in FGIs significantly lessens patient and operator exposure doses.⁶⁷

A dose aware (DA) real-time monitor was utilized while using the C-arm fluoroscopy intraoperatively in a retrospective study by Müller et al.⁶⁸ The results showed a significant

reduction for all evaluated procedure types except for internal fixation of distal radius fractures. The conclusion drawn was that use of DA dose monitoring system reduces radiation exposure of the orthopedic surgeon and instantly demonstrates the effects of dose-reduction techniques.⁶⁸

James et al also found significantly decreased radiation exposure in phase 2 (real-time values observed) for all roles except physician A, concluding that real-time dose monitoring might help to lower occupational radiation exposure during diagnostic cerebral angiography procedures for health care workers.⁶⁹ Additionally, a similar study conducted in a pediatric interventional radiology setting also concluded that a significant reduction in staff operator exposure may occur with a real-time dose monitor due to increased staff compliance with the use of radiation protection equipment and dose reduction techniques.¹⁹

The Hawthorne effect may have contributed to some reduction in staff dose from the start of the study. That is, even though all participants were blinded in phase 1, it is possible that just the presence of this new piece of equipment, even though the screen was darkened (blinded), may have caused altered behavior. Faculty and staff may have focused the behavior on conceived actions that led to altered exposure in phase 1. Vigilance of action in phase 1, although blinded, may have led to less difference between the groups in phase 2. Reinforcement of presence of the device also occurred by the recruitment and consent documents in which all participants were given the opportunity to gain understanding and to answer questions regarding the study. However, it is expected the novelty of the device probably wore off fairly quickly and so the Hawthorne effect may have had little effect.

An additional benefit of a real-time dose monitor is a decrease in radiation exposure for the patient. Awareness of elevated radiation exposure can lead to actions, which result in lower radiation exposure for the patient. The RaySafe Company indicates a 10% reduction of patient

dose by using its product.⁶⁶ “Patients undergoing interventional procedures in cardiology face radiation exposure in the order of 1,000 or more times than that involved in conventional radiography.”^{4 (p1)} These patients may accrue greater exposure and some patients experience several procedures within a relatively short period of time. In addition, patients undergoing EP procedures tend to be younger, which is of concern for the stochastic effects of radiation as the latency period for inducement of most cancers is 10 years; this is not as great a concern for older patients. Counseling is suggested for patients before the procedure if the risk of radiation injury is thought to be significant. Important aspects of the patient’s medical history that should be considered when estimating radiation risk are genetic factors, coexisting diseases, medication, radiation history, and pregnancy.¹⁴ Additionally, a medical physicist should be consulted to help optimize interventional procedures while minimizing risk.¹⁴

Fluoroscopy systems include multiple variables, which may be adjusted to assist in lowering overall exposure. Overall variables to be considered include regulating the amount of radiation and image quality are tube voltage (kilovolts), the tube current (milliamperere), and pulse duration (milliseconds). These settings are autoregulated by the signal received by the detector (Figure 20), which is used mainly to compensate for the patient’s weight.⁷⁷ The operator can select different settings for image quality levels. The following are additional considerations for reducing radiation exposure.

1. **Cine:** Cine involves a series of rapidly recorded multiple images that are taken sequentially and displayed on the monitor. The radiation level during this time is approximately 10 times higher than during conventional fluoroscopy.⁷⁸ It is advocated that the use of cine should be limited as much as possible and used only when necessary.⁷⁷

2. **Collimation:** A collimator is a device that narrows the beam of particles or waves.⁷⁹

Therefore, increasing collimation decreases exposure and scatter. At the beginning of the case, a larger view may be more desirable. As the case proceeds and focus is narrowed to a particular region, greater collimation is possible and desirable.

3. **Magnification:** In order to view an image, a certain amount of radiation is necessary to reach each point on the detector. If magnification is increased, then a given amount of anatomy is spread out over a larger area of the detector. This would result in less radiation per pixel, and the image would be too dark. To correct for this, greater radiation is required to improve the clarity of the image. Greater magnification requires greater radiation exposure and produces more scatter. When possible, magnification should be targeted to the lowest amount.⁸⁰

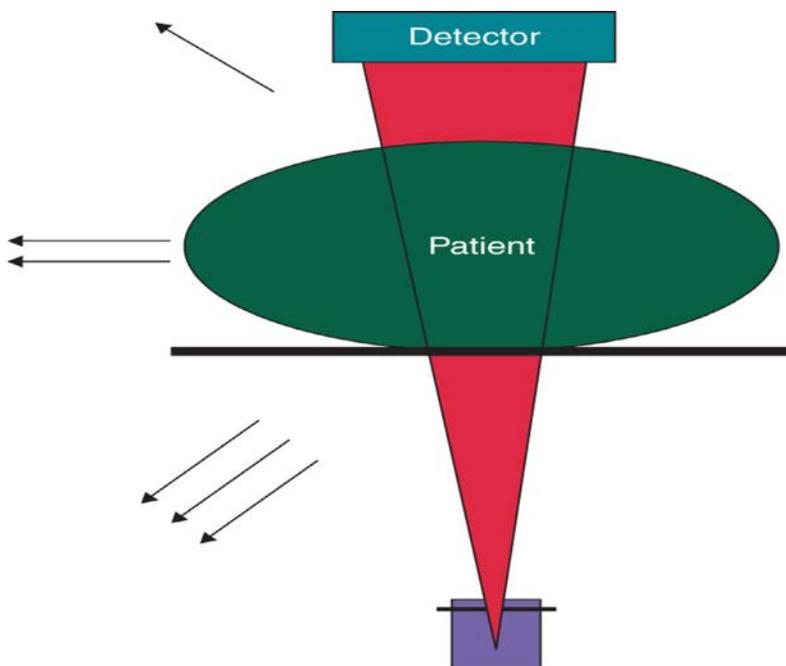


Figure 21: Beam Direction. Schematic indicating the beam (purple) direction to be received by the detector. Most scatter originates from the beam entrance site, which is much closer to the operator for procedures from the groin for the LAO tube.^{77(p952)}

4. **Projection angle:** Certain angles of the biplane (fluoroscopy equipment) are associated with higher amounts of radiation exposure and scatter than others. During catheter ablation procedures, the left anterior oblique (LAO) angle leads to a 40% to 50% higher dose rate for patients than the right anterior oblique projection⁷⁷ (Figure 21).⁸¹ This is because the spinal column and more cardiac tissue increase the tube settings. The LAO projection, the beam entrance site where most scatter originates is much closer to the operator than with the anterior posterior (AP) or the right angle oblique (RAO) projections.⁷⁷ The patient also acts as a poor shield of the entrance site to the operator. Radiation near the operator can be 6 times higher with LAO than with RAO.⁷⁷ In the work setting, the anesthesia providers are predominately located at the left side of head of the bed, putting them at risk for elevated exposure.
5. **Frame rate:** This term refers to the frame frequency and represents the frequency rate at which an imaging device displays consecutive images called frames. The greater the number of frames, the higher the radiation exposure. When possible, frame rate should be reduced.⁷⁷
6. **Fluoroscopy time:** Fluoroscopy time refers to the time in which the beam is on. It should be minimized as much as possible to reduce the radiation exposure to the patient and staff.⁷⁷

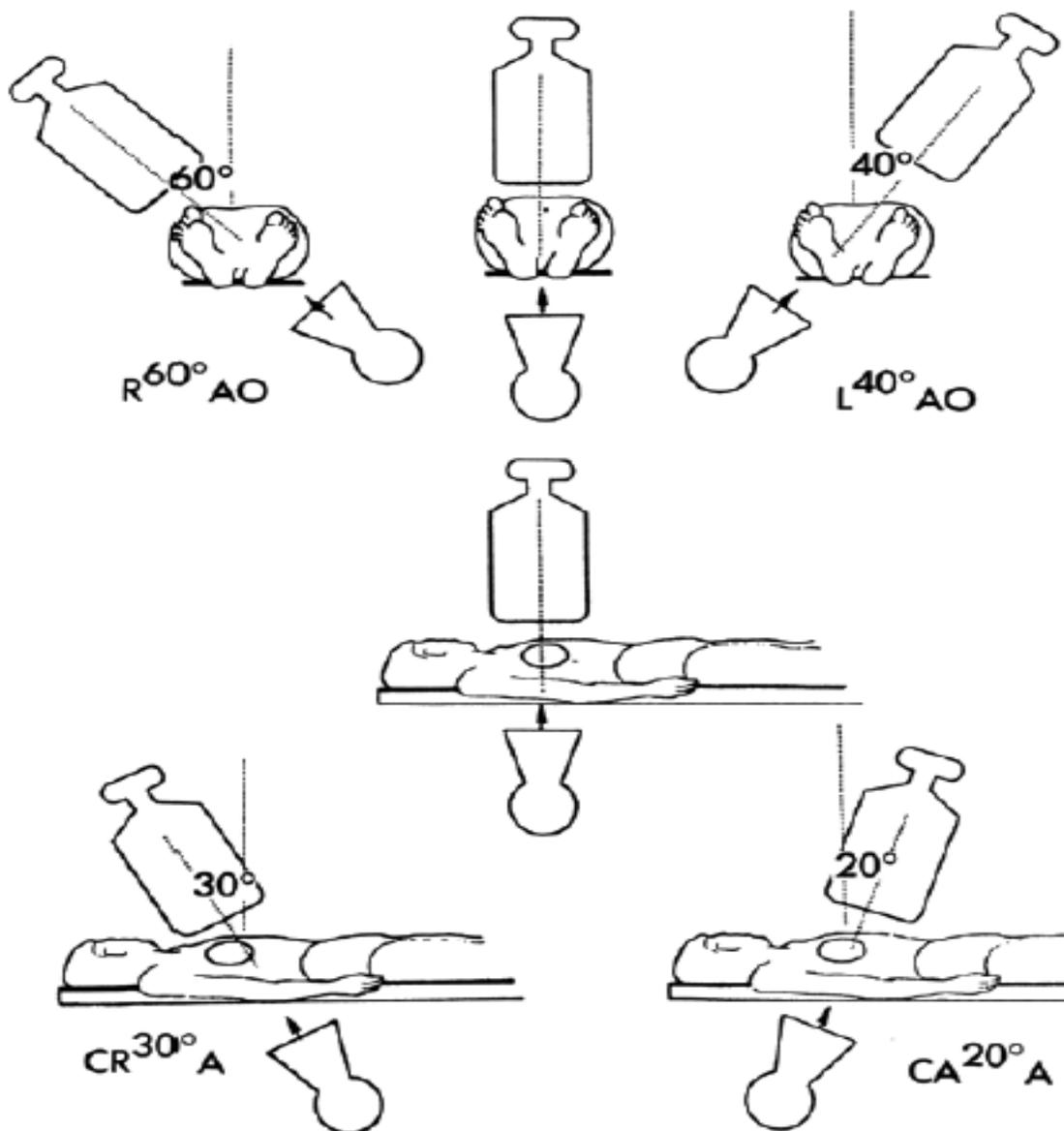


Figure 22: Nomenclature for Radiographic Projections. The small black arrowheads show the direction of the x-ray beam. Top 3 panels (left to right): right (R) Anterior oblique (AO), anterior–posterior, left (L)AO. Middle panel, anterior posterior viewed from patient’s side. Bottom left: If the intensifier is tilted toward the head of the patient, a cranial view is produced. Bottom right: If the intensifier is tilted toward the feet of the patient, a caudal view is produced. (Redrawn from Paulin S. *Cathet Cardiovasc Diagn.* 1981;7:341-344, and reproduced in Kern MJ (Ed.) *The Cardiac Catheterization Handbook*. 5th ed. Elsevier, Philadelphia, Pennsylvania: 2011:152.⁸¹

There were several limitations of the study. First, it was not possible for the PI to make any observations of behavior in EP lab 3. This was due primarily to the investigator acting alone without additional resources for data retrieval and documentation of all case data. The PI did not ask interview participants to learn if they altered their behavior based on the exposure data they were seeing. The PI also did not observe the time the electrophysiologist-fellow may have overlapped in the operator position. The PI retrieved information at least 1 to 3 times per week to ensure the equipment was functioning properly and to retrieve any badges that may have been missing due to failure to return them from the day's use.

Another limitation was the inability to comment on additional factors, which may have increased or decreased exposure. The weight of the patient was not recorded, which is contributory to increase exposure as scatter increases with increased mass. Additionally, the angle of the biplane was not recorded, which, as previously noted, certain positions such as LAO is associated with increased exposure.⁷⁷

Additional limitations include issues associated with the equipment. The screen was optimally designed for the operator role, and all participants did not have equal viewing ability of their exposure. Many participants, such as RNs and CRNAs, could not view their exposure at all because of their position in the room. Second, the PDM (badges) from RaySafe are intended to be issued to individual participants and not shared and required multiple calculations from the PI, which was very time consuming and prone to error. Third, the CRNA badges malfunctioned twice requiring replacement and 7 days' worth of data lost for this category of participant.

Future suggestions for improvement would be to repeat this study, perhaps as a larger pilot study involving additional labs in EP or Interventional radiology. It is further suggested

additional staff be allocated to this project to fully observe behavior and interview participants for verbal feedback regarding the device.

CONCLUSION/RECOMMENDATIONS

In summary, using the linear mixed effect model, the fixed effect variable phase showed a significant decrease in radiation levels in phase 2, as compared with phase 1 for the operator position represented by the combined interventionist-fellow role with a *P* value of .025. Several prior studies have demonstrated similar results when participants are aware of their exposure.^{19,67,68,69} Lower exposure may decrease the risk of the stochastic effects of protracted exposure, namely cataract and cancer induction. In general, dose values were low, and all dose values were well within the current US maximum allowable exposure of 5,000 mrem per year.

The other categories of participants, including CRNA and RN, did not achieve significance for phase in part because they could not see the screen, which was optimally positioned for the operator. However, although other staff groups did not achieve significance, it is still important for staff members to wear their badges. The health team should work together to monitor the radiation screen and perhaps communicate effectively to lessen exposure.

To remedy, the deficit of increased visualization for all team members, it is recommended that additional software, available in the past year, be included in the real-time dose monitoring system. The new software called Dose Aware Extend transfers data from the base station to an additional large LED screen displayed prominently in many operating rooms. Presence of the LED screen enhances communication, safety, and transparency in real time in any operating room. Many components of the patient's care are conveyed on the screen, such as procedure, allergies, blood loss, and provider names. It is recommended that the RaySafe occupational exposure data be considered an essential piece of patient information included on this screen to enhance the safety of faculty and staff working in the room.

Educating all staff regarding the availability and necessity real-time dose monitoring is

also an important aspect of eliciting change. Robert Stevenson, MD, cardiologist and electrophysiologist, at Good Samaritan Hospital, Lebanon, Pennsylvania, stated, “There is always room for improvement and everyone from the physicians, staff to the administrators, share in that responsibility. The hospital is responsible to provide the latest technology to protect the staff and the day-to-day proper operation of the equipment and its ability to protect the staff is the responsibility primarily of the physician,” he explained.⁶⁵ Miles Carver, director of Invasive Cardiology Services at Good Samaritan Hospital, Lebanon, Pennsylvania, further stated, “Education is the key to making lasting changes. You also need a champion radiation safety committee, and the committee needs to be very active.”⁶⁵ It is recommended through education, real-time dose monitoring systems will be more prevalent in suites such as EPLs as well as other radiologic areas to optimize the occupational health and safety of all faculty and staff exposed to ionizing radiation.

AUTHORS

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Shawn Fryzel, DrAP, MS, CRNA, is program director for the University of Michigan Flint/Hurley Medical Center Anesthesia Program, Flint, Michigan.

Appendix 1 : University of Michigan IRB Approval for Study



Medical School Institutional Review Board (IRB/MED) • 2800 Plymouth Road, Building 520, Suite 3214, Ann Arbor, MI 48109-2800 • phone (734) 763 4768 • fax (734) 763 9603 • irbmed@umich.edu

To: Kathleen Chardenet

From:

Michael	Geisser
Alan	Sugar

Cc:

Milo	Engoren
Kathleen	Chardenet
Elizabeth	Jewell
Donna	Carnahan
Shawn	Fryzel
Anna	Dubovoy
Joann	Prisciandaro
Ray	Elmblad
Emmanuel	Christodoulou

Subject: Initial Study Approval for [HUM00085102]

SUBMISSION INFORMATION:

Study Title: Radiologic monitoring of faculty and staff in the electrophysiology lab using a Real-Time Dose Monitoring System
 Full Study Title (if applicable): Radiologic monitoring of faculty and staff in the electrophysiology lab using a Real-Time Dose Monitoring System
 Study eResearch ID: [HUM00085102](#)
 Date of this Notification from IRB: 5/15/2015
 Review: Full Committee
 Initial IRB Approval Date: 4/16/2015
Current IRB Approval Period: 4/16/2015 - 4/15/2016
Expiration Date: Approval for this expires at: **11:59 p.m. on 4/15/2016**
UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))
OHRP IRB Registration Number(s): IRB00000244

Approved Risk Level(s):

Name	Risk Level
HUM00085102	No more than minimal risk

Appendix 2: Consent Form University of Michigan IRB

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

Name of Study and Researchers

Title of Project: Radiologic monitoring of faculty and staff in an Electrophysiology lab using a real time dose monitoring system

Principal Investigator: Kathy Chardenet, CRNA, MSA

Faculty Advisor: Dr. Milo Engoren MD

Consultants: Dr. E. Christodoulou, PhD, Dr. Joann Prisciandaro PhD

Co-Investigators: Dr. Anna Dubovoy MD, Dr. Shawn Fryzel DrAP

GENERAL Information

We are conducting research regarding radiologic monitoring of faculty and staff in an Electrophysiology lab using a real time dose monitoring system. The purpose of this study is to assess whether the use of a real time monitoring system will result in decreased individual and aggregate exposure among faculty and staff working in an electrophysiology lab (EP). To gather information, we are asking 150 participants, including EP Interventionists, EP fellows, EP RN's, EP technicians, and nurse anesthetists to participate. This study will be conducted for 3 months in EP lab 3.

If you agree to participate in this study, you will be asked to utilize radiation protective equipment as normally specified by your job duties. You should continue to wear the radiation monitoring dosimeters (Landau-radiation monitoring dosimeters), issued by the UM-OSEH/RSS as normal to meet the regulatory requirements. You should also use the mandatory protective aprons and thyroid shields required by the State's Michigan Dept. of Licensing and Regulatory Affairs (LARA), hospital policies, and OSEH/RSS.

In addition to your normal radiation safety procedures, you will be asked to wear both a passive dosimeter and a real time dose monitor for all cases for the day you are assigned to an electrophysiology lab. You will not see the readings on the real-time monitor for the first half of this study (roughly 6 weeks), and you will be able to see the readings during the second half.

Scatter levels for the real time dose monitor will be measured in aggregate for all participants and individually for Interventionist, Fellow and Anesthesia staff. Break times currently are not recorded for the technician and RN staff and therefore their individual levels cannot be determined. Individual cumulative total exposure from your passive dosimeter will continue to be monitored via our existing

Radiation Safety service. Although the PI or study team members may know the name and radiologic exposure of participants on any given day of the study, results from the study will be presented only in terms of trends or overall findings and will not include information about specific participants

This project is deemed as no more than minimal risk. The study team does not foresee or anticipate any direct risk to the subjects. You may not receive any personal or direct benefit from being in this study. There may be an indirect benefit due to possible improvement of awareness to radiologic exposure to you as well as to other faculty and staff participating in cases that involve radiation. There will be no compensation for participating in the study. Unfors RaySafe, the manufacturer of the real time dose monitoring system, could profit from the results of the study.

You will not be identified in any reports on this study. Records will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, the sponsor of the study, (University of Michigan Hospitals) or university and government officials responsible for monitoring this study may inspect these records.

A video will also be provided at the time of consent for regarding the Real Time Dose monitoring system. Viewing the video is voluntary. The video was produced in conjunction with Phillips and the RaySafe Corporation, and can be found in advance at:
<https://www.youtube.com/watch?v=VdbgAVGPMIlg>

Your participation in this project is voluntary. Even after you sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise be entitled.

If you have questions or concerns about this study or feel that the study has caused you any harm, Contact the study PI:

Kathy Chardenet CRNA, MS, BBA
Department of Anesthesiology, 1H247 UH, SPC 5048
1500 East Medical Center Drive, Ann Arbor, MI 48109-5048
telephone 734-936-4270, page at 12240
email: kpagels@umich.edu

Additionally you may contact

Dr. Milo Engoren engorenm@med.umich.edu or 734-470-6644,
Dr. Anna Dubovoy aodnopo@med.umich.edu or 734-647-2777
Dr. E. Christodoulou Manos@med.umich.edu or 734-615-0120
Dr. J. Prisciandaro Joannp@med.umich.edu or 734-936-6192

or contact the hospital operator at 734-936-8000 and ask to have any of these individuals paged.

If you have any questions or concerns about your rights as a research subject, or any grievance, you may also contact the Institutional Review Board for Human Subject Research (IRBMED), University of Michigan, 2800 Plymouth Road, Building 520, Room 3214, Ann Arbor, MI 48109-2800; telephone 734-763-4768.

SIGNATURES**Research Subject:**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with Kathy Chardenet, Donna Carnahan or Ray Elmblad. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed above. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Study ID: _____ Date of Birth: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understand the nature of the study and the risks and benefits of participating.

Name: _____

Title: _____

Signature: _____

Date of Signature: _____

Appendix 3: Figure 20: Recruitment form-University of Michigan IRB

Dear Colleague,

I ask for your participation at the University of Michigan Hospitals in a research study entitled, "Radiologic monitoring of faculty and staff in a electrophysiology lab using a real time dose monitoring system - [HUM00085102](#)".

Currently, a passive dosimeter to measure scatter from radiation over a one month time period is utilized. A real time dose monitoring system represents another option for monitoring radiologic scatter and provides immediate and cumulative feedback to the participant during the case regarding their exposure. Participation in this study is voluntary. There is no direct benefit to you for participating, however, you may experience improvement in you awareness of radiologic exposure. The research question is, will the use of a real time monitoring system result in decreased individual and aggregate exposure among faculty and staff working in an electrophysiology lab (EP)?

The study setting will involve EP lab 3 at the Cardiovascular Center. The real time dose monitoring system will be fixed to the gantry for the duration of the study.

All participants in this 3-month quantitative cross over study will be asked to wear the radiation monitoring dosimeters (Landau-radiation monitoring dosimeters), issued by the UM-OSEH/RSS to meet the regulatory requirements. They should also use the mandatory protective aprons and thyroid shields required by the State's Michigan Dept. of Licensing and Regulatory Affairs (LARA), hospital policies, and OSEH/RSS. Radiation goggles and rolling shields are also suggested.

Scatter levels for the real time dose monitor will be measured in aggregate for all participants and individually for Interventionist, fellow and Anesthesia. This is due to break times currently are not recorded for the technician and RN therefore individual levels cannot be determined. Individual cumulative total for the passive dosimeter will continue to be determined per Radiation Safety. The PI or study team members may know the name and radiologic exposure of participants on any given day of the study. Results from the study will be presented only in terms of trends or overall findings and will not include information about specific participants.

The eligible study population includes faculty and staff assigned to work in the EP lab for the study at the CVC Hospital, University of Michigan hospitals that work strictly with an adult population of patients. Eligible personnel population, ()=indicates total possible participants) includes the EP interventionist (10), cardiology fellow (10), nurse anesthetist (95), registered nurse (20) and technician (15). Exclusion criteria are people who do not work in EP with an adult population of patients or who decline to not be studied.

A video will be provided at the time of consent for those who wish to view the technology and concept of a Real Time Dose Monitor.

You need to give your written informed consent to participate. **The date for the consenting process is _____, at _____ locations at the time of _____.** For questions regarding your rights as a participant in human subjects research, you may contact the University of Michigan Hospitals IRBMED (734) 763-4768 or Email: irbmed@umich.edu.

If you have any questions regarding the purpose or procedures for this study, you may contact Kathy Chardenet, MSA, CRNA kpagels@umich.edu, or 734-936-4270 or pager 12240, Dr. Milo Engoren engorenm@med.umich.edu or 734-614-7679, Dr. Anna Dubovoy aodnopo@med.umich.edu 734-936-9479, Dr. E. Christodoulou Manos@med.umich.edu or 734-615-0120, Dr. J. Prisciandaro Joannp@med.umich.edu or 734-936-6192 or call the hospital operator at 734-936-8000 and ask to have any of these individuals paged.

I sincerely thank you for your time and consideration.

Sincerely,

Kathy Chardenet, CRNA, MS
DRAP student
University of Michigan-Flint

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