

# Safe Clinical Use of Fluoroscopy

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### Faculty

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### Faculty Disclosure

Contributing faculty, Berthina Coleman, RN, MD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planners and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

### Audience

This course is designed for physicians, nurses, radiology technicians, surgical technicians, and all healthcare staff involved in ensuring safe clinical use of fluoroscopy.

### Accreditations & Approvals



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### Special Approvals

This course meets the California requirement for 4 hours of education in radiation safety for the clinical uses of fluoroscopy.

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

### About the Sponsor

The purpose of NetCE is to provide challenging curricula to assist healthcare professionals to raise their levels of expertise while fulfilling their continuing education requirements, thereby improving the quality of healthcare.

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### Disclosure Statement

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### Course Objective

The purpose of this course is to provide healthcare providers with an understanding of the challenges encountered when using fluoroscopy in clinical practice and the tenets of safe fluoroscopy use in clinical practice.

### Learning Objectives

Upon completion of this course, you should be able to:

1. Outline the history of fluoroscopy.
2. Define terms used in discussion of fluoroscopy.
3. Describe the components of a standard fluoroscopy unit.
4. Discuss the use of contrast media in obtaining fluoroscopy images.
5. Identify limitations of fluoroscopy in diagnostic and interventional radiology.
6. Analyze the various uses of fluoroscopy in diagnostic and interventional radiology.
7. Evaluate key issues in radiation exposure and potential deterministic and stochastic effects.
8. Outline the various ways that patient and staff radiation doses are measured and documented.
9. Identify tenets of radiation safety when working with fluoroscopy.
10. Describe radiation safety issues for special populations, including pregnant women and children.



Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the course material for better application to your daily practice.

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## INTRODUCTION

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Fluoroscopy is a radiography technique used to produce real-time images using continuous x-rays transmitted through a tissue of interest onto an image receptor. Image receptors can either be an image intensifier or a flat-panel detector. The main focus of this type of radiography is to image tissues or objects that are constantly moving. Fluoroscopy is usually used for several minutes with the intent to save only some of the images. In general, the last image on a fluoroscopy loop can be saved; on some new machines, several parts of the loop can be saved. The total fluoroscopy time should always be recorded for each procedure. It is important to note that the total fluoroscopy time does not include the time used for fluorography, which is documented separately [1].

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## HISTORY OF FLUOROSCOPY

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Fluoroscopy can be traced back to 1895, when Wilhelm Röntgen noticed a barium platinocyanide screen fluorescing due to exposure to what he would later define as x-rays. The first fluoroscopes were invented several months after Röntgen's discovery of x-rays. Early fluoroscopes were simple boxes made of cardboard that were open at one end (the narrow end) for the eyes of the observer. The other, wider end was closed with a thin cardboard piece coated on the inside with a layer of fluorescent metal salt. The resultant images obtained from these old "fluoroscopes" were very faint. In an effort to produce enhanced images, Thomas Edison discovered that calcium tungstate screens produced brighter images. Edison is also credited with creating and designing the first commercially available fluoroscope some time prior to 1900 [2].

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## DEFINITION OF TERMS

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Any discussion about fluoroscopy and the radiation safety concerns that are irrefutably involved with its use necessitates a basic understanding of certain terms and concepts. The following basic glossary provides a framework for this discussion.

**Absorbed dose:** The energy imparted into a tissue by ionizing radiation at a specific point, as measured in grays (Gy). When assessing the dose or risk of radiation to patients in general, the quantity calculated and documented is usually the mean absorbed dose. The unit of absorbed dose is expressed in joules per kilogram (J/kg) [3]. The absorbed dose in air is referred to as the air kerma.

**Air kerma:** The energy obtained from an x-ray beam per unit mass of air in a volume of irradiated air. Air kerma is also measured in Gy and is the dose delivered to a specific volume of air [3].

**As low as reasonably achievable (ALARA):** An important principle in the protection of the general public and staff members occupationally exposed to radiation. However, the protection of patients has been recognized as requiring a different approach, given that the primary goal is a good clinical outcome. A minimal patient dose is not necessarily in the patient's best interest and may even be harmful in the sense that using lower radiation doses may be less diagnostically or therapeutically successful. The goal in patient care should be to give the optimal dose to allow clinical goals to be safely met.

**Biologic variation:** Individuals differ significantly in terms of the amount of radiation required to produce a deterministic effect and in the extent of damage caused by the same radiation dose. There are several factors contributing to biologic variation in radiation dose, including the patient's age, underlying disease, and idiopathic etiology. In addition, different skin types and different parts of the body vary in sensitivity to radiation [3].

**C-arm fluoroscopy system:** A system comprised of a coupled x-ray tube and image receptor. Typically, a C-arm fluoroscopy system has the ability to rotate along two planes: the craniocaudal direction and the left-to-right direction. Most C-arm fluoroscopy systems have an isocenter that is the identifiable center of rotation. The object placed at the isocenter will remain centered in the beam even as the C-arm rotates in all directions. Some C-arms have a fixed distance between the source and the image receptor while others have variable distances between the source and the image receptor. It is important to recognize that radiation protection strategies for each type of C-arm system will vary [3].

**Effective dose:** The sum of the products of the dose in an organ and the tissue weighting factor for that organ. Is often used to denote radiogenic risk. Techniques used for estimating effective dose rely on a computer-model body and statistical simulations of radiation exposure. All estimates of effective dose should take into account biologic tissue variation. The stochastic radiation risk to an average member of an irradiated population is expressed in Sieverts (Sv). When calculating effective dose, it is important to include adjustments for age and sex [3].

**Equivalent dose:** A measurement used for radiation protection purposes that takes into account the different probability of effects that occur with the same absorbed dose delivered by radiations with different radiation weighting factors. Equivalent dose is measured in Sv.

**Fluoroscopic image:** A single recorded image obtained by using an image intensifier or digital flat panel as the image receptor. A digital angiographic loop consists of a series of fluorographic images.

**Fluorographic time:** Total time of fluoroscopy used during an imaging or interventional procedure, with the exception of fluorographic procedures.

**Hounsfield units:** A single computed tomography (CT) image generated by the scanner is divided into many tiny blocks of different shades of black and white, known as pixels. The actual gray scale of each pixel on a CT depends on the amount of radiation absorbed at that point, which is termed an attenuation value. Attenuation values are expressed in Hounsfield units (HU). The HU scale assigns air a value of -1,000 HU and dense bone a value of +1,000 HU. Water is assigned 0 HU.

**Interventional reference point:** Identified on isocentric fluoroscopy systems, this refers to the point located about 15 cm from the isocenter of the central x-ray beam in the direction of the focal spot (close to the patient's entrance skin surface). In cases in which non-isocentric geometries are used, it is the responsibility of the U.S. Food and Drug Administration (FDA) to define the location of the interventional reference point [3]. The interventional reference point is also called the patient entrance reference point [1].

**Isocentric fluoroscopy system:** An imaging system in which there is a specific point in space through which the central ray of an x-ray will pass regardless of the orientation of the beam. This point is defined as the isocenter. When an image is placed at the isocenter of this type of fluoroscopic system, the image will not move across the field of view if the imaging system is rotated in any direction [3].

**Kinetic energy released in matter (kerma):** The amount of energy (measured in Gy) transferred from the x-ray beam into charged particles in the tissue of interest. This is the energy extracted from an x-ray beam per unit mass of a specified tissue in a small irradiated volume of material or tissue (e.g., bone, fat, muscle). For diagnostic x-ray procedures, this is equivalent to absorbed dose in the specified medium [1].

**Kerma-area product:** The estimate of the absorbed radiation dose to air across the entire beam emitted from the x-ray tube. It is an integration of both the air kerma and the kerma and is used to determine the total amount of radiation delivered to the patient, as expressed in  $\text{Gy cm}^2$ . The International Commission on Radiation Units and Measurements' symbol for kerma-area product is PKA. The kerma-area product is usually estimated without including scatter radiation. Previously, this was referred to as the dose-area product. It can be measured with a dosimeter or calculated by the fluoroscope [1].

**Peak skin dose:** The highest dose to any portion of a patient's skin during any part of a radiologic procedure. The peak skin dose includes both the dose delivered by the primary x-ray beam as well as the dose delivered from scatter.

**Qualified medical physicist:** A professional who has completed education and training and has been granted certification in one or more medical physics subfields (e.g., nuclear, therapeutic, diagnostic).

**Reference point air kerma:** The air kerma accumulated at a specific point in space relative to the interventional reference point on the fluoroscopic gantry during a procedure. Measurements of reference point air kerma do not include radiation scatter from the patient. It is sometimes called the cumulative dose, the reference dose, or the cumulative air kerma [1]. Also referred to as the cumulative dose.

**Significant radiation dose:** An established threshold used to initiate or trigger multiple-dose management actions. It is important to recognize that there is no assumption that doses less than the significant radiation dose threshold are safe or that doses greater than the significant radiation dose level will always have deleterious effects. Instead, this level should prompt providers to take certain actions when the dose is reached.

**Threshold dose:** The minimum radiation dose at which a specified deterministic effect can occur. It will vary greatly in each individual due to biologic variation. In addition, the threshold dose for different anatomic sites on the same individual will vary. For example, the threshold dose for skin on the eyelid is much different than the radiation threshold dose for the sole of the foot.

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## AN OVERVIEW OF FLUOROSCOPY

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Radiography is one of the most commonly used modalities in imaging. It is basically defined as the use of x-rays to generate images. There are multiple terms commonly used to refer to plain films, including x-rays, radiographs, and conventional radiographs. Traditionally, x-ray has been used to describe the images generated, but in reality, x-rays are the beams used to generate the images [4].

Conventional radiographs are created by passing an x-ray beam through a patient and using an x-ray plate to capture the attenuated x-ray beam. The image produced is created by the different densities in the human body and how they lessen (attenuate) the x-ray beam. For example, bone will attenuate the beam much more than muscle or fat.

The x-rays produced via fluoroscopy are polychromatic because they cover a wide spectrum of energy levels. This is in contrast to the monoenergetic rays, such as gamma-rays, produced by nuclear sources of radiation.

Fluoroscopic images can be obtained in one of two ways. A single image is typically obtained using an image intensifier and an image receptor. An angiographic run of fluorographic images usually involves multiple images, often subtracted from a mask image to produce subtraction angiographic images. It is important to note that fluorographic images differ from fluoroscopic images. Fluorography requires much larger amounts of radiation than fluoroscopy [1].

Over the last several decades, fluoroscopically guided interventional procedures have revolutionized medical care. For example, the use of percutaneous stent placement has replaced surgical bypass for arterial revascularization. Surgical decompression of portal hypertension has become a rare procedure as a result of the efficacy of the transjugular intrahepatic portosystemic shunt (TIPS) procedure. Hysterectomy for symptomatic fibroids has largely been replaced by uterine artery embolization. The advantages of these procedures include the obvious benefit of fewer complications associated with less invasive procedures, decreased length of stay necessary, and reduced healthcare costs [5].



According to the American College of Radiology, the written or electronic request for fluoroscopic procedures should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination. (<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MgmtFluoroProc.pdf>. Last accessed July 21, 2022.)

**Level of Evidence:** Expert Opinion/Consensus Statement

## STANDARD FLUOROSCOPY UNITS

The x-ray image generation chain of the standard fluoroscopy unit can be distilled to three major parts: the x-ray generator, the x-ray tube, and the image intensifier.

### X-Ray Generator

The x-ray generator provides the power source necessary to accelerate the electrons through the x-ray tube. The duration of x-ray exposure is similar to the shutter speed on a regular camera, and it can be adjusted and optimized for the tissue being examined. For example, exposure may be increased

for more mobile organs and slowed for less mobile organs [6]. Exposure times of 3 to 6 msec reduce the blurring effect associated with movement, which is ideal for cardiac studies. Most modern x-ray generators can provide sufficient and precise power with automatically adjusted exposure timing. They are enabled with multiple phase and long versus short widths that are automatically adjusted for ideal exposure. The manual settings on modern x-ray generators (which are operator-selected) are available in film frame rates, such as 60, 30, or 15 frames per second.

### X-Ray Tube

The purpose of the x-ray tube is to convert electrical energy provided by the generator into an x-ray beam. Electrons are emitted from a cathode (a heated filament) and are accelerated toward a rapidly rotating disc (the anode). Usually, the anode is made from high atomic target material (e.g., tungsten). When these electrons collide with their target, they undergo conversion to x-radiation. However, approximately 99% of the collisions simply result in the heating of the target. The heat capacity of x-ray tubes is a major limiting factor in their design. Approximately 0.2% to 0.6% of the electrical energy provided to the tube is eventually converted to x-rays. Therefore, in the x-ray tube, a thermal overload interrupt switch becomes a necessity [7].

In addition to the exposure times (controlled by the generator system) and the size of the imaging field (controlled by the x-ray tube), there are two other factors of the x-ray that determine the quality of x-ray for proper image exposures: the electrical current and the level of kilovoltage. Modern radiographic equipment allows for variability of the amperage and voltage to attain optimal quality radiographic images. These modern machines are capable of automatically adjusting exposure times as well as current and voltage in order to produce the most optimal radiographic images [7].

The electrical current is a measure (in milliamperes or mA) of the number of photons generated per unit of time. The greater the electrical current, the greater the number of photons, leading to an improved image resolution. If the photon volume is suboptimal, the resulting image may have a spotty appearance [6]. It is important to recognize that increasing the milliamperage will improve image quality, but the level of milliamperage is limited by the heat capacity of the x-ray tubes. In addition, higher milliamperes significantly increase radiation exposure and scatter to patients and staff members involved in the procedure.

The kilovoltage refers to the energy spectrum of the x-ray beam, which is a function of the beam's wavelength. The higher the kilovoltage, the shorter the wavelength of radiation and, therefore, the greater the ability of x-rays to penetrate target tissue.

It is important to use increased kilovoltage in certain patients (e.g., those with high body mass) in order to increase penetrance and obtain better images. However, a high kilovolt level will yield a lower resolution because of the increased scatter. This also leads to greater radiation exposure to patients and radiology personnel.

### **X-Ray Tube Housing**

The x-ray tube is capable of producing x-rays, but it does not independently manage, manipulate, or modify the x-rays produced. The x-ray tube housing, a lead-lined structure, is capable of modifying the images. The housing includes the x-ray beam filter, the beam collimator, and the thermal switch. The beam collimator functions to limit the x-ray field size, while the thermal switch senses the degree of overheating of the x-ray tube and acts accordingly.

The x-ray tube housing also serves as a barrier against x-rays. According to FDA regulation, the x-rays escaping the tube housing (termed "leakage x-rays") must result in a radiation exposure rate less than 0.1 roentgen per hour, measured 1 m from the x-ray source, when operated at its maximum voltage energy and maximum continuous tube current [7].

### **X-Ray Beam Filter**

The x-ray tube also contains x-ray beam filters, usually aluminum or copper metal filters, put in place to generate a cleaner and more effective beam. The filter eliminates lower energy rays, which do not contribute to the creation of the diagnostic image.

When the refined, higher energy beams reach the patient, they are attenuated selectively by the tissues. Eventually, the x-rays exit the patient and interact with the image intensifier, initiating the process of image creation.

### **Collimator**

The x-ray beam can never be wider than the image intensifier's diameter, and the purpose of the collimator is to fit the x-ray beam exiting the tube to the image intensifier. It is critical to position the image intensifier such that it intercepts the x-ray beam. Manufacturers place a cone that acts as a collimator at the x-ray tube to fulfill the beam-size criteria, but mishandling can compromise the beam-to-image intensifier alignment.

### **The Image Intensifier**

The image intensifier assembly in a fluoroscopy unit contains an anti-scatter grid to reduce the number of scattered x-rays entering the fluoroscopy unit. It also includes a vacuum tube (consisting of photoabsorptive and electroemissive surfaces, electrostatic focusing electrodes, and an output phosphor), light-focusing lenses, diaphragm, and video signal pickup. In addition, image intensifiers have electronic shielding and a lead-lined enclosure, which serves as the primary x-ray barrier.

The electrostatic focusing lenses are able to compress or expand the stream of electrons coming from the photocathode surface. This results in a reduction or magnification of the resultant image being captured. The output phosphor's purpose is to produce light photons.

Other components of the imaging system include the x-ray control panel, the exposure activation switches (typically a "dead man"-type foot switch), and the image display and recording device.

### **The Image Display and Storage Device**

The image display and storage device is the final component of the diagnostic imaging process. The monitors must be of adequate resolution and brightness to clearly display the progress of the procedure. Usually, stored images can be easily projected for review and transfer to other storage devices. However, a finite number of images can be stored. When the storage capacity has been exceeded, the unit usually overwrites the oldest image in storage and then continues on from that point. When operating fluoroscopy units, there is a “last image hold” feature, which allows the last recorded position of the device to be visualized. Therefore, the fluoroscope operators do not need to maintain the x-ray beam “on” at all times to review progress in the procedure [7].

The typical portable fluoroscope used today is versatile and mobile and occupies less space in confined quarters than fixed units. These units also allow one to store and archive images for scanning, reprinting, or illustrating details, such as where needle placements are located. Electronic images and reports are transmitted digitally in digital imaging and communication in medicine (DICOM) format. Non-image data, such as scanned documents, may be incorporated as well.

### **C-Arm Fluoroscopes**

As discussed, a fluoroscopic system in which the image receptor and x-ray tube are mounted at the opposite ends of a C-shaped arm allows the x-ray tube and image receptor to be rotated at least 90° relative to the patient with no motion of the x-ray tube relative to the image receptor [7]. Stationary C-arm fluoroscopic units, such as those found in a busy interventional suite, can come equipped with an 18-inch image intensifier, although a 15-inch intensifier is more common [7]. Mobile C-arm units are equipped with wheels and a steering mechanism for transport to the procedure room or operatory.

### **OPTIMIZING FLUOROSCOPIC IMAGE QUALITY**

As discussed, increased voltage produces x-rays of higher energy that penetrate without attenuation, resulting in an image that is brighter but with less contrast between different tissues, reducing image detail. The clarity of small structures, or image detail, can be improved by lowering the voltage, reducing the distance between the patient and the image intensifier, and using collimation to limit the field of exposure to only those structures of interest.

Fluoroscopic images have less sharpness at the periphery due to a falloff in brightness and spatial resolution, a phenomenon called vignetting. Placing the structure of interest in the center of the image will yield maximum image detail. “Pincushion distortion” also occurs toward the periphery of the image because the x-rays emanate from a spherical surface and are detected on a flat surface. This results in an effect much like a fisheye camera lens, with a splaying outward of objects toward the periphery of the image. This can lead to particular difficulties when attempting to advance a needle using a coaxial technique if the needle is toward the periphery of the image. Within the past several years, manufacturers have developed electronic flat-panel detectors to replace conventional image intensifiers. These employ a grid-like detector that eliminates both vignetting and pincushion distortion, providing optimum image quality from the center to the peripheral portions of each image. Flat-plane digital detectors are rapidly replacing traditional image intensifiers, because they are capable of dramatically reducing radiation while improving image quality [8].



## USE OF CONTRAST MEDIA IN FLUOROSCOPY

As mentioned, one of the major advantages of fluoroscopy is the ability to confirm needle placement in real time. This ability is significantly increased by the use of contrast media. To date, iodine is the only element that has been deemed satisfactory as an intravascular radiographic contrast medium. It is responsible for producing radiopacity; other portions of the medium act as carriers, improving solubility and reducing the toxicity of the medium as a whole. Organic carriers of iodine are likely to remain in widespread use for the foreseeable future [8]. All of the currently used contrast media are based on the 2,4,6-tri-iodinated benzene ring, and these contrast media have a higher viscosity and greater osmolality compared with blood, plasma, and cerebrospinal fluid (CSF).

Today, there are four types of iodinated contrast being used: ionic monomers, non-ionic monomers, ionic dimers, and non-ionic dimers. Upon intravascular injection, the contrast is distributed relatively rapidly into the extravascular space. On average, about 90% of the contrast is eliminated from the kidneys within 12 hours after administration. Iodinated contrast does not enter into the intracellular space. Because iodine is the element responsible for the radiopacity property, the iodine concentration correlates with the degree of radiopacity. Currently, the non-ionic dimers offer increased radiopacity at low osmolar concentrations but are not in widespread clinical use and offer an equivocal clinical advantage.

Osmolality depends on the number of particles of solute in solution, and in general, the ionic contrast agents tend to have higher osmolalities. Adverse reactions, particularly discomfort on injection, are reduced with the use of low-osmolar radiopaque contrast material. In modern fluoroscopic images, digital subtraction electronically enhances the image, significantly reducing the volume of contrast necessary to enhance the images.

Ionic molecules dissociate into cation and anion in solution, but non-ionic molecules do not. Non-ionic molecules are used in procedures such as myelograms in which erroneous placement within the CSF is a possibility during the injection process [8].

Contrast media most frequently used in interventional pain procedures, such as iohexol (Omnipaque), iopamidol (Isovue), and iodixanol (Visipaque), are considered low-osmolality contrast media, with osmolality only two to three times that of serum. In general, low-osmolality contrast agents have a much lower incidence (0.2%) of mild and moderate contrast reactions compared with high-osmolality contrast media (6% to 8%). The incidence of severe reactions is similar, but anaphylactoid reactions occur less frequently with low-osmolality contrast media [9].

The most frequently used ionic monomers are diatrizoate (Urografin) and iothalamate (Conray). These monomers are still used for intravenous pyelography. The most common non-ionic monomers in clinical use include iodixanol, iohexol, iopamidol, and ioversol (Optiray). Iohexol and iopamidol are commonly used in interventional pain procedures and are labeled for intrathecal use. The non-ionic monomers are more stable in solution and less toxic than the ionic monomers [8]. These agents provide a balance with the low risk of adverse reaction occurrences and adequate radiopacity for identifying intravascular and intrathecal placement.

### Specific Considerations when Administering Iodinated Contrast Medium

#### *Cardiac Abnormalities*

Patients with a history of cardiac disease, including prior cardiac arrest or chest pain, have been shown to have an increased incidence and severity of cardiovascular side effects following administration of contrast medium [10]. Pulmonary angiogram and intracardiac coronary artery injections carry the greatest risk for cardiovascular side effects, including arrhythmias, tachycardia, hypotension, and congestive heart failure.

### **Metformin Interaction**

Patients with type 2 diabetes receiving metformin may have an accumulation of the drug after administering iodinated radioactive contrast material, resulting in biguanide-related lactic acidosis with symptoms of vomiting, diarrhea, and somnolence. Metformin-related lactic acidosis has been reported to be fatal in approximately 50% to 83% of these cases, but it is very rarely reported in patients with normal renal function [11]. Therefore, in patients with normal renal function and no known comorbidities, there is no need to discontinue metformin before iodinated radiographic contrast use or to check creatinine levels following the imaging study. However, in patients with renal insufficiency, metformin should be discontinued the day of the study and withheld for 48 hours. Postprocedure creatinine level should be measured at 48 hours, with metformin resumed when kidney function is normal [12].

### **Contrast-Induced Nephropathy**

Although there are no standard criteria for the diagnosis of contrast-induced nephropathy, diagnosis is usually made if any of the following scenarios occur within 48 hours after the administration of iodinated contrast:

- A more than 50% or 0.3 mg/dL increase in serum creatinine from baseline
- A decrease in the urine output to less than 0.5 mL/kg/hour for at least six hours

The etiology of contrast-induced nephropathy remains unknown, but it has been reported to be related to tubular obstruction, tubular toxicity, and renal ischemia secondary to vasoconstriction [12].

High doses of iodinated radiopaque contrast materials can impair renal function in certain patients for up to five days. However, serum creatinine levels will usually return to baseline in 10 to 14 days, and contrast-induced nephropathy occurs in less than

5% of patients with normal renal function. Up to 25% of patients with contrast-induced nephropathy will have persistent abnormalities in renal function [13]. The clinical manifestations of contrast-induced nephropathy range from no clinical signs and symptoms to oliguria. It is the third most common cause of acute kidney injury in hospitalized patients [14].

There are several factors that put patients at increased risk for contrast-induced nephropathy, including diabetes, chronic kidney disease, congestive heart failure, concurrent diuretic use, dehydration, older age, low hematocrit level, hypertension, ejection fraction less than 40%, and chronic kidney disease (i.e., creatinine clearance less than 60 mL/min). Of these, diabetes and pre-existing renal disease confer the greatest risk [12; 14]. Less common risk factors include nephrotic syndrome, hyperuricemia, end-stage liver disease, renal transplant, renal tumor, multiple myeloma, and the administration of chemotherapy, aminoglycoside, or nonsteroidal anti-inflammatory agents. There are also certain procedure-related factors that increase the risk for contrast-induced nephropathy. These include multiple contrast-enhanced studies performed in a short time, large contrast bolus infusion, increased contrast viscosity, high-osmolar contrast agents, and ionic contrast administration [12].

Contrast-induced nephropathy remains a controversial topic, and a review of multiple meta-analyses reveals that there is no absolute creatinine level that necessitates prohibition of the use of the contrast media [12]. The consensus remains that the threshold should be lowered in patients with diabetes. It is important to note that patients with end-stage renal disease on dialysis can receive iodinated contrast media and then get dialysis with no significant adverse effects. Preferably, these patients should receive iso-osmolar or low-osmolar contrast agents [12].

Prevention of contrast-induced nephropathy should be a priority. Hydration prior to contrast administration remains the primary method for prevention of contrast-induced nephropathy [14]. Preprocedural IV hydration with normal saline at 100 mL/hour beginning 12 hours before and continuing for 12 hours after the procedure has been shown to reduce the incidence of contrast-induced nephropathy. The use of sodium bicarbonate has not been shown to definitely reduce the incidence [15; 16]. The use of *N*-acetylcysteine in place of hydration is not recommended. One systematic review and meta-analysis determined that prophylaxis with *N*-acetylcysteine supplementation was more beneficial in patients with kidney dysfunction and high-contrast medium dose than in those with normal kidney function and low dose of contrast agent [17]. Furosemide has been found to increase the risk of contrast-induced nephropathy [12; 14].

### **Extravasation**

Extravasation of a large volume of contrast material can occur if there is no monitoring with electrical skin impedance devices. Side effects of extravasation of iodinated radiographic contrast materials are primarily the result of hyperosmolality and include pain, edema, swelling, and cellulitis. These side effects may not be evident immediately, and it may take up to 48 hours for the inflammatory response to reach its peak. Compartment syndrome can occur secondary to mechanical compression as a result of tissue edema and cellulitis.

Management of extravasation includes stopping the contrast injection immediately, elevating the affected extremity above the level of the heart, and notifying the responsible providers. Manual massage is recommended to promote drainage in cases of large-volume extravasation. If the patient remains symptomatic, a plastic surgery consultation is recommended. Occasionally, the patient may need to be admitted to the hospital for observation.

### **Adverse Reactions**

Modern contrast agents have greatly reduced, but not completely eradicated, the risk of adverse reactions. In order to mitigate the risk of adverse events, radiopaque contrast material should be used in the lowest concentrations and smallest doses possible to allow adequate visualization. Contrast reactions fall into three general groups: anaphylactoid or idiosyncratic, non-anaphylactoid, and mixed. As noted, the risk of adverse reactions is significantly greater with the use of high-osmolar, ionic agents when compared with low-osmolar, non-ionic agents.

Anaphylactoid reactions are the most serious type of reaction. They occur independent of dose and will occasionally lead to fatal outcomes. This type of reaction occurs relatively more frequently in patients with a history of asthma, allergies, previous reactions, or cardiovascular or renal disease, and in patients currently receiving beta blockers.

The symptoms associated with anaphylactoid reactions can range from skin rash, nausea, and pruritus to severe reactions such as hypotension, bronchospasm, laryngeal edema, seizures, and life-threatening arrhythmias. The overall risk for severe reactions from low-osmolar contrast media is 0.03% [9].

It is not possible to reliably predict or prevent anaphylactoid reactions. These reactions usually begin within five minutes of injection and can progress rapidly to life-threatening cardiovascular collapse and death unless swift action is taken [8].

The severity of non-anaphylactoid reactions depends on qualities of the medium, including the concentration of iodine, whether or not the contrast injected is ionic, the level of osmolality, and the volume of contrast injected. In addition, intra-arterial route of administration is more likely to cause a reaction. Epinephrine is the drug of choice for the treatment of anaphylaxis; the usual adult starting dose is 0.01 mg/kg, with a maximum dose of 0.5 mg [8].

Reactions are theorized to be caused by disturbances in homeostasis, specifically alterations in blood circulation. Symptoms typically include warmth, nausea, vomiting, a metallic taste, bradycardia, hypotension, and vasovagal reactions. Pretreatment with a corticosteroid, antihistamine, or both may be considered in patients with previous reactions or with significant risk factors. The most commonly affected systems are the respiratory, gastrointestinal, and nervous systems [9].

Non-anaphylactoid reactions to contrast media can be classified as mild, moderate, or severe. When administering large volumes of IV contrast materials, the incidence of mild reactions is about 5% to 15%. These reactions include flushing, anxiety, nausea and vomiting, pain at the injection site, pruritus, and headaches. In general, mild reactions are self-limiting, requiring no specific treatment. Occasionally, an oral antihistamine may be administered to manage pruritus and anxiety [8]. Moderate adverse reactions occur in 0.5% to 2% of those receiving IV contrast media and include more severe symptoms outlined for mild reactions as well as moderate hypotension and bronchospasm.

Severe, life-threatening non-anaphylactoid reactions occur in less than 0.04% of those receiving IV contrast agents and include convulsions, unconsciousness, laryngeal edema, severe bronchospasm, pulmonary edema, severe cardiac arrhythmias, and cardiovascular collapse. Treatment of these reactions is urgent, necessitating the immediate availability of full resuscitation equipment and trained personnel who routinely respond to these events [8]. Management of severe adverse reactions includes adhering to advanced cardiovascular life support guidelines, including airway management, oxygen administration, mechanical ventilation, external cardiac massage, and electrical cardiac defibrillation.

Recognition of the factors that predispose patients to adverse reactions when receiving contrast materials is the most important step in prevention. As mentioned, the risk is increased in those with previous reaction to contrast agents, asthma, allergies/atopy, and advanced heart disease. Patients with an unstable arrhythmia, recent myocardial infarction, diabetic nephropathy, renal failure from other causes, anxiety, or hematologic or metabolic disorders (e.g., sickle cell anemia, pheochromocytoma) are also at risk [8]. If there is any possibility that contrast agents could be injected into the subarachnoid space, a low-osmolar, non-ionic contrast agent should be used.

There is no known premedication regimen that completely eliminates the risk of severe reactions to contrast agents. The most frequent medications used include corticosteroids (e.g., prednisone) and antihistamines. Some experts recommend the addition of H<sub>2</sub>-antagonists such as ranitidine [18]. This approach has been shown to be effective in reducing the incidence of subsequent adverse reactions in those with a history of previous reaction to high-osmolar contrast agents. It remains unclear whether prophylactic treatment is necessary prior to the use of a low-osmolar, non-ionic contrast agents.

### **Use of Gadolinium as an Alternative to Iodinated Radiographic Contrast Media**

Gadolinium chelates are IV contrast agents commonly used to enhance vascular structures during diagnostic magnetic resonance imaging (MRI). Gadolinium chelates are capable of attenuating x-rays and have been used successfully in place of iodinated contrast media for angiography and spinal injection procedures under fluoroscopy [8].

Gadolinium-based contrast agents have also been successfully used as an alternative contrast in patients with known allergy to iodinated agents. However, the radiopacity of gadolinium is less than that of iodinated contrast agents, resulting in a less conspicuous appearance on fluoroscopic images.

The application of digital subtraction techniques has been shown to improve visualization in these cases.

Gadolinium-based contrast agents are less likely to cause adverse reactions compared with iodine-based agents. The frequency of any acute adverse events is approximately 1% to 2% of all injections containing 0.1–0.2 mmol/kg of gadolinium chelate. The majority of adverse events are mild, including coldness, warmth, or pain at the injection site; headache; nausea and vomiting; pruritus; paresthesias; and dizziness. Some reactions resemble an allergic-type reaction, including hives and bronchospasm. Severe anaphylactic reactions are extremely rare, accounting for 0.001% of all adverse reactions to gadolinium; fatal reactions are even more rare. Gadolinium-based agents are not nephrotoxic at approved doses for MRI. However, there is a risk of nephrogenic systemic fibrosis in patients with severe renal dysfunction, and these agents should be used with caution in this group.

Some extracellular MRI agents have been known to interfere with serum chemistry. For example, pseudohypocalcemia has been noted up to 24 hours after MRI with gadolinium-based contrast administration. Other electrolytes may also be affected, including magnesium and iron. In general, all electrolyte measurements are more reliable when performed 24 hours after exposure to gadolinium.

### ***Nephrogenic Systemic Fibrosis***

The use of gadolinium-based contrast agents has been linked to the subsequent development of nephrogenic systemic fibrosis in patients with pre-existing renal disease, but the risk is low given the small doses being administered [8].

Nephrogenic systemic fibrosis is a fibrosing disease affecting the skin and subcutaneous tissues, heart, lungs, esophagus, and skeletal muscle. The signs and symptoms tend to develop and progress rapidly. Some patients develop contractures and immobility within a few days after exposure to gadolinium-based contrast. In some patients, visceral organ involve-

ment may lead to death. The average onset varies between two days and three months. Overall, about 4% of patients with severe kidney problems will develop nephrogenic systemic fibrosis [19].

### **LIMITATIONS OF FLUOROSCOPY**

The major drawback of fluoroscopy is exposure to ionizing radiation. It is the responsibility of each operator to use fluoroscopy cautiously to ensure that the benefits outweigh its potential risks. In order to be proficient at making this distinction, clinicians should understand the biologic effects of ionizing radiation. A well-rounded radiation management program is not only concerned with minimizing exposure to the patient but also to the interventional radiology team. It also focuses on providing appropriate meticulous preprocedural and postprocedural patient care [5].

The daily use of fluoroscopy requires a skilled technician to assist in proper device function and appropriate patient positioning. Routine maintenance is required for the fluoroscope in order to ensure safe delivery of appropriate and intended radiation doses.

As fluoroscopy becomes more indispensable as an interventional imaging tool, there are increased concerns about radiation safety for patients and radiology professionals. Modern fluoroscopic equipment and newer techniques have significantly contributed to lower dose rates. However, fluoroscopy procedures are still responsible for the greatest radiation exposures in radiology. There are continuous efforts to explore methods to further reduce the rates of radiation exposure.

Fluoroscopy has several other disadvantages. Acquisition and maintenance costs are a barrier for physicians in private practice. The cost of the device may take several years to be recuperated. The actual cost of storage space is another disadvantage, as the unit requires a large amount of square footage compared to other imaging modalities, such as ultrasound.

## CLINICAL USE OF FLUOROSCOPY

Fluoroscopy is commonly used in gastrointestinal imaging, interventional radiology, musculoskeletal radiology, and genitourinary radiology. Outside of radiology, fluoroscopy is used in urology, surgery, interventional pain, cardiology, and orthopedics, among other disciplines.

### UPPER GASTROINTESTINAL STUDIES

Although it is becoming rarer, fluoroscopy is still used to evaluate the pharynx and esophagus relatively frequently. Specifically, a modified barium swallow is used to evaluate swallowing ability. The modified barium swallow is usually performed in conjunction with a speech pathologist who guides the patient as they swallow different textures and liquid consistencies. The following section will review some common studies performed using fluoroscopy in the field of diagnostic radiology.

#### Esophagram

In the case of an air-contrast esophagram, the images are obtained in the upright and in slightly left anterior obliquity. An effervescent agent is first administered, followed by a thick barium suspension. The barium coats the mucosal surface, whereas the gas from the effervescent agent distends the lumen. This provides fine mucosal detail and is most useful for the evaluation of small, plaque-like mucosal tumors and mucosal irregularities of esophagitis. If a patient is unable to undergo the air-contrast portion of the thoracic esophagogram, prone full-column imaging may be obtained in two orthogonal planes as an alternative [20].

Air-contrast images of the pharynx are not always necessary, because this region is amenable to endoscopic inspection. However, in some cases, such as with tumors that arise in the hypopharynx, air-contrast images are useful. After the administration of a thick barium suspension, phonation and a modified Valsalva maneuver are used to distend the pharynx [20].

### Modified Barium Swallow

A modified barium swallow evaluates the coordination of the swallow reflex and is most often used to determine the cause and severity of aspiration into the trachea. The speech pathologist, using appropriate radiation safety precautions, administers barium suspensions of varying thickness (e.g., thin liquid, thick liquid, nectar, paste, solid) while the radiologist observes fluoroscopically in the lateral projection. The entire examination is recorded and can be reviewed at a later time.



EVIDENCE-BASED  
PRACTICE  
RECOMMENDATION

For functional assessment with barium swallow, the American College of Radiology recommends the fluoroscopic portion of the examination should be recorded on high-resolution videofluorographic and/or rapid digital fluorographic imaging. For morphologic assessment, spot images and/or rapid digital fluorographic imaging with double-contrast or single-contrast technique should be used.

(<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Modified-Ba-Swallow.pdf>. Last accessed July 21, 2022.)

**Level of Evidence:** Expert Opinion/Consensus Statement

The various barium suspensions are intended to mimic different food consistencies and provide a more complete assessment of aspiration risk. If tracheal aspiration or laryngeal penetration is identified with the head in a neutral position, the speech pathologist may direct the patient to perform certain maneuvers in order to protect the airway, including chin tuck, neck turn, and a forced cough after swallowing. The examination can be supplemented with images in the frontal projection to evaluate symmetry of the piriform sinuses.

Functional endoscopic evaluation of swallowing with or without sensory testing has been proposed as an alternative to the modified barium swallow. However, the modified swallow provides a more appropriate physiologic environment, because the

endoscope is not present to interfere with motility. Additionally, protective maneuvers cannot be used during an endoscopic swallowing evaluation. Finally, the modified barium swallow evaluates the upper phases of swallowing in greater detail than an endoscopic evaluation. Most clinicians consider endoscopic swallowing evaluation and the modified barium study as complementary but not interchangeable [20].

Occasionally, there may be brief contrast penetration into the larynx, which may or may not clear rapidly. If the laryngeal penetration clears rapidly and without cough, the patient is not considered at risk for tracheal aspiration. However, if there is penetration and pooling of contrast in the valleculae or in the piriform sinuses, the patient is at risk for aspiration, especially if the peristaltic wave does not clear this contrast [20].

Both cineradiography, which produces high-resolution images obtained at a low frame rate, and video capture, which produces low-resolution images obtained at a high frame rate, are useful in performing esophagrams and modified barium studies. Cineradiography offers better mucosal detail, while video capture provides an evaluation of function with less radiation.

### **Oral Contrast Agents**

The barium suspension is the best fluoroscopic contrast agent available, but its use is contraindicated in some patients. Perforation of the pharynx or esophagus is a risk factor for barium extravasation into the soft tissues of the neck or chest. Extravasated barium may incite an extensive inflammatory reaction or may become inspissated over time and fail to resorb [20].

Water-soluble contrast agents, such as those used for IV contrast CT, may be used as an alternative. Unfortunately, water-soluble agents are not as dense as barium agents, so they are less sensitive to small leaks. If no leak is detected after the administration of a water-soluble agent, the examination should be repeated with barium.

Ionic contrast agents have another disadvantage; if they are aspirated into the lungs, they may cause chemical pneumonitis and pulmonary edema. Non-ionic water-soluble agents are presumed to be safer and thus should be used if there is a preprocedural risk of aspiration or if there is a tracheoesophageal fistula present. Oil-based contrast agents for the evaluation of the larynx and pharynx are no longer being used in clinical practice [20].

### **TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT**

TIPS is an interventional radiology procedure indicated for patients with portal hypertension, typically as a result of end-stage cirrhosis. The interventional radiologist creates a shunt as a means to decompress the overloaded portal system. A stent is placed between the intrahepatic portion of the portal vein and the hepatic vein using angiographically guided endovascular techniques [21]. Paracentesis may be necessary prior to the procedure if the patient has large-volume ascites.

The TIPS stent can become narrowed over time due to hyperplasia of the endovascular intima secondary to turbulent flow from two separate venous systems. Bare metal stents have been associated with greater intimal hyperplasia than covered endograft stents, which are less likely to become occluded [21].

### **PERCUTANEOUS TRANSCATHETER EMBOLIZATION**

Percutaneous transcatheter embolization procedures are usually performed using fluoroscopy. Patients are generally placed under moderate sedation with concordant administration of analgesics. The Seldinger technique is used to advance a catheter via an entry site into the arterial system (usually the femoral artery) to the target tissue (e.g., uterus, kidneys, spleen).

After selective catheterization, a diagnostic angiogram is performed to evaluate the organ. The interventional radiologist then focuses on assessing for extravasation, narrowing, and/or abnormal vascularity and subsequently performs the appropriate intervention. For example, when treating patients with uterine fibroids, transcatheter embolization is performed targeting the arteries feeding the fibroids. Embolization agents are tiny particles or microspheres, coils, gel foam, or glue used to occlude the arteries of interest. In general, patients receive a dose of prophylactic antibiotics prior to initiating the procedure [22].

## **PAIN MEDICINE**

Over the past several years, the use of fluoroscopy has allowed interventional pain physicians to perform injections with precision guidance [2]. In interventional pain procedures, the ability to clearly visualize critical structures or unwanted intrathecal spread of the injectate is a major reason to perform fluoroscopically guided procedures.

## **CARDIOLOGY**

### **Endomyocardial Biopsy**

The two most common indications for an endomyocardial biopsy are to evaluate for cardiac transplant rejection or for cardiotoxicity from anthracycline. Other possible indications include cardiomyopathy and myocarditis.

Major contraindications to endomyocardial biopsy are anticoagulation therapy and anatomic abnormality making it unsafe to place the biptome. Complications occur more frequently in patients with cardiomyopathy than those with heart transplant and may include arrhythmias and perforation.

### **Cardiac Catheterization**

Cardiac catheterization is a commonly employed revascularization technique after a myocardial infarction. Other uses of fluoroscopic techniques in the field of interventional cardiology include trans-septal cardiac catheterization to evaluate aortic or mitral stenosis or prosthetic valve dysfunction.

Left heart catheterization is indicated for conditions that require a direct measurement of pressure (e.g., pulmonary venous disease, hypertrophic cardiomyopathy) and conditions that necessitate access for mitral balloon catheter valvuloplasty and/or the deployment of atrial septal defect closure devices.

Contraindications to trans-septal cardiac catheterization include left or right atrial thrombus, atrial myxoma, low platelet counts, current anticoagulation therapy, or hemostatic dysfunction. Patients with an inferior vena cava mass or obstruction are also contraindicated from undergoing endovascular catheterization. Trans-septal left heart catheterization should be considered carefully in patients with distorted cardiac anatomy as a result of congenital heart disease, marked atrial enlargement, or a severely dilated aortic root. Possible serious complications of this procedure include perforation of the coronary sinus, the aortic root, or the posterior free wall of the atrium.

### **Pericardiocentesis**

Pericardiocentesis is performed to aid in the diagnosis and management of acute and chronic pericardial effusions; it can be a life-saving procedure in cases of cardiac tamponade. A significant degree of skill is necessary in order to perform this procedure safely and to avoid damage to the pericardium and the heart. Pericardiocentesis is performed from a subxiphoid approach into the pericardial space. In general, an echocardiogram is performed prior to pericardiocentesis to confirm the presence and amount of pericardial fluid. However, in acute situations when tamponade is suspected or known, an echocardiogram may cause unnecessary delay.

### **Intra-Aortic Balloon Counterpulsation**

Intra-aortic balloon pump counterpulsation, first introduced in 1967, consists of a balloon pump positioned in the descending aorta to improve hemodynamics (i.e., the balance between myocardial oxygen supply and demand). It is used for temporary mechanical support of patients in a variety of clinical settings, including the cardiac catheterization suite, the intensive care unit, and the operating room.



The balloon pump works by inflating during diastole to increase coronary blood flow and deflating at the end of diastole to decrease myocardial oxygen consumption and increase cardiac output. Common indications for intra-aortic balloon pumps include hypotension unresponsive to volume loading or intravenous pressor agents, refractory angina, acute myocardial infarction with or without cardiogenic shock, weaning from cardiopulmonary bypass, bridge to cardiac transplantation, and right ventricle failure. Contraindications include severe peripheral vascular disease, severe aortic incompetence, active bleeding, thrombocytopenia, and acute stroke. Potential complications of intra-aortic balloon pump placement include perforation of the superficial femoral artery, forceful arterial dissection due to advancement of the guidewire, hemorrhage, and thrombus formation [6].

## ORTHOPEDIC PROCEDURES

Fluoroscopy plays an important role in the evaluation of joint motion and is often used by orthopedic surgeons to monitor placement of hardware. It may also be of assistance in positioning patients for unusual or difficult conventional radiographic views.

In some cases, fluoroscopy may be indicated to help guide injections. Certain joints, such as the hip, are difficult to evaluate and inject blindly, so intra-articular hip injection is typically performed under fluoroscopy in order to minimize extra-articular injections and associated risks. In cases of fluoroscopy-guided injections, fluoroscopy is used to verify proper injection site at the superior lateral aspect of the femoral neck. The needle should pass through the joint capsule until bone is encountered. A small amount of contrast could be injected under fluoroscopy to verify placement into the joint space. After the position is confirmed, the medication is injected and the needle is withdrawn [23].

## INTRAOPERATIVE CHOLANGIOGRAPHY

Intraoperative cholangiography is usually performed during a laparoscopic cholecystectomy, after the identification and dissection of the common bile duct. Cholangiography is usually performed under fluoroscopy and is used to determine if there is a stone in the common bile duct.

## UROLOGY

Although CT and MRI have become more common choices, conventional radiography and fluoroscopy remain useful for preoperative and postoperative evaluation of various urologic conditions. Conventional radiographic studies (including fluoroscopy) used in urology include abdominal plain radiography, intravenous excretory urography, retrograde pyelography, loopography, retrograde urethrography, and cystography.

### Intravenous Urography

Although IV urography was once the standard in urologic imaging, it has essentially been replaced by CT and MRI. With the ability of new scanners to perform axial, sagittal, and coronal reconstruction of the upper urinary tract system, essentially all of the data and information obtained by traditional IV urography can be realized with CT imaging. In addition, some parenchymal defects, cysts, and tumors can be better delineated with CT than with IV urography.

IV urography may be indicated to assess the renal collecting systems and ureters, including investigation of the level of ureteral obstruction and demonstration of intraoperative opacification of the collecting system during extracorporeal shock wave lithotripsy. It may also be used to demonstrate renal function during emergent evaluation of unstable patients. Finally, it can demonstrate renal and ureteral anatomy after interventions such as transuretero-ureterostomy and urinary diversion.

## Percutaneous Nephrostomy

Percutaneous nephrostomy (PCN) provides a less invasive means to drain the renal collecting system in cases where obstruction of the kidney and ureter has resulted in hydronephrosis. Most often used for patients with kidney stones or bladder or pelvic tumor obstructions, PCN may be used to divert urine from the renal collecting system to allow leaks and fistulas to heal. The procedure is often performed after attempts at placing a ureteral stent through retrograde cystoscopy have proven unsuccessful. Providing drainage for that kidney is an urgent necessity, and PCN provides an exact method of accomplishing this task.

The approach is extremely important for PCN, and the procedure is performed under ultrasound or fluoroscopic guidance. In some cases, a small amount of intravenous iodinated contrast is administered at the start of the procedure to opacify the collecting system. The patient is placed in the prone position with both arms above his or her head or one arm up and the other at the noninvolved side. The entry site is prepped and draped and infiltrated with local anesthetic. A small puncture is made with a scalpel, and a posterior lateral approach is made with a needle and directed toward a lower calyx of the kidney. If the tip of the needle has entered a dilated part of the collecting system, urine will flow back from the needle when the stylet is removed. A specimen should be collected and sent to the laboratory for microscopic and bacterial studies. Obviously, infected urine will be cloudy and turbid.

Hemorrhage is the major risk of PCN, but the risk can be reduced substantially with use of a very small needle. Nephrostomies are performed frequently in interventional radiology departments and are a major part of the treatment for patients with malignant obstructions, renal stones, and other kidney problems.



When using fluoroscopy for percutaneous nephrostomy, the American College of Radiology recommends tight collimation should be used and radiation dose should be minimized. Radiation dose estimates should also be recorded in the patient's medical record. In accordance with the ALARA principle, a radiation dose reduction package, including pulsed fluoroscopy and last image hold capabilities, is recommended.

(<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Percutaneous-Nephros.pdf>. Last accessed July 21, 2022.)

**Level of Evidence:** Expert Opinion/Consensus Statement

## Retrograde Pyelography

Retrograde pyelograms are performed to visualize the ureters and intrarenal collecting system by the retrograde injection of contrast media. Any contrast media that can be used for excretory urography is also acceptable for retrograde pyelography. It is important that measures are taken to attempt to sterilize the urine before retrograde pyelography, because there is a risk of introducing bacteria into the upper urinary tract or the bloodstream. Although many studies are able to document the presence or absence of dilation of the ureter, retrograde pyelography has the unique ability to document the patency of the ureter distal to the level of obstruction and to help better define the extent of the ureteral abnormality.

Retrograde pyelograms are usually performed with the patient in the dorsal lithotomy position. An abdominal plain radiograph (i.e., scout film) is obtained to ensure that the patient is in the appropriate position to evaluate the entire ureter and intrarenal collecting system. Next, the ureteral orifice is identified via cystoscopy, and contrast may be injected through either a non-obstructing or obstructing catheter.

Non-obstructing catheters include whistle tip, spiral tip, or open-ended catheters. These catheters allow passage of the device into the ureter and up to the collecting system, over a guidewire if necessary. Contrast can then be introduced directly into the upper collecting system and the ureters visualized as the catheter is withdrawn.

Obstructing ureteral catheters include bulb-tip, cone-tip, and wedge-tip catheters. These catheters are inserted into the ureteral orifice and then pulled back to effectively obstruct the ureter. Contrast is then injected to visualize the ureter and intrarenal collecting system. Depending on the indication for the study, it may be useful to dilute the contrast material with sterile fluid. This prevents subtle filling defects in the collecting system or ureter from being obscured. Care should be taken to evacuate air bubbles from the syringe and catheter before injection, as such artifacts could be mistaken for stones or tumors.

Historically, when a retrograde pyelogram consisted of a series of radiographs taken at intervals, it was important to document various stages of filling and emptying of the ureter and collecting systems. Because of peristalsis, viewing the entire ureter is often not possible with a single static exposure or view. With modern equipment, including tables incorporating fluoroscopy, it is possible to evaluate the ureter during peristalsis in real time, thus reducing the need for static-image documentation. Occasionally, still images may be saved for future comparison. In general, however, urologists interpret retrograde pyelograms in real time as they are performed.

Indications for retrograde pyelogram include the evaluation of congenital ureteral obstruction, evaluation of acquired ureteral obstruction, elucidation of filling defects and deformities of the ureters or intrarenal collecting systems, opacification or distention of the collecting system to facilitate percutaneous access (in conjunction with ureteroscopy or stent placement), evaluation of hematuria, surveillance of transitional cell carcinoma, and evaluation of traumatic or iatrogenic injury to the ureter or collecting system.

Retrograde pyelography may be difficult in cases in which there is diffuse inflammation or neoplastic changes of the bladder, especially when bleeding is present. In these cases, identification of the ureteral orifices may be facilitated by the IV injection of indigotindisulfonate sodium (indigo carmine) or methylene blue. Changes associated with bladder outlet obstruction may result in angulation of the intramural ureters, which may make cannulation with an obstructing catheter difficult. Attempts to cannulate may result in trauma to the ureteral orifice and extravasation of contrast material into the bladder wall. The potential for damage to the intramural ureter should be weighed against the potential information obtained by the retrograde pyelogram.

### **Loopography**

Loopography is a diagnostic procedure performed in patients who have undergone urinary diversion. Historically, the term loopogram has been associated with ileal conduit diversion, but it may also be used in reference to any bowel segment serving as a urinary conduit. Because an ileal conduit urinary diversion usually has freely refluxing uretero-intestinal anastomoses, the ureters and upper collecting systems may be visualized. In other forms of diversion, the uretero-intestinal anastomoses may be purposely non-refluxing [12].

The patient is positioned supine and an abdominal plain radiograph is obtained before introduction of contrast material. A commonly employed technique is to insert a small-gauge catheter into the stoma of the loop, advancing it just proximal to the abdominal wall fascia. The balloon on such a catheter can then be inflated to 5–10 mL with sterile water. By gently introducing contrast through the catheter, the loop can be distended, usually producing bilateral reflux into the upper tracts. Oblique films should be obtained in order to evaluate the entire length of the loop. Because of the angle at which many loops are constructed, a traditional anteroposterior view will often show a foreshortened loop and could miss a substantial pathology. A drain film should also be obtained, as this may demonstrate whether there is obstruction of the conduit [12].

Indications for a loopogram include evaluation of infection, hematuria, renal insufficiency, or pain after urinary diversion. It can be used for surveillance of upper urinary tract obstruction or urothelial neoplasia, or it may be used to evaluate the integrity of the intestinal segment or reservoir [12].

### **Retrograde Urethrography**

A retrograde urethrogram is a study performed to evaluate the anterior and posterior urethra, usually in male patients. It may be particularly beneficial in demonstrating the total length of a urethral stricture that cannot be negotiated by cystoscopy and the anatomy of the urethra distal to a stricture that may not be assessable by voiding cystourethrography. This procedure is performed in the radiology department or in the operating room before performing visual internal urethrotomy or formal urethroplasty [12].

A plain film radiograph is obtained before injection of contrast, and the patient is usually positioned slightly obliquely to allow evaluation of the full length of urethra, with the penis placed on slight tension. A small catheter may be inserted into the fossa navicularis with the balloon inflated to 2 mL with sterile water. Contrast is then introduced via a catheter-tipped syringe. Alternatively, a penile clamp may be used to occlude the urethra around the catheter. Indications for a retrograde urethrogram include evaluation of urethral stricture disease (including location and length of a stricture), assessment for foreign bodies, evaluation of penile or urethral penetrating trauma, and evaluation of traumatic gross hematuria [12].

### **Voiding Cystourethrogram**

A voiding cystourethrogram is performed to evaluate the anatomy and physiology of the bladder and urethra. The study provides valuable information regarding the posterior urethra in pediatric patients and has long been used to demonstrate vesicoureteral reflux.

Voiding cystourethrogram may be performed with the patient supine or in a semi-upright position using a table capable of bringing the patient into

the full upright position. A preliminary plain pelvic radiograph is obtained. In children, a tube (8 French or smaller) is used to fill the bladder to the appropriate volume, as determined by the radiologist's needs and patient comfort. In the adult population, a standard catheter may be placed and the bladder filled to 200–400 mL. The catheter is then removed and a film is obtained. During voiding, anteroposterior and oblique films are obtained. The bladder neck and urethra may be evaluated by fluoroscopy during voiding. Bilateral oblique views may demonstrate low-grade reflux, which is not able to be appreciated on the anteroposterior film. In addition, oblique films will demonstrate bladder or urethral diverticula, which are not always visible in the straight anteroposterior projection. Post-voiding films should also be performed [12].

Indications for a voiding cystourethrogram include evaluation of the urethra, possible reflux, and structural and functional bladder outlet obstruction. There are certain limitations with a voiding cystourethrogram. Using a catheter may be traumatic in children and difficult in some patients with anatomic abnormalities of the urethra or bladder neck. Filling of the bladder may stimulate bladder spasms at low volumes, and some patients may be unable to hold adequate volumes for investigation. Bladder filling in patients with spinal cord injuries higher than T6 may precipitate autonomic dysreflexia [12].

### **Diagnosis of Urolithiasis**

The use of unenhanced CT imaging is now the standard diagnostic tool to evaluate renal colic. It offers the advantage over IV urography of avoiding contrast and enabling diagnosis of other abdominal abnormalities that can cause pain. Multi-dose CT scan can readily diagnose radiolucent stones, which may not be seen on IV urography, as well as small stones, even in the distal ureter. With the exception of some indinavir stones, almost all renal and ureteral stones can be detected on helical CT scan. In the detection of urolithiasis, unenhanced CT has a sensitivity ranging between 96% and 100% and specificity ranging between 92% and 100% [12].

Stones in the distal ureter can be difficult to differentiate from pelvic calcifications. In these cases, the urologist will look for other signs of obstruction indicating the presence of a stone, including ureteral dilation, inflammatory changes in the perinephric fat, hydronephrosis, and a soft tissue rim surrounding the calcification within the ureter. The soft tissue rim around a stone represents irritation and edema in the ureteral wall [12].

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## OVERVIEW OF RADIATION EXPOSURE

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The biologic effects of ionizing radiation are directly proportional to the time of radiation exposure, and radiation exposure is inversely proportional to the square of the distance from the radiation source. This implies that the greater the distance between the radiation source and a person, the lower the exposure.

Biologic tissues interact with radiation in different ways, and the type of radiation affects the reaction. Generally, radiation is categorized as ionizing or non-ionizing. Both types of radiation can cause injury to human tissue, but ionizing radiation has more energy and more potential to cause damage. Ionizing radiation can directly cause damage to human cells by inciting chemical reactions and altering molecules within the cell structure, including proteins and other macromolecules that comprise deoxyribonucleic acid (DNA) [24].

Ionizing radiation is further categorized as directly or indirectly ionizing. Electromagnetic radiation (e.g., gamma photons) is indirectly ionizing. This means that the photons give up their energy in various interactions, which produces a charged particle that reacts with a target molecule within biologic tissue. On the other hand, charged particles (e.g., alpha and beta particles) react directly with biologic tissue [24]. In general, indirectly ionizing radiation tends to be more damaging to tissues than directly ionizing radiation.

Radiation is ubiquitous and can be naturally occurring or man-made. Potential sources include the sun, naturally occurring radioactive decay, nuclear reactors, tobacco cigarettes, and phosphate-based fertilizer. In the United States, the greatest average annual radiation dose is from radon and thoron (the result of the natural decay of elements) [25]. This is followed by CT, nuclear medicine, and interventional fluoroscopy.

Ultimately, the concern with radiation exposure (and ionizing radiation in particular) is its potential to induce changes that may increase the risk of cancer. There is also a risk that the changes may cause genetic mutations or possibly birth defects. Examples of ionizing radiation include x-rays, gamma rays, and other rays at the higher ultraviolet (UV) end of the electromagnetic spectrum. Examples of non-ionizing radiation include radio waves and sun (UV-A and UV-B) exposure.

One important attribute of ionizing radiation is its ability to penetrate structures in the body. Some ionizing particles (e.g., alpha particles) have a very limited range and are incapable of penetrating the skin. In these cases, all clinically significant hazardous health exposures are from an exposure caused by ingestion, inhalation, or injection. Beta particles, on the other hand, have an intermediate range of penetration and can be stopped by a thin object or substance (e.g., sheet of paper). Gamma rays or x-rays have a very high range of penetration and must be stopped by very dense materials (e.g., lead) [24].

## BIOLOGIC EFFECTS OF RADIATION

With the growth of interventional radiology, fluoroscopy and other imaging technologies have proven to be invaluable. The guidance and visibility they provide make many interventional treatments possible. However, fluoroscopy inherently carries some risk from radiation exposure. In today's era of medicine, an estimated 48% of the radiation the average American is exposed to originates from medical procedures [25].

A challenge in any discussion of radiation exposure is the fact that the medical literature is inconsistent in its use of units. Fortunately, for the purposes of the clinician using fluoroscopy, many of these units can often be considered equivalent. Different types of radiation cause varying biologic effects despite having comparable absorbed doses. In order to predict the biologic effects from different types of radiation, the rad unit (defined as the absorbed dose of ionizing radiation) is converted to roentgen equivalent man (rem) or Sv in the International System of Units. This conversion is accomplished by multiplying either rad or Gy by a quality factor unique to the type of radiation. For example, the quality factor for x-ray radiation is 1, while it is 20 for an alpha particle or fast neutron radiation. Given that the quality factor for x-ray radiation is 1, it allows exposure, dose, and dose equivalent to be considered equal despite their different meanings and uses (i.e., 1 roentgen [R]  $\approx$  1 rad  $\approx$  1 rem) [9].

As noted, damage to the body from radiation occurs from direct cellular damage and/or indirect damage from the creation of reactive oxygen species. Direct cellular damage is most likely to occur in cells that are in the G1 or M phases of the cell cycle. During the M stage, DNA is packed tightly into chromosomes, and there is an increased risk of a lethal double-strand DNA break. The repair process is usually completed in one to two hours, so an increase in time between radiation doses causes an increase in cell survival.

Indirect cellular damage is the result of hydrolysis of water, resulting in production of reactive oxygen species. Two-thirds of radiation-induced DNA damage is attributable to hydroxyl radicals. A reactive oxygen species may combine with protein, resulting in the loss of important enzymatic activity in the cell. Antioxidants that can scavenge free radicals are therefore important in minimizing this type of damage.

The x-rays produced during fluoroscopy are a form of ionizing radiation with a great potential to result in significant biologic effects. Small doses of ionizing radiation may incite changes at a molecular level that can take years to manifest in the form of cancerous

transformation. Exposure to low doses of ionizing radiation is generally considered to be inconsequential, because biologic cells have normal cellular mechanisms to repair damage to DNA. However, it is important to remember that individuals react to radiation exposure in different ways to produce varying deterministic effects or different degrees of effects. Biologic variation can be idiopathic or may be affected by different patient factors, including the state of disease and prior exposures [1].

It is well-established that radiation-induced DNA damage increases with dose. However, we now know that cells do not passively take insults from radiation sources. Cells have three known techniques for addressing radiation injury: repairing DNA, attacking reactive oxygen species, and eliminating mutated or unstable cells.

Responses to low doses of radiation cannot be accurately predicted based on the observed reaction at high doses. There are several reasons for this unpredictability. First, biologic tissue exposed to low doses of penetrating radiation will unevenly absorb energy. Additionally, the stochastic effects particles generated along their paths (e.g., ionizations, excitations, creation of reactive oxygen species) also have unpredictable results.

Biologic tissue contains numerous macromolecules that will likely influence the type of cellular response generated by radiation exposure. DNA damage in the form of double strand breaks caused by endogenous reactive oxygen species occurs up to three times more frequently than damage from exposure to natural background radiation. Macromolecules include endogenous antioxidant enzymes (e.g., superoxide dismutase) and antioxidants gained through diet. The oxidative stress reactions induced by radiation are responsible for initiating the enzyme system to recreate homeostasis within the microenvironment and for activating multiple signaling pathways.

In addition to activation of macromolecules, numerous genes are activated or inhibited after exposure to radiation. This occurs at doses much lower than those that incite mutagenesis.

Previously, double sequence breaks in DNA and cellular damage were believed to be inseparably linked, but there are multiple studies showing non-DNA-related effects and coordinated tissue responses from cells not directly exposed to radiation, termed bystander effects [26]. These bystander effects may either cause damage to DNA or may initiate adaptive protective responses in cells that have not been irradiated. After exposure to low doses of radiation, more cells are activated bystanders than are directly irradiated. This raises the concern that there are increased late effects from DNA damage.

### MAXIMUM PERMISSIBLE DOSES TO TISSUES

The National Council on Radiation Protection and Measurements has published estimates of the maximum permissible doses of annual radiation to various organs and tissues [8]. Exposure below these levels is less likely to cause any significant deleterious effects, but the International Commission on Radiological Protection (ICRP) recommends that individuals should not receive more than 10% of the maximum permissible dose [8]. The annual maximum permissible dose for the thyroid gland, the extremities, and the gonads is 500 mSv (50 rem). The maximum permissible dose for the eye lens is 150 mSv (15 rem). The maximum permissible dose for pregnant women is 5 mSv (0.5 rem) to the fetus [8].

Skin injuries were reported in patients as a direct result of complex fluoroscopically guided interventional procedures as early as the 1980s. The rise in reporting these adverse events resulted in FDA action in 1994 and in U.S. federal regulations limiting the x-ray tube output of interventional fluoroscopic equipment. The minimum dose for acute skin erythema to occur is approximately 2 Gy, while for delayed deep skin ulcers it is about 12–15 Gy. The risk for deterministic injury rises if multiple subsequent procedures are performed at the same anatomic region (e.g., multiple Y-90 embolization procedures in the liver, TIPS placement and eventual revision).

As noted, there are multiple risk factors for skin injury secondary to radiation exposure, including connective tissue diseases, obesity, and diabetes. Minimizing the risk of the deterministic effects of radiation should be a major focus of any radiation safety initiatives [5].

### DETERMINISTIC EFFECTS OF RADIATION

The damaging effects of radiation can be divided into two basic categories: stochastic and deterministic. Deterministic effects are detrimental health effects caused by radiation, the severity of which varies with the dose and level of exposure. When the threshold is crossed, an individual may begin to experience effects with increasing severity as the dose grows. Examples of deterministic effects of radiation exposure include hair loss, cataracts, bone marrow depression, spontaneous miscarriage, congenital defects, and fetal growth restriction [3]. The incidence of deterministic injuries is between 1 in every 10,000 to 100,000 radiologic procedures [27].

Apart from cataracts, all of the deterministic effects of radiation are linked to apoptosis (cell death). The rate of apoptosis varies in each living cell, and cells that are actively dividing are the most sensitive to radiation effects. Cells that have already undergone mitosis are not as sensitive to radiation effects.

There are multiple factors that affect whether deterministic effects occur after radiation exposure and the extent of the effects, including the dose received, the volume of tissue irradiated, the quality or the type of exposure, and the time over which the dose was received. Different types of cells have different sensitivities (threshold levels) to radiation and a different time course for the presentation of effects. Radiologic effects that present initially may be secondary to effects on parenchymal cells, while later clinical signs may be due to damage to vascular cells. The incidence of deterministic effect-related injuries increases with increased body mass, the complexity of the procedure, the radiation history of the patient, the presence of other diseases (e.g., pre-existent cancer), and other conditions.

## Skin Effects

The National Cancer Institute has created a grading system for radiation dermatitis (**Table 1**) [28]. A single-site acute skin dose between 0–2 Gy will usually cause no observable effects. A dose between 2–5 Gy will produce transient erythema within two weeks. There will be some hair loss within 8 weeks, with recovery of hair lost within 52 weeks with no expected long-term effects. With slightly higher doses (5–10 Gy), some erythema and permanent partial hair loss may be observed after 56 weeks. Long term, patients exposed to 5–10 Gy may notice permanent dermal atrophy and/or skin induration.

A radiation dose between 10–15 Gy will cause transient erythema within two weeks. Within eight weeks, one may note erythema, hair loss, and desquamation. After eight weeks, prolonged erythema and permanent desquamation are often noted. Long term ( $\geq 40$  weeks), telangiectasia, dermal atrophy, and induration may be present.

A radiation dose greater than 15 Gy will almost certainly cause transient erythema. At these high doses, acute ulceration and edema may develop. Up to eight weeks post-injury, erythema, hair loss, and moist desquamation may be present. After 8 weeks and up to 52 weeks, dermal atrophy accompanied by ulceration (due to the failure of moist desquamation to heal) is likely. Finally, dermal necrosis may make the need for a surgical intervention inevitable.

The Joint Commission identifies prolonged fluoroscopy with a peak skin dose greater than 15 Gy to a single field over a period of six months as a sentinel event [29]. However, the American Association of Physicists in Medicine has requested that the definition of this sentinel event be modified, because they challenge the Joint Commission implication that the radiation dose is always unexpected and preventable [30]. In some cases, a life-saving measure may require radiation doses that exceed the 15-Gy threshold. In addition, this level could be attained if a patient has had prior procedures requiring radiation to be delivered to the same area.

## STOCHASTIC EFFECTS OF RADIATION

Stochastic effects are the effects of radiation to which no clear relationship exists between the magnitude of the dose and the severity of the injury. Examples include genetic mutation and induction of cancer.

All estimations of the incidence of stochastic effects have been based on a no-threshold linear model assumption from the effects secondary to the atomic bomb detonations during World War II. These assumptions are not universally accepted, and because of this uncertainty, the current resolution is that stochastic effects have no threshold dose. Therefore, no radiation dose can be considered absolutely safe. In order to minimize risk and damage, it is imperative that fluoroscopically guided diagnostic and therapeutic procedures be performed under the safest conditions possible [5]. Although independent of dose, the risk of stochastic effects increases with the total amount of radiation applied to the patient.

The most concerning stochastic injury is the induction of malignancy, but the chance of an invasive radiologic procedure inducing malignancy is less than the natural occurrence of malignancy. The probability of a fatal cancer in adults assuming an effective dose of 100 mS and an average lifespan is about 0.5%, compared with the 16.5% probability of a non-radiation-induced malignancy being diagnosed in the next 10 years in a man 60 years of age [3].

Procedures performed in children tend to be less complex, requiring less radiation. However, their relatively smaller body mass puts children at risk for experiencing a higher dose impact if proper collimation technique is not used. When treating pediatric patients and young adults, it is critical to consider the stochastic effects of radiation, especially when radiosensitive organs (e.g., thyroid, gonadal tissues, breasts) are involved. The longer potential lifespan of this group and their increased susceptibility to radiation-induced injuries are considerations. In newborns, the risk for radiation-induced injuries is three times that of adults [31]. Adolescents may have adult-sized bodies, but they still have a greater risk of radiation toxicity.



NATIONAL CANCER INSTITUTE GRADING SYSTEM FOR RADIATION DERMATITIS <sup>a</sup>	
Grade	Characteristics
1	Faint erythema or dry desquamation
2	Moderate-to-brisk erythema Patchy moist desquamation, mostly confined to skin folds and creases Moderate edema
3	Moist desquamation in areas other than skin folds and creases Bleeding induced by minor trauma or abrasion
4	Life-threatening consequences, such as skin necrosis or ulceration of full thickness dermis Spontaneous bleeding from involved site Skin graft indicated
5	Death
<sup>a</sup> Radiation dermatitis is defined as a finding of cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation.	
Source: [28]	

Table 1

Some fluoroscopic equipment allows for monitoring of peak skin dose while performing the procedure. However, this tool is fraught with faults and limitations, including backscatter (which can increase skin effects by up to 40%) and failure to consider patient size and position relative to the beam [32]. A perfect method for skin dose measurement is not yet available for clinical use, but a real-time dose mapping method using the anatomy of the patient would be the ideal solution [32]. The ability to measure the skin dose will help predict the location and risk of skin injury and hair loss after radiologic procedures.

In the case of CT-guided procedures, the initial localizing scan is the greatest contributor to the effective dose, because it is distributed over a large area. Subsequent scans obtained during guidance of the needle, catheter, or probe are the greatest contributors to the peak skin dose, because these scans are repeatedly performed in approximately the same location. Therefore, subsequent scans are usually performed at dose settings 5 to 15 times less than the peak skin dose related to a typical diagnostic scan [3].

## RADIATION DOSE MEASUREMENT AND DOCUMENTATION

The likelihood of deterministic and stochastic effects in any individual patient cannot be predicted unless that patient's radiation history is known, and this is the principal reason for recording patient radiation dose. Monitoring and recording patient dose data can also be valuable for both quality-assurance purposes and for improving patient safety. Feedback to the operator may help to optimize radiation doses overall.

As recently as 2011, the federal government had not issued any regulatory standards with respect to the recording or documentation of radiation doses or the reporting of radiation dose exposure for interventional procedures. Consequently, each state had varying degrees of regulation on the topic. Multiple agencies regularly provide guidelines on radiation safety, including the FDA, the Conference of Radiation Control Program Directors (CRCPD), and the International Atomic Energy Agency, but few had specific recommendations regarding radiation dose documentation.

Recommendations from the Society of Interventional Radiology (SIR) state that the radiation dose in general and all available specific dose data should be recorded for all fluoroscopic procedures [3]. This is concordant with the recommendations put forth by the CRCPD in 2010 [33]. In contrast, the ICRP recommends that radiation doses should only be measured if the dose exceeded 3 Gy or 1 Gy if the procedure is likely to be repeated [34]. They also recommend that only peak skin dose and the skin dose map be recorded. The FDA asserts that the facility is responsible for identifying the types of procedures for which doses should be recorded [35].

### **ESTIMATING PATIENT RADIATION DOSES**

Four methods have been used to measure dose during interventional fluoroscopic procedures (excluding CT fluoroscopy) [1]:

- Peak skin dose
- Reference air kerma
- Kerma-area product
- Fluoroscopy time

All statements of patient dose contain some degree of uncertainty due to variances in the physical measurement of dose and methods of estimation. For example, fluoroscopy time can be accurately measured, but factors can influence the accurate conversion of fluoroscopy time to patient dose, including the varying effects of patient size, beam orientation, and the configuration of the fluoroscope [1]. While fluoroscopy time and number of fluorographic images are simple to calculate and are easily available, they are the least useful measurements.

Kerma-area product is a good indicator of stochastic risk for the patient, correlates with operator and staff dose, and has been recommended for patient dose monitoring for fluoroscopic procedures [1]. While it is considered a surrogate measure of skin dose, it does not correlate well with skin dose for individual cases of a procedure. As such, this approach does not accurately identify deterministic risk in fluoroscopy [1].

Reference air kerma is a cumulative approximation of the total radiation dose to the skin, summed over the entire procedure [1]. This assumes a constant level of risk, however, which is not realistic to most interventional procedures, in which the beam moves or is redirected periodically. As a result, this measurement generally overestimates the likelihood of radiation-induced skin injury [1].

Peak skin dose theoretically measures the highest radiation point at any point on the patient's skin, which is an accurate determiner of the likelihood and severity of radiation-induced skin injury. It is often recommended that peak skin dose be measured during interventional radiology procedures, but this has proved difficult in practice [1]. Dosimeters placed on the patient's skin are generally used for this purpose. However, data derived from point measurement devices are likely to underestimate true peak skin dose unless the measurement device is placed at the exact site of irradiation [1].

### **RECORDING PATIENT RADIATION DOSES**

Compliance with recording radiation dose is a vital step in the fluoroscopy process. Although radiation dose management is an important consideration, one must remember that the ultimate goal is to treat patients and provide them the best care possible [3]. The American College of Radiology (ACR)-SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures recommends that radiation dose data be recorded in the final report for all fluoroscopically guided procedures and that, if technically possible, all radiation dose data recorded by the fluoroscopy unit should be transferred and archived with the images from the procedure [36]. Radiation dose data may also be recorded in the immediate post-procedure note and/or the procedure worksheet. Each institution should specify where and how this information is to be recorded in accordance with the needs of its own quality-improvement program and its medical record guidelines [37].



The American College of Radiology recommends that all available radiation dose data should be recorded in the patient's medical record. If cumulative air kerma or air kerma-area-product data are not available, the fluoroscopic exposure time and the number of acquired images (radiography, cine, or digital subtraction angiography) should be recorded in the patient's medical record.

(<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MgmtFluoroProc.pdf>. Last accessed July 21, 2022.)

**Level of Evidence:** Expert Opinion/Consensus Statement

A potentially high-radiation-dose procedure is one in which more than 5% of cases of that procedure result in a reference air kerma exceeding 3 Gy or kerma-area product exceeding 300 Gy cm<sup>2</sup>. Certain procedures are known to be associated with relatively high patient radiation doses and are always classified as potentially high-dose. It is particularly important that patient radiation dose data are recorded for all instances of these procedures. To simplify the categorization of high-dose procedures, SIR has previously recommended that all embolization procedures, TIPS procedures, and arterial angioplasty or stent placement procedures anywhere in the abdomen or pelvis should be considered potentially high-dose procedures [37]. Patient radiation dose data should also be recorded for other fluoroscopically guided procedures, even those that are unlikely to result in high patient radiation doses, such as venous access procedures. Recording patient dose data for all procedures makes it less likely that the process will be omitted inadvertently for high-dose procedures.

High radiation doses should prompt further action. Institutions may also wish to participate in the International Atomic Energy Agency's SAFety in RADiological procedures (SAFRAD) reporting system, a voluntary, confidential reporting system whereby the patient's dose report and relevant data are included in an international database for the purposes of education and quality improvement [37].

## MEASURING PATIENT RADIATION EXPOSURE

The methods to monitor the dose in radiology can be classified into two categories: direct and indirect. For direct measurements, a dosimeter is placed on the patient's skin; for indirect measurements, estimation is done using quantities derived from the radiology machine parameters, providing essentially a measurement of the air kerma [32].

A direct measurement of radiation dose can be obtained using a dosimeter. Dosimeters may be categorized as real-time (e.g., ionization chamber, diode, optical fiber) or non-real-time (e.g., thermoluminescent dosimeter, optically stimulated luminescence [OSL]).

### Real-Time Dosimeters

#### *Ionization Chamber Dosimeter*

The ionizing chamber dosimeter includes a gas-filled cavity with positive and negative electrodes with a voltage applied. Ionization chambers measure the amount of radiation passing through the cavity. The chamber is connected through a cable with an electrometer to make the measurement. Ionization chambers are the reference dosimeters for radiology and can be used for quality assurance and cross-calibration of other dosimeters. The International Atomic Energy Agency recommends two types of ionization chambers for use in radiology: cylindrical or plane-parallel chambers [32].

#### *Diode Dosimeter*

The diode dosimeter consists of diodes that are more sensitive and have a smaller size compared to ionization chambers. The irradiation of a semiconductor induces electron-hole pairs, causing the junction to become conductive and produce a current, which in turn increases with the rate of electron-hole pair's production [32]. The diode shows some energy dependence, with a variation in dose response with temperature, dose rate, and angular incidence with the beam [32].

### **Metal-Oxide Semiconductor Field Effect Transistor Dosimeter**

The metal-oxide semiconductor field effect transistor (MOSFET) dosimeter is a miniature silicon transistor with higher sensitivity and energy dependence. The disadvantage of the MOSFET is that it is visible in radiographs [32]. It is recommended to read the MOSFET signal during the first 15 minutes after irradiation.

### **Diamond Dosimeter**

The diamond dosimeter is well-suited for in vivo measurements because of its small size, tissue equivalence, and resistance to radiation damage. These dosimeters have been evaluated and used for proton therapy, stereotactic radiosurgery beams, and megavoltage x-ray fields [32]. However, if a diamond dosimeter is used for low-energy x-ray, correction factors are necessary to estimate dose rate and energy.

### **Optical Fiber Dosimeter**

Optical fiber dosimeters detect the light resulting from the irradiation of a plastic scintillator. The light (scintillation photon) is guided and transmitted from the sensitive element to a photomultiplier tube via a transmission fiber, and then the signal is analyzed by a computer. The use of a photomultiplier tube allows a real-time monitoring of the light output from the dosimeter.

The main disadvantage of the optical fiber dosimeter is the noise signal produced in the light-guide by Cerenkov radiation for higher megaelectron volt and fluorescence for low-energy x-ray beam. Optical fiber dosimeters can be used from 10 mcGy/minute with ophthalmic plaque dosimetry to about 10 Gy/minute for external beam dosimetry. This dosimeter has no significant directional dependence and does not need correction factors for temperature or pressure [32].

### **Non-Real-Time Dosimeters**

#### **Thermoluminescent Dosimeter**

Thermoluminescent dosimetry is based on the physical property of certain crystals to emit light when they are heated after having been irradiated. The quantity of light is proportional to the energy deposited during irradiation. The detection system consists of a heating component and a light measurement device. Dosimeters most commonly used in medical applications are based on lithium fluoride doped with magnesium and titanium, because of its tissue equivalence and high sensitivity. These dosimeters can be used to measure doses ranging from 10 mcGy to 10 kGy [32].

#### **Optically Stimulated Luminescence**

OSL is based on a similar principle to that of the thermoluminescent dosimeter. Instead of heating, the light from a laser is used to release the trapped energy and generate the luminescence. The most common OSL dosimeter is aluminum oxide coated with carbon. If appropriately instrumented, the OSL can deliver the dose information immediately after the irradiation, in conditions close, but not equal, to real-time measurements [32].

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## **TENETS OF RADIATION SAFETY IN CLINICAL PRACTICE**

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The SIR has issued practice guidelines to assist providers using interventional radiology technology in safely providing high-quality care. The goal of the guidelines was not to provide rules that must be adhered to but rather to create a framework for defining practice principles. Ultimately, the SIR has recommended leaving the ultimate judgement for patient care up to the physician, and decisions should be made based on individual patient characteristics as well as available resources [3].

As discussed, the FDA released guidelines for documenting radiation doses and radiation use after receiving multiple reports of radiation-induced skin injuries associated with interventional fluoroscopy. These guidelines were initially released in 1994 and 1995 and were last updated in 2018 [35]. The ACR published its recommendations on patient radiation exposure in 2007. These guidelines were more focused on radiation exposure secondary to diagnostic radiology procedures rather than interventional procedures. The ACR then issued recommendations in 2008 that complement those put forth by the SIR [3].

The SIR advocates a thorough and complete approach that requires preprocedural planning, intraprocedural management, and postprocedure care. After the decision is made to do a procedure, obtaining informed consent is the most critical step in preprocedural planning. Included in the informed consent is discussion of radiation dose and risk associated with said dose.

During an interventional procedure, radiation data are available to the operator. It is up to the operator to remain informed continuously throughout the procedure about the radiation dose levels and whether or not it is necessary to continue the procedure given the current radiation doses. Evaluation of the risk-benefit balance ratio should be constant throughout the procedure, and the decision of whether to continue will vary for each patient and each clinical scenario.

## PREPROCEDURAL MANAGEMENT

The ACR and the SIR recommend that all personnel involved with interventional procedures, including nurses, technologists, physicians, and other allied staff, should receive initial training in radiation management [36]. In general, radiation training should be in accordance with the facility's policy as well as government regulations. Initial radiation safety training should include information about the potential adverse effects of radiation on patients,

a brief review of the operation of the fluoroscopic equipment, factors that affect patient radiation dose, and interventions that could be implemented to reduce radiation dose.

It is important to ensure that interventions with a significant radiation dose are scheduled in the fluoroscopy suite that allows for radiation dose monitoring. The SIR gives a brief review of procedures that are known to have high radiation doses. Examples of these procedures include [38]:

- Renal or visceral angioplasty
- TIPS creation or revision
- Complex biliary interventions
- All embolizations, including chemotherapy embolizations
- Complex multilevel vertebroplasty or kyphoplasty

Also, there are several patient factors that increase the risk for radiation-related injuries. When these criteria are identified in the preprocedural planning, it is important to discuss the associated risks during the consent process. These patient factors include:

- Weight less than 10 kg or greater than 135 kg
- Pregnancy
- Procedures on pediatric patients or young adult patients involving radiosensitive tissues or organs such as the breasts, gonads, or thyroid

In addition, if the procedure is recognized to be technically challenging or prolonged, this should be discussed during the consent process. Any procedures involving the use of radiation in the same anatomic region within 60 days should trigger a discussion about radiation risk. At this point, it is critical to document in the patient's medical record that the radiation risk discussion was conducted and the patient verbalized understanding prior to initiating the procedure.

In the past, interventional radiology procedures were comprised of diagnostic imaging followed by an intervention within the same session. However, with the increased sophistication of the diagnostic imaging quality, this is becoming less necessary. When planning the procedure, it is important to review all prior images and if images from an outside facility are available, it is recommended that these images be reviewed rather than repeating the study. Every effort should be made to obtain outside images and upload them to the institution's picture archiving and communication system.

When repeating imaging is unavoidable, clinicians should consider using modalities associated with fewer radiation risks (e.g., MRI, ultrasonography). If CT imaging must be used, it is important to use dose-reduction techniques or a low-dose protocol. Techniques that decrease dose without critically compromising image quality include decreasing the tube voltage and using automatic tube current modulation.

Reconstructed images from MR angiography and CT angiography allow for accurate anatomic detail for pretreatment planning. Although multi-detector CT enterography requires some radiation, its use instead of digital subtraction angiography may result in reduced radiation doses to the patient. The use of CT angiography is limited in the evaluation of vessels with extensive atherosclerotic disease.

In addition to radiation risks, it is important to recognize the adverse effects associated with interventional radiology procedures, including adverse reactions secondary to iodine- or gadolinium-based contrast agents. In each clinical situation, it is paramount to weigh the potential of acquiring misleading or non-diagnostic images versus the risk to the patient.

## INTRAPROCEDURAL MANAGEMENT

Radiation doses should be monitored throughout the procedure. The responsibility is ultimately that of the physician performing the procedure. However, it may be delegated to a nurse, radiology technologist, or other personnel in accordance with an institution's policy and relevant laws and regulations.

There are several rules when monitoring radiation doses during a procedure. For fluoroscopy units that provide estimates of peak skin dose, the operator should be notified when the peak skin dose reaches 2,000 mGy and then every 500 mGy after that point. For units with air kerma capabilities, the operator should be given initial notification at 3,000 mGy and then every 1,000 mGy after that point. These numbers correspond to an initial peak skin dose of approximately 1,800 mGy and an increment of about 500 mGy.

For units with kerma-area-product capability, the notification level is determined on a procedure-dependent basis informed by the nominal x-ray field size at the patient's skin. For example, with the use of 100 cm<sup>2</sup> field, the initial report will be at 300 Gy cm<sup>2</sup>. Subsequent dose increments of 100 Gy cm<sup>2</sup> require additional notification. Clinicians should keep in mind that different fluoroscope brands may report the kerma-area-product using different units. In these cases, conversion factors should be used.

For units that only monitor fluoroscopy time, the operator should be notified when the total fluoroscopy time has reached 30 minutes and subsequently notified at a maximum of 15-minute increments. Fluoroscopy operators should be careful when performing studies with a relatively large number of fluorographic images, specifically angiographic images; notification intervals should be reduced for such procedures. All fluoroscopes are capable of displaying fluoroscopy time, but there is poor correlation between dose metrics and fluoroscopy time. In biplane systems, doses received from each plane should be considered independently when the fields do not overlap. When the fields overlap, the doses are considered to be additive.

Procedures are unlikely to be stopped entirely because of radiation dose, but when the operator receives these notifications he or she should consider the radiation dose already delivered to the patient and any additional radiation necessary to complete the procedure. It is important to note that the clinical benefits of a successful interventional procedure almost always exceed the detrimental effects the patient may be at risk for secondary to radiation exposure. Nonetheless, if maximum radiation thresholds are reached during a procedure, any additional procedures performed in the subsequent 60 days should be closely monitored, as these will be considered additive to the previously received dose.

### **Occupational Dose Measurement and Monitoring**

All medical radiation workers are required to participate in a facility-based radiation dosimetry monitoring program. Regulations regarding these programs vary from state to state, but generally, an imaging service that may result in the operator or exposed staff receiving more than 10% of the yearly allowable maximum radiation exposure will necessitate the use of radiation dosimeters [7]. Typically, workers are issued dosimeters to be worn outside the lead apron at neck level. These dosimeters record a dose that approximates that of the exposed head and neck. Some programs also include a second dosimeter to be worn under the lead apron at the waist level to serve as a proxy for the gonadal dose. Worker dosimeters are read at monthly intervals. Doses that exceed permissible levels are followed up by the facility's radiation safety office. Follow-up measures may include recommendations regarding a change in work habits or a change in shielding methods [5].

Thyroid shields and leaded glasses are optional pieces of protective equipment, but in very busy or higher exposure environments, they may be required. The quality and condition of the radiation safety protective wear for the staff, visitors, patients, and family members should be regularly assessed.

Records should be kept of the initial x-ray inspection of a new shield by radiation safety staff, assignment of a unique inventory identifier of the shield, yearly visual evaluation by the local user or staff, and any notifications of suspected defective equipment.

### **POSTPROCEDURAL CARE**

Ideally, the estimated radiation dose should be included in the medical record for every procedure. As mentioned, the peak skin dose and kerma-area product should both be recorded, as they are the most useful predictors for the deterministic and stochastic effects of radiation, respectively. If the peak skin dose is not available on the fluoroscopy system, the reference point air kerma is an acceptable substitute. If neither the peak skin dose nor the kerma-area product are available, the fluoroscopy time should be used as the radiation dose metric. Recording the number of fluoroscopic images obtained during a fluoroscopic procedure is also helpful in the calculations involved in estimating the radiation dose. Procedures with long fluoroscopy times (or high doses, if a more precise metric is available) should be reviewed routinely as part of a quality assurance process to ensure the radiation exposure is medically justified and to determine whether practice trends emerge.

A periodic report of dose recording performance and dosage utilization should be obtained for each institution. The SIR recommends that a dose recording compliance rate of less than 95% for any fluoroscopy operator should prompt additional radiation safety training [3]. The SIR also recommends a review of the medical necessity for radiation utilization in all procedures that are above the 95th percentile in terms of dose distribution compared with similar procedures for the particular institution [3]. The goal is to prompt better radiation dose-reduction techniques. At a minimum, an annual review of image quality in relation to radiation dose should be performed as part of quality control programs for individual institutions.

### **Patient Follow-Up**

Any patient who receives a significant radiation dose during a fluoroscopic procedure should be followed up after the procedure and should receive written radiation follow-up instructions upon discharge. The patient should be instructed to notify the fluoroscope operator or the medical physicist after discharge in case of the development of signs or symptoms of adverse radiation effects. A medical physicist should review the dosimetry of the procedure performed in these cases. In circumstances in which the same anatomic area has been irradiated in the previous 60 days, follow-up should be performed at lower radiation doses.

Standards for patient follow-up have not been established with respect to monitoring for potential fluoroscopy-induced skin injury. Multiple factors contribute to this lack. First, significant skin injury is rare, even in patients who have undergone long fluoroscopically guided procedures. Second, there is no clear evidence that early intervention changes outcomes when injury does occur. Finally, practitioners are reluctant to alarm patients when they have no clear recommendations for management of such an injury. In an ideal postprocedural setting, the patient should know that the procedure was medically necessary and performed in a way that optimizes the risk/benefit ratio, should be told that development of a rash in the region that was imaged could be due to radiation exposure, and should be instructed to call the interventionalist if a rash or irritation occurs. The interventionalist's responsibility is to then refer the patient to a dermatologist or plastic surgeon who is aware that radiation injury is a possibility and can incorporate that information into treatment planning. Biopsy of a radiation injury should be avoided because it may not heal well [5].

### **EQUIPMENT PURCHASE AND MAINTENANCE**

When addressing radiation exposure management, planning should begin at inception, with interventional suite design. It is important to involve the interventionalist at the room-design and equipment-purchasing stages. For existing interventional suites, appropriate maintenance and updating of existing equipment are critical. Preventive maintenance of fluoroscopes and replacement of parts before their deterioration contributes to increased radiation doses are encouraged.

#### **Inspection of C-Arm Equipment**

All institutions accredited by the Joint Commission are required to perform safety inspections of radiologic equipment at least yearly [39]. State and local governments may have more stringent requirements and retain the right to conduct public health inspections and examine x-ray-producing equipment, the records associated with their continued use, and the maintenance provided.

Hospital facilities with large radiology, nuclear medicine, and/or radiation oncology departments are likely to have medical physicists on staff to perform equipment inspection tasks and to ensure that patient images are of the highest possible quality. A preventive maintenance program will also identify any equipment that is failing to perform as intended. This is essential for the safe and accurate diagnostic imaging services of the institution and is a valuable resource to the clinicians and the technologists who image patients [7].



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## SPECIAL POPULATIONS

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### RADIATION AND PREGNANCY

Epidemiologic studies of populations exposed to acute, high doses of ionizing radiation have been traditionally used to assess the risks of cancer and other diseases linked to radiation. The results of these studies have shown that developing organisms are more vulnerable, but the actual effects of exposure to ionizing radiation on a conceptus depend on the absorbed dose and the stage of gestation. A special concern for the unborn in a medical setting requires the protection of pregnant or potentially pregnant patients and radiology staff.

With the increasing use of medical radiation, many women who are pregnant or potentially pregnant are being exposed to ionizing radiation. In most circumstances, the radiation risk to the fetus is small in comparison to the risk of spontaneous abortion (15%), spontaneous or inherited genetic abnormalities (4% to 10%), and malformations (2% to 4%) in the general population. However, increased anxiety and termination of pregnancy may result if the patient and staff are not properly educated [40].

As noted, risks to the fetus from radiation depend on the dosage and the stage of pregnancy. The risk is usually greatest during organogenesis in the first trimester and least in the third trimester. Whenever possible, diagnostic tests or procedures that involve radiation should be deferred until after pregnancy or replaced with safer options. In all cases, the patient should be adequately informed of any chances of radiation exposure.

Estimated fetal radiation doses for diagnostic tests vary based on the type of procedure and the stage of the pregnancy. A plain anteroposterior radiograph of the pelvis carries a dose of about 1.5 mSv. A lumbar spine anteroposterior radiograph at 3 months' gestation results in about 2 mSv of exposure; this increases to 9 mSv when performed near term. A CT scan of the mother's head delivers less than 0.005 mSv, but an abdominal CT scan can lead to 8 mSv of fetal exposure [40].

### Fetal Effects

The major adverse effects of radiation exposure on the fetus include abortion, teratogenicity, developmental or intellectual disability, intrauterine growth restriction, and the induction of cancer. Normal diagnostic procedures seldom involve sufficient dosage to induce malformations, fetal death, or central nervous system defects, but the threshold may be exceeded with complicated interventional procedures.

Based on animal studies, malformations after in utero exposure to radiation doses less than 100 mSv are not expected. Central nervous system malformations may appear if a dose threshold of 100 mSv has been exceeded. Fetal doses of 100 mSv or higher, especially if incurred between 8 and 16 weeks' gestation, can be associated with reduction of intelligence and microcephaly. As an example, in victims exposed to in utero radiation during the 1945 atomic bombing of Hiroshima, the risk of intellectual disability has been estimated to be about 0.04% per mSv of exposure, with an estimated loss of 2 to 3 IQ points per mSv [40].

It has been shown that prenatal exposure at high doses of radiation is associated with deterministic effects. In the first two weeks after conception, when the number of cells is small, radiation can terminate the pregnancy or the conceptus can recover completely (an all-or-none effect). During this early period of gestation, the blastocyte or embryo has a decreased sensitivity to teratogenic effects and a greater degree of sensitivity to the lethal effects of irradiation. A reversal of these effects is observed in the organogenesis period, from the 3rd to the 8th week after conception. Because of the high sensitivity to teratogenic effects during this period, the most likely form of damage is malformation of the organs of the fetus. As has been observed in the offspring of the survivors of atomic bomb detonations, there is a risk for microencephaly, about 1 in 100 per centigray (cGy) (1% per rad). From the 8th to 15th week of gestation, there is a potential for intellectual or developmental disability; the risk is about 4 in 1,000 per cGy (0.4% per rad). After the 16th week, the central

nervous system becomes less radiosensitive. During the last trimester, major organ malformations and functional anomalies are unlikely.

The threshold dose for deterministic effects is in the range of 100–200 mGy (10–20 rad) for acute exposure to the whole body. The majority of diagnostic extra-abdominal x-ray examinations result in doses to the conceptus of less than 1 mGy (100 mrad). Examinations involving the abdomen or pelvis may deliver higher doses to the fetus or embryo. In cases of accidental irradiation, doses to the conceptus may be greater than 50 mGy (5 rad), especially if the total time of fluoroscopy exceeds seven minutes. However, it is uncommon for diagnostic x-ray examinations to exceed 100 mGy (10 rad). Therefore, deterministic effects are unlikely to be observed after diagnostic x-ray studies.

Stochastic effects should be considered, but the risk for cancer from prenatal radiation exposure at low doses remains a controversial issue. Case-control studies and several studies of twins have shown an increased risk for childhood leukemia after in utero irradiation, but cohort studies have not supported this association [41]. The power of epidemiologic studies is usually not sufficient to demonstrate the existence of these effects in exposed populations.

If the conceptus absorbed dose is 50 mGy (5 rad), the risk for childhood fatal cancer is 0.3%. This value, however, coincides with the natural risk for fatal childhood cancer, which is also about 0.3%. Therefore, fatal childhood cancer risks after pelvic procedures (e.g., barium enema, CT scan) are similar to the natural incidence of fatal cancer before 15 years of age. The risk for carcinogenesis due to radiation exposure is relatively low for conceptus doses less than 100 mGy (10 rad). At doses greater than 100 mGy, both deterministic and stochastic effects of radiation should be considered [41].

Studies have also been carried out to investigate the possible effects on the children of personnel exposed to ionizing radiation occupationally. Some researchers found a borderline increase of chromosomal anomalies other than Down syndrome in the children of female radiographers, but Doyle et al. found no evidence of an association between exposure to low-level ionizing radiation before conception and increased risk for malformations in the offspring of staff members working in the nuclear industry [41; 42].

### **Considerations for Pregnant Staff**

Based on federal law, a pregnant woman can choose to continue to receive occupational radiation exposure at the level allowed for adult workers. However, it is recommended that an occupationally exposed pregnant woman declare pregnancy for the purpose of reducing the risk to the unborn child. After pregnancy is declared, additional precautions should be adopted to protect the fetus and limit the radiation exposure to recommended levels [40].

When an expectant mother is a radiation worker, her occupational radiation is monitored in accordance with radiation protection regulations. There is a difference in the dose limits for the unborn in the United States and those set by the ICRP. The ICRP states that “the working conditions of a pregnant worker, after declaration of pregnancy, should be such as to ensure that the additional dose to the embryo/fetus would not exceed about 1 mSv during the remainder of the pregnancy” [43]. In the United States, federal regulations pertinent to nuclear radiation require licensees to ensure that the dose to an embryo or fetus during the entire pregnancy due to the occupational exposure of a declared pregnant woman does not exceed 5 mGy (500 mrad) during the gestational period [44]. Many state regulations extend these requirements to x-rays, and some place additional restrictions on the dose (equivalent) that a declared pregnant woman may receive during a one-month period (one-tenth of the limit). Although the dose limits for the conceptus of a pregnant staff member differ among radiation protection agencies,

most countries and institutions have in place radiation protection programs to address the needs of pregnant personnel. The education and counseling of a woman who formally declares her pregnancy in writing is the most important element of a program designed to protect the conceptus of an occupationally exposed worker.

In the fluoroscopy environment, one method of planning the protection of pregnant personnel (interventionalists in particular) is to measure air kerma rates separately for each projection of a fluoroscopic procedure. This information may aid in establishing an acceptable workload per week and for the entire pregnancy. This method, however, may be impractical in some circumstances, for example, for a general interventionalist who performs a broad range of procedure types and whose workload may not be easy to adjust because of staffing constraints and patient care demands. Another approach to reducing occupational exposure is to gather dosimetry information before pregnancy and use it in planning shielding methods to be used during pregnancy. A worker planning pregnancy can request a radiation dosimeter (if she is not already assigned one by her facility) to wear under the lead apron to acquire data about her radiation dose before pregnancy. She may use the information to adjust her workload, shielding, or work habits.

Modifications in shielding to reduce dose, even in instances in which dose reduction may not be strictly necessary from a regulatory standpoint, could include, in extreme circumstances, increasing the thickness of lead aprons from 0.5 mm to 1.0 mm lead equivalent or using additional boom-mounted, floor-mounted, or patient-mounted protective shielding to reduce scatter. The latter options have the advantage of not adding to the weight carried by pregnant workers. Real-time dose information with an audible radiation monitor could be included in a radiation protection program, in addition to standard dosimetry badges read monthly, to provide immediate feedback as to the effectiveness of radiation protection measures.

There are some data to support the contention that a 1-mGy fetal dose limit is feasible for full-time interventional fluoroscopy physicians. In a study of 30 interventional radiologists, readings from waist-level dosimeters worn under a lead apron for a two-month period ranged from 0.02 mSv to 0.39 mSv (2 mrem to 39 mrem). The projected yearly dose equivalent at the waist under lead for this study group was estimated to be 0.22–4.11 mSv (22–411 mrem) for a 10.6-month work-year. Substantial differences in the average projected yearly dose value related to lead apron thickness were noted, with 0.4 mSv (40 mrem) and 1.3 mSv (130 mrem) noted for persons wearing 1.0-mm and 0.5-mm lead equivalent aprons, respectively. These data suggest that additional radiation protection above the standard 0.5-mm lead equivalent apron may be warranted for some workers in the interventional radiology environment [41].

## **RADIATION SAFETY IN CHILDREN**

Children are more sensitive than adults to radiation by as much as a factor of 15, depending on age and gender. However, it is important to realize that induction of fatal cancer by low-level radiation is uncertain; therefore, cautious interpretation of risks during medical imaging is warranted, particularly in discussions with individual patients, families, and caregivers [45].

In general, low-level radiation exposure is defined as doses less than 100–150 mSv. Risks associated with radiation doses greater than this level are not debated; however, there is disagreement regarding possible risk at lower levels. There are a great many variables that come into play, including gender, age, area of exposure, genetic susceptibility, and acute versus protracted exposure.

The linear no-threshold model is considered by many organizations to be the most conservative and reasonable model to estimate the probability of radiation-induced cancer, although this has been recently debated. In general, the teaching has been that there is a 5% risk of developing fatal cancer for every 1.0 mSv of exposure. Therefore, an effective dose of 100 mSv would result in a 0.5% (or 1 in 200) risk of cancer, and 10 mSv exposure would lead to a 0.05% (or 1 in 2,000) risk of cancer. Again, this effective dose determination does not take into account age differences, and it may be that risk should be adjusted up for younger children [45]. There is some suggestion of a significant risk of cancer for exposures less than 50 mSv in children [46]. The Childhood Cancer Survivor Study (CCSS) has been compiling data from 22,343 childhood cancer survivors over the last 20 years [47]. Of the survivors, 57.3% received radiation therapy, with 9.3% having received a maximum dose of at least 50 Gy to the brain and 11.2% having received at least 30 Gy to the chest. Excess relative risk per Gy of radiation were calculated for second primary malignancies in the brain, breast, thyroid gland, bone, skin, and salivary gland, and the results have been reviewed [48; 49; 50; 51; 52; 53; 54; 55; 56]. In line with what is known from atomic bomb survivors and children treated for benign conditions, the thyroid gland showed the highest excess relative risk at 1.38 per Gy, followed by bone (1.32) and skin (1.09) [57].

In one study, differences in organ doses from several dental cone-based CT scanners are analyzed; the differences in equivalent doses to the lens of the eye, the thyroid, and other key head and neck organs were compared for children and adults (using anthropomorphic phantom heads) [58]. Researchers found that the equivalent doses for children's organs were generally higher than for adults when similar exposure settings were used. In addition, certain organs received more radiation in children than adults, most likely due to the difference in their size and location.

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## CULTURAL CONSIDERATIONS FOR INFORMED CONSENT

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Informed consent is now the backbone of Western bioethics; however, it was not an ethical mandate until 1957, when it was explicitly formalized in the Code of Ethics of the American Medical Association [59]. The Code of Ethics requires physicians and any helping professionals to communicate diagnoses, prognoses, courses of treatment or intervention, and alternative options in such a manner that is understood, so an informed decision regarding treatment may be made by the client/patient [59]. An individual's ability and prerogative to make one's own decision about treatment is now seen as a vital expression of autonomy and a prerequisite to participation in treatment or interventions [60]. As discussed, obtaining informed consent is an essential component of preprocedure planning any time that fluoroscopy is used. Ensuring that the patient has a clear understanding of the procedure and its risks and benefits is the responsibility of the clinician, and this understanding may be affected by linguistic and cultural factors.

The process of informed consent entails the explicit communication of information in order for the individual to make a decision. Western cultures value explicit information, which is centered on American consumerism, that is, the belief that having and exercising choice extends to healthcare purchases [61]. However, some cultures believe that language and information also shape reality [62]. In other words, explicit information, particularly if it is bad information, will affect the course of reality.

A signature is required on most Western informed consent forms to represent understanding and agreement on the part of the individual involved. Yet, this might be viewed as a violation of social etiquette in some cultures. For example, in Egypt, signatures are usually associated with major life events and legal matters. Therefore, requiring a signature outside these circumstances would imply a lack of trust, particularly when verbal consent has been given [63].

Consent forms also often contain technical and legal jargon that may be overwhelming to the native English-speaking individual, but can be much more daunting for immigrants who may not be proficient in English or familiar with various legal concepts. Asking for a signature on a consent form that contains foreign legal and technical terms may place some immigrants at risk for secondary traumatization, as some were persecuted, tortured, and forced to sign documents in their homelands [64].

Cultural dissonance can be a challenge to many general healthcare and mental health practitioners. Cultural experts may help mitigate this challenge by assisting with the interpretation and navigation of the complex web of cultural interactions.

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## CONCLUSION

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Fluoroscopy has many uses in modern medicine, expanding beyond standard x-rays films. While these procedures have clinical benefits, they are not without risks, particularly related to radiation exposure. A major focus of this course has been the risk and average doses patients and clinicians incur when undergoing fluoroscopy procedures. The overall goal and purpose of radiation safety and dose management is to conduct individual radiation risk assessment for each patient, providing the patient involved with an opportunity to give informed consent relating to her/his radiation risk [3]. Studies indicate that improved clinician education can help to limit radiation dose and associated complications.

### Implicit Bias in Health Care

The role of implicit biases on healthcare outcomes has become a concern, as there is some evidence that implicit biases contribute to health disparities, professionals' attitudes toward and interactions with patients, quality of care, diagnoses, and treatment decisions. This may produce differences in help-seeking, diagnoses, and ultimately treatments and interventions. Implicit biases may also unwittingly produce professional behaviors, attitudes, and interactions that reduce patients' trust and comfort with their provider, leading to earlier termination of visits and/or reduced adherence and follow-up. Disadvantaged groups are marginalized in the healthcare system and vulnerable on multiple levels; health professionals' implicit biases can further exacerbate these existing disadvantages.

Interventions or strategies designed to reduce implicit bias may be categorized as change-based or control-based. Change-based interventions focus on reducing or changing cognitive associations underlying implicit biases. These interventions might include challenging stereotypes. Conversely, control-based interventions involve reducing the effects of the implicit bias on the individual's behaviors. These strategies include increasing awareness of biased thoughts and responses. The two types of interventions are not mutually exclusive and may be used synergistically.

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