# ACR-SIR-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF ARTERIOGRAPHY

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

#### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care 1. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

#### I. INTRODUCTION

This parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

For purposes of this parameter, the term "arterial intervention" refers to all catheter-based procedures performed on arteries, and it may be referred to elsewhere as "interventional procedure" or "endovascular surgery."

Arteriography with fluoroscopy is established and safe for diagnosis and for guidance in endovascular interventions. It has been accepted as the gold standard in the evaluation of other vascular imaging modalities. In comparison with other vascular imaging modalities, however, arteriography is procedural and has an inherent, but small, risk of complications [1].

This parameter has been developed to provide recommendations for the best practice of arteriography, including pre- and postprocedural care, with minimal risk and optimal imaging quality. This imaging parameter will not include the practice of arteriography in the coronary or cervicocerebral circulation (see the <u>ACR-ASNR-SIR-SNIS Practice Parameter for the Performance of Diagnostic Cervicocerebral Catheter Angiography in Adults</u> [2]).

These parameters are designed as recommendations; it is understood that variation from these recommendations in the practice of arteriography may be necessary depending upon specific clinical scenarios.

# II. INDICATIONS, CONTRAINDICATIONS, AND ALTERNATIVE STUDIES

#### A. Indications

- 1. Pulmonary arteriography [3-13]
  - a. Suspected acute pulmonary embolus, in particular when other diagnostic tests are inconclusive or discordant with clinical findings
    - i. Indeterminate ventilation-perfusion imaging study or nondiagnostic CT scan in a patient suspected of having a pulmonary embolus
    - ii. Low-probability ventilation-perfusion imaging study in a patient with a high clinical suspicion of pulmonary embolus
    - iii. Ventilation-perfusion imaging study or CT pulmonary angiography scan cannot be performed.

High-probability ventilation-perfusion imaging study when there is a contraindication to anticoagulation

- i. Known or suspected chronic pulmonary thromboembolism
- ii. Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired vascular anomalies, tumor encasement, and vascular malformations
- iii. Foreign body retrievals within the pulmonary vasculature
- iv. Spontaneous hemorrhage
- v. Evaluation and treatment of iatrogenic injury
- 2. Spinal arteriography [12-15]
  - a. Spine and spinal cord tumors
  - b. Vascular malformations
  - c. Spinal trauma
  - d. Preoperative evaluation prior to open or endovascular aortic or spinal surgery
  - e. Spontaneous hemorrhage
- 3. Bronchial arteriography [6,7,12,13,16-18]
  - a. Hemoptysis
  - b. Suspected congenital cardiopulmonary anomalies
  - c. Assessment of distal pulmonary artery circulation (through collaterals) in patients who are potential candidates for pulmonary thromboendarterectomy
  - d. Bronchial artery aneurysm

#### e. Spinal arteriovenous malformations

# 4. Aortography [12,13,16,19]

- a. Abnormalities including acute traumatic injury, dissection, aneurysm, occlusive disease, aortitis, and congenital anomaly
- b. Evaluation of the aorta and its branches prior to selective studies
- c. Spontaneous hemorrhage

# 5. Abdominal visceral arteriography [12,13,20-26]

- a. Acute or chronic gastrointestinal hemorrhage
- b. Blunt or penetrating abdominal trauma
- c. Intra-abdominal tumors
- d. Acute or chronic intestinal ischemia
- e. Evaluation of mesenteric, splenic, and portal vein patency
- f. Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, and vasculitis
- g. Preoperative evaluation prior to open surgical procedures
- h. Preoperative and postoperative evaluation of organ transplantation
- i. latrogenic vascular injury
- j. Spontaneous hemorrhage

# 6. Renal arteriography [12,13,27,28]

- a. Renovascular occlusive disease (eg, for hypertension or progressive renal insufficiency)
- b. Renal vascular trauma
- c. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis
- d. Renal tumors
- e. Hematuria of unknown cause
- f. Preoperative and postoperative evaluation for renal transplantation
- g. latrogenic vascular injury
- h. Spontaneous hemorrhage

#### 7. Hepatic arteriography [29-33]

- a. Hepatic vascular trauma
- b. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis
- c. Hepatic tumors, including radioembolization/chemoembolization with associated dosimetry planning
- d. Preoperative and postoperative evaluation for hepatic transplantation
- e. latrogenic vascular injury
- f. Spontaneous hemorrhage

# 8. Pelvic arteriography [12,13,23,34]

- a. Atherosclerotic aortoiliac disease
- b. Trauma
- c. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis
- d. Male impotence caused by arterial occlusive disease
- e. Pelvic tumors
- f. Benign prostatic hyperplasia
- g. Uterine leiomyoma; adenomyosis
- h. Postpartum hemorrhage
- i. latrogenic vascular injury
- j. Tendinopathy/enthesopathy, osteoarthritis
- k. Spontaneous hemorrhage
- I. Assessment of arterial anatomy, such as before free flap harvesting or organ transplantation

- 9. Extremity arteriography [12,13,35-41]
  - a. Atherosclerotic vascular disease, including aneurysms, emboli, occlusive disease, and thrombosis
  - b. Vascular trauma
  - c. Preoperative planning and postoperative evaluation
  - d. Evaluation of surgical bypass grafts and dialysis grafts and fistulas
  - e. Other primary vascular abnormalities, such as vascular malformations, vasculitis, entrapment syndrome, and thoracic outlet syndrome
  - f. Extremity tumors
  - g. Tendinopathy/enthesopathy, osteoarthritis
  - h. latrogenic vascular injury
  - i. Spontaneous hemorrhage
     There may be circumstances where arteriography prior to, during, or after arterial intervention is justified on other vessels not cited above.

# B. Contraindications [12,13,42]

There are no absolute contraindications to diagnostic arteriography. Relative contraindications include:

- 1. Severe hypertension
- 2. Uncorrectable coagulopathy or thrombocytopenia
- 3. Clinically significant sensitivity to iodinated contrast material
- 4. Renal insufficiency based on the estimated glomerular filtration rate (eGFR)
- 5. Congestive heart failure
- 6. Certain connective tissue disorders (reported complications at the puncture site)
  For optimum patient management, these relative contraindications should be addressed prior to the procedure. Every effort should be made to correct or control these clinical situations before the procedure, if feasible.
- C. As there are continual advances in medical diagnostic, therapeutic, and imaging technology, many of the indications listed below may also be investigated by alternative diagnostic technologies, including, but not limited to:
  - 1. Ultrasound
  - 2. MRI (including MR angiography)
  - 3. CT (including CT angiography)
  - 4. Nuclear medicine, including PET
  - 5. Functional and perfusion imaging
  - 6. Physiologic testing (eg, pulse volume recording)
  - 7. Segmental blood pressure measurements

It is incumbent upon the physician to determine the relative benefit and risk of diagnostic arteriography compared with the alternative diagnostic techniques for each patient prior to suggesting and/or performing diagnostic arteriography.

Some of these alternative tests may be used as an adjunct to diagnostic arteriography. The use of serial tests in medical decision-making is well recognized and, in appropriate clinical circumstances, is justified. Such appropriate use of serial testing should be documented in the medical record.

# **III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

# A. Physician

Core Privileging: This procedure is considered part of or amendable to image-guided core privileging.

Image-based diagnosis and treatment planning require integrating the angiographic findings with the patient's history, physical findings, and prior imaging studies. Therefore, the physician must be clinically informed and understand the specific questions to be answered by diagnostic arteriography prior to the

procedure to plan and perform it safely and effectively.

The physician performing a diagnostic arteriogram must fully appreciate the benefits, alternatives, and risks of the procedure. The physician must have a thorough understanding of vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety, and physiologic monitoring equipment and have access to an adequate supply of catheters, guidewires, and personnel to perform the procedure safely.

Diagnostic arteriography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications pertinent to the scope of services to be provided and the specific privileges sought:

- 1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s) [43,44].
- 2. Successful completion of radiology residency training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include interventional radiology residency and/or interventional/vascular radiology fellowship, and must have training in a service that is primarily responsible for the performance of percutaneous peripheral, visceral, and neurovascular diagnostic arteriography. Documented formal training in the performance of invasive catheter angiographic procedures must be included. During this training, the physician should have performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s) [43].
- 3. Successful completion of an ACGME-approved nonradiology residency or fellowship training, and must have trained on a service that is primarily responsible for the performance of percutaneous peripheral, visceral, or neurodiagnostic arteriography and vascular/interventional radiology. Documented formal training in the performance of invasive catheter arteriographic procedures must be included. During this training, the physician should have performed peripheral, visceral, or neurodiagnostic arteriograms, with most of them as the primary operator, and these cases must be documented so the director of the training program can certify that the physician is proficient in the performance of the procedures, with acceptable success and complication rates within the quality assurance threshold rates laid out in this parameter [43].
- 4. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have documented confirmation that they are familiar with all of the following:
  - a. Indications and contraindications for the procedure.
  - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications. For pediatric cases, this includes dedicated training in pediatric angiography and the underlying causes of pediatric vascular disease as well as knowledge of age-based normal ranges for vital signs, and signs and symptoms of complications; or the availability of team members with such expertise (such as pediatric sedation and monitoring personnel). This also includes knowledge of the normal amounts of fluids that can be administered during the procedure (including fluids going through sheaths) to prevent volume overload.
  - c. Pharmacology of drugs used for sedation and analgesia, and recognition and treatment of adverse reactions and complications. For pediatric cases, this includes knowledge of weight-based pediatric dosages, contraindications, and signs and symptoms of adverse reactions and complications.
  - d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical

injectors, digital subtraction, and other electronic imaging systems.

- e. Principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to patients and personnel, including appropriate dose-reduction strategies for children [45].
- f. Pharmacology and dosing of contrast agents and recognition and treatment of potential adverse reactions.
- g. Percutaneous needle and catheter introduction techniques. Ultrasound guidance may be used for access, most often in children. For neonates, this also implies the potential use of the umbilical artery as a possible catheter access site for angiographic procedures.
- h. Technical aspects of performing the procedure, including the use of alternative catheter and guide-wire systems, invasive monitoring devices such as pressure transducers, selective angiographic methods, appropriate injection rates and volumes of contrast media (weight-based in children), and imaging sequences [46].
- i. Recognition of periprocedural complications and knowledge of treatment options for these complications (eg, stenting, embolization, thrombolysis, suction embolectomy, surgery).
- j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature, including normal variants.
- k. Interpretation of diagnostic arteriographic studies including common artifacts (eg, standing wave, bone subtraction artifact).

The documented confirmation should come from the chief of interventional radiology, chief of neuroradiology, chief of interventional neuroradiology, or chair of the department of the institution in which the physician will be providing these services[1]. Confirmation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional, neurointerventional, or neuroradiology chief or the chair who solicits the additional input.

#### Maintenance of Competence

Physicians must perform a sufficient number of overall procedures applicable to the spectrum of core privileges to maintain their skills, with acceptable success and complication rates as laid out in this parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates. Consideration should be given to the physician's lifetime practice experience.

#### **Continuing Medical Education**

The physician's continuing education should be in accordance with the <u>ACR Practice</u> <u>Parameter for Continuing Medical Education (CME)</u> [47].

#### B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education</u> (<u>CME</u>)) [47].

The appropriate subfield of medical physics for this parameter is Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, or Diagnostic Imaging Physics). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (e.g., acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

NPRPs can be valuable members of the interventional radiology team. Their participation in angiography procedures should be specifically under the supervision of appropriately qualified and credentialed physicians. See the <u>ACR-SIR-SNIS-SPR Practice Parameter for the Clinical Practice of Interventional Radiology</u> [48].

# D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position the patient[2] for the arteriographic procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

The technologist should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the diagnostic arteriography procedure.

# E. Nursing Services

Nursing services are an integral part of the team for periprocedural and intraprocedural patient management and education and are recommended in monitoring the patient during the procedure.

- [1] At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ [48].
- [2] The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available.\* There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 revised in 2007, revised 2017 Resolution 12c)

\*For the purposes of this parameter, "personally and immediately available" is defined in manner of the "personal supervision" provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001

#### IV. SPECIFICATIONS OF THE EXAMINATION

#### A. Access Site

The common femoral artery has been the historical standard access site for arteriography. However, advances in devices and techniques have allowed a multitude of alternative arterial access sites to become commonplace for many arterial procedures. Examples include, but are not limited to, the radial artery and tibiopedal arteries. Notably, some arterial procedures may necessitate more than one access site. Several technical requirements are necessary to ensure safe and successful diagnostic arteriograms. These include adequate arteriographic equipment, institutional facilities, physiologic monitoring equipment (including intravascular pressure measurement systems), and personnel.

# B. Arteriographic Equipment and Facilities

"The following are considered the minimal arteriographic equipment required for obtaining diagnostic arteriograms. In planning arteriographic facilities, equipment and facilities more advanced than those outlined below may be desired to produce higher-quality studies with reduced risk and time of study" [42]. In general, the facility should include at a minimum:

1. A high-resolution flat-panel detector or image intensifier and television chain with standard arteriographic filming capabilities, including large-format image intensifiers (14 inch or greater) with minimum 1,024- image matrix. Smaller image intensifiers may be used in primarily pediatric settings. Digital angiographic systems are strongly recommended because they allow for reduced volumes of contrast material, reduced examination times, and reduction of radiation dose [42]. Features such as last image hold, pulsed fluoroscopy, and road mapping capabilities are strongly recommended for dose reduction. Imaging with cone beam CT (CBCT) is commonly available in fluoroscopy suites. CBCT equipment and image analysis/targeting software provide 3-D rendering of vasculature, both arterial and venous, with excellent anatomic correlation and catheter guidance capabilities. Imaging and image recording must be consistent with the "as low as reasonably achievable" radiation safety guidelines. Appropriate shielding for the operator should be available on all angiographic systems [49]. The equipment should be capable of recording the radiation dose received by the patient so it can be made part of the patient's permanent medical record [50].

# C. Physiologic Monitoring and Resuscitation Equipment

Sufficient equipment should be present in the arteriography suite to allow for monitoring the patient's heart rate, cardiac rhythm, blood pressure, and  $O_2$  saturation and capnography [42]. If the patient receives sedation, the <u>ACR-SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia</u> should be followed [51].

#### D. Support Personnel

- 1. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing and imaging the procedure [42]. "They should be able to demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. Technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment" [42].
- 2. If the patient does not receive sedation, a member of the procedural team should be assigned to periodically assess the patient's status [42]. If the patient undergoes sedation, a nurse or other appropriately trained individual should monitor the patient as their primary responsibility [42]. "This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information" [42]. Nursing personnel should be qualified to administer sedation (see the ACR—SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [51]). For pediatric cases, personnel should be experienced and qualified in pediatric sedation, monitoring, and airway maintenance. Having Pediatric Advanced Life Support (PALS) training and current certification is recommended. Children may easily slip between depths of sedation during the case. Therefore, there must be experienced and qualified personnel available to manage the airway and rescue children from deep sedation or apnea should this occur (see the ACR—SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [51]). Anesthesia team support should be considered as an alternative to sedation in patients if nursing staff is uncomfortable with sedation of patients or if there are extensive comorbidities.

# E. Surgical Support

For additional information, see the <u>ACR-SIR-SNIS-SPR Practice Parameter for the Clinical Practice of Interventional Radiology</u> [48].

"Although complications of diagnostic arteriography only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly" [42]. For both

hospital-based and freestanding sites, access to comprehensive surgical care at an acute care hospital should be readily available.

#### F. Patient Care

#### 1. Preprocedural care

"The indications for elective arteriographic studies should be documented as described below. For emergency procedures, a note should be written summarizing the indications for the study, the pertinent history and physical findings, if available, and the proposed procedure" [42].

- a. relevant history should include indications for the procedure and conditions that may necessitate specific periprocedural care [42].
- b. A relevant physical examination should be performed and should include evaluation of potential access sites and baseline vascular status for postprocedural comparison. For most patients with chronic lower-extremity atherosclerotic disease, noninvasive vascular imaging may help in planning the arteriographic approach. Laboratory evaluation may be indicated, including measurement of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters [42].
  - Informed consent must be in compliance with state laws and the <u>ACR-SIR Practice Parameter</u> on <u>Informed Consent for Image-Guided Procedures</u> [52].

#### 2. Procedural care

a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings including bedside The organization should have processes and systems in place for reconciling differences in staff responses during the "time-out."

#### 3. Postprocedural care

a. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress If sedation was administered prior to and during the procedure, safe and adequate recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician, a physician assistant, or a nurse. See the ACR—SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [51]. Postprocedure documentation should be in accordance with the ACR—SIR—SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [53]. "A procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications" [42]. This note may be brief if an official interpretation will be available within a few hours. "However, if the official interpretation is not likely to be in the medical record the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure" [42]. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

# **V. DOCUMENTATION**

Reporting should be in accordance with the <u>ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [53].

#### VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). <a href="https://www-

#### pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (<a href="www.imagegently.org">www.imagegently.org</a>) and Image Wisely® for adults (<a href="www.imagewisely.org">www.imagewisely.org</a>). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children [50,54]. The Image Gently coalition has provided useful guidance in this regard, including the Step Lightly campaign [55]. The Image Wisely campaign has been formed to provide similar guidance for radiation safety in adult patients.

As noted in the ACR—AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures: [56] "If the cumulative air kerma at the reference point exceeds the substantial radiation dose level (SRDL), which is typically set at 5 gray (Gy), provisions should be made for patient follow-up to allow for detection and management of possible radiation effects [50,54,57]. (For specific classes of procedures, if a higher or lower SRDL is chosen it should be supported by published literature or data collected by the facility [58].) If follow-up for possible radiation injury is indicated, the patient should be advised of the potential for radiation injury to the skin and be given instructions for proper follow-up, and these steps should be documented in the medical record [50]. When potentially high-dose procedures are repeated, (eg, TIPS, or for neuroembolization), previous skin exposure should be considered [59]." The SIR—CIRSE Cardiovascular and Interventional Radiological Society of Europe guidelines for patient radiation dose management recommend that follow-up should be performed if the cumulative air kerma at the reference point exceeds 5 Gy [54,56].

#### VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on Quality Control & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

#### **VIII. QUALITY IMPROVEMENT**

Angiography should always be performed in the setting of an active quality improvement program. These guidelines are intended to assist in appropriate clinical practice, taking into account patient selection, procedural performance, and appropriate patient monitoring both during the procedure and for adverse sequelae of procedures.

No physician strives for less than perfect outcomes with invariable success and no complications; however, in real-world clinical practice this is not possible. QI case review is appropriate after any case involving either a clinical failure or a complication. It is also appropriate to compare rates of complication to established thresholds to ensure that physicians have benchmarks for appropriate clinical practice.

Thresholds for success in parameters such as these only apply to populations of patients and are not useful in assessing individual cases on specific patients. However, they do provide a benchmark level at which institutions should consider comprehensive assessment of technique surrounding angiographic procedures to ensure patients are receiving quality care. Outcomes can also be compared with other institutions when characterized by SIRestablished guidelines (<a href="https://www.jvir.org/article/S1051-0443(07)61221-4/pdf">https://www.jvir.org/article/S1051-0443(07)61221-4/pdf</a> [60]).

These thresholds should not apply to institutions receiving complex or unusual case referrals. In these cases, institutions can adjust the thresholds to apply more specifically to their practice environment. Broadly, however, outcomes that fall outside of these thresholds for success or complications should trigger a department review of whether there are appropriate changes required in clinical care.

Complications are most appropriate to stratify based on clinical outcome that broadly would be considered major if they require significant escalation in clinical care and minor if they do not. More granular details on guidelines are appropriate to classify based on the <a href="Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee">Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee</a> [61].

# A. Measure of Success Successful completion of diagnostic arteriogram should be possible in 95% of typical cases.

#### B. Complication Rates and Thresholds

When performed by appropriately trained radiologists, complications from angiography in adults or children over 10 kg are uncommon. Complications such as arterial spasm, thrombosis, and hematoma are more common in infants and small children due to small vessel size and the size of existing devices. Digital subtracted angiography (DSA) can be used to decrease contrast dose and procedure time with the tradeoff of increased radiation dose [62-65]. This can be important in pediatric patients or in patients with renal insufficiency in which contrast dose is of significant clinical importance.

Major complications from puncture are rare in clinical practice, generally occurring in 1.5% to 2.3% of cases depending on which vessel is accessed [66,67]. The vessel accessed can be of significant importance depending on adjacent structures. Minor complications can be as high as 10%, with hematoma representing the most frequent minor complication [65,67,68].

Vascular closure devices (VCDs) were developed to decrease recovery time and potentially improve hemostasis rates in retrograde femoral access [69]. The literature is mixed as to whether there are increased or decreased complications associated with the use of VCDs. Some studies show higher complications [69,70], whereas others show equivalent or decreased complications [71,72]. VCD can improve patient satisfaction, decrease hospital stay, and allow early mobilization of patients [72,73]. There are currently no approved VCDs for pediatric patients, and they should only be used with caution [46]. Puncture site infection is uncommon. There is, however, an increased risk in patients who are diabetic or immunosuppressed as well as in patients with extended time of sheath placement or multiple temporally close punctures of the same vessel. Prophylactic antibiotics are generally not recommended [74,75] except in specific high-risk clinical situations [76].

Systemic complications are generally minor and occur in less than 5% of procedures [77-80]. The incidence of nephrotoxicity is uncertain because of inconsistent definitions in the literature as well as changes in understanding of nephrotoxicity [81-84]. For pediatric patients, it is important to understand the specific limits for contrast (generally <5 mL/kg) as well as adjunctive techniques such as CO<sub>2</sub> angiography to decrease contrast load to small children. Discussion of management of contrast-related issues are discussed in detail in the <u>ACR—SPR Practice Parameter for the Use of Intravascular Contrast Media</u> [85] and the <u>ACR Manual on Contrast Media</u> [86].

Complications such as dissection and emboli are rare, occurring in less than 0.5% of procedures [65,67,87]. Pediatric angiography presents additional challenges. Vessels are not just smaller and more vasospastic, but patients can also develop unique complications with vascular injury such as limb-length discrepancy.

Advancements in devices and real-time ultrasound-guided arterial punctures have decreased the frequency of these complications, but detailed understanding of complications is important in the care of these patients [46].

Although these thresholds were determined by consensus after pertinent literature review, they remain recommendations only. Individual institutional needs are paramount to determining the degree to which these guidelines are applicable and to what degree they should be incorporated in an institution-specific QI program. It is, however, important that institutional QI should be robust and should be comprehensive of all procedures performed and all physicians involved in patient care.

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<sup>\*</sup>Parameters and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For parameters and standards published before 1999, the effective date was January 1 following the year in which the parameter or standard was amended, revised, or approved by the ACR Council.

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