ACR-SIR PRACTICE PARAMETER FOR THE PERFORMANCE OF DIAGNOSTIC INFUSION VENOGRAPHY

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 practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR).

Diagnostic infusion venography is a radiographic study of venous anatomy using contrast media injection via a peripheral intravenous access. The term does not imply a specific method, type, or rate of contrast media injection. Such a study will often visualize the venous system to the right atrium. The term diagnostic infusion venography does not include central or selective venography through an angiographic or central venous

catheter.

Diagnostic infusion venography is an established, safe, and accurate method when used as indicated and is considered the diagnostic standard for venous imaging by which the accuracy of other venous imaging modalities should be judged [1]. However, alternative methods of studying the venous system such as duplex ultrasound, computed tomography (CT) venography, and magnetic resonance (MR) venography may be preferable or complementary in specific clinical situations [2-5]. Duplex ultrasound has largely replaced diagnostic infusion venography of the upper or lower extremity because the sensitivity and specificity of duplex ultrasound above the elbow or knee are excellent for diagnosing acute deep venous thrombosis (DVT) and venous insufficiency [6-21]. More so, infusion venography is an invasive procedure with small but definite risks including nephrotoxicity, contrast allergy, and/or infection [22-34].

The information obtained by infusion venography, combined with other clinical and noninvasive imaging findings, can be used to diagnose a problem, and/or plan therapy or intervention, and/or evaluate results of treatment.

This practice parameter can be used in institution-wide quality improvement programs to assess the practice of venography. The most important processes of care are 1) patient selection, preparation, and education; 2) performing and interpreting the procedure; and 3) monitoring the patient. The outcome measures for these processes are indications, success rates, and complication rates.

II. INDICATIONS AND CONTRAINDICATIONS

Noninvasive imaging has largely replaced the need for diagnostic infusion venography. In the majority of patients in whom there is suspicion for venous thrombosis, duplex ultrasound is the imaging modality of choice to diagnose thrombosis of both deep and superficial veins of the upper and lower extremities, as well as the jugular veins [8,13]. In these same venous segments, duplex ultrasound is generally sufficient for venous mapping or the detection of venous reflux [6,8,12,15,21,35-37]. In patients in whom ultrasound is limited or inadequate, or where there is persistent high clinical suspicion despite a negative ultrasound, imaging with CT venography, MR venography, or diagnostic infusion venography may be of clinical utility.

CT and MR venography has demonstrated high sensitivity and specificity for the detection of DVT, with these techniques particularly useful for evaluating for thrombosis or encasement of the deep thoracic, abdominal, or pelvic veins [29,38].

Indications for diagnostic infusion venography include, but are not limited to [40]:

- 1. Diagnosis of DVT in patients not a candidate for, or with a limited, CT or MR venogram, when duplex ultrasound is:
 - a. Limited
 - b. Negative, but there is a high clinical suspicion for DVT or calf-vein thrombosis.
 - c. In the setting of symptomatic extremity after joint replacement
- 2. Evaluation of valvular insufficiency before treatment (thermal ablation, stripping, ligation, etc).
- 3. Evaluation of perforator incompetency before sclerotherapy, thermal ablation, or subfascial endoscopic ligation.
- 4. Venous mapping before, during, or following a surgical or interventional procedure such as dialysis access.
- 5. Evaluation of venous stenosis, anatomic entrapment, or venous hypertension.
- 6. Evaluation of venous malformations.
- 7. Preoperative evaluation for tumor involvement or encasement in patients not a candidate for, or with a limited, CT or MR venogram.
- 8. Evaluation for deep pelvic, thoracic, or caval thrombosis in a patient not a candidate for, or with a limited, CT or MR venogram.
- 9. Evaluation for central venous catheter placement in the setting of no suitable access site by ultrasound and failed attempts with the use of anatomic landmarks, when CT or MR venography is infeasible or nondiagnostic.

The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the department should review the process of patient selection [40].

There are no absolute contraindications to diagnostic infusion venography. Relative contraindications include, but are not limited to [40]:

- 1. Cellulitis or local infection for which venous access and imaging needs to be obtained.
- 2. Severe allergy to iodinated or other used contrast media.
- 3. Iodinated and gadolinium contrast administration is relatively contraindicated in patients with renal insufficiency not on dialysis, particularly those with diabetes or congestive heart failure. Carbon dioxide would be an appropriate contrast agent in these patients.

For the pregnant or potentially pregnant patient, see the <u>ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation</u> [41].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

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

Diagnostic infusion venography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

 Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, 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 venography procedures to demonstrate competency as attested by the supervising physician(s).

or

2. Completion of radiology or interventional radiology residency program approved by the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association and has performed (with supervision) a sufficient number of venography procedures to demonstrate competency as attested by the supervising physician(s).

or

3. In the absence of appropriate approved residency training as outlined in section III.A.2 above or postgraduate training that included comparable instruction and experience in diagnostic venography, the physician must have experience and demonstrated competency as the primary operator in diagnostic venography under the supervision of an on-site qualified physician, during which extremity venograms were performed with documented success and complication rates that meet the threshold criteria in section VIII.

and

- 4. Physicians meeting any of the qualifications in 1, 2, and 3 above must also have written substantiation that they are familiar with all of the following:
 - a. Indications and contraindications for the procedure.
 - b. Preprocedural assessment, monitoring, and management of the patient and complications.
 - c. Fluoroscopic and radiographic equipment and other electronic imaging systems.
 - d. Principles of radiation protection, the hazards of radiation, and radiation monitoring requirements.
 - e. Pharmacology of contrast agents and recognition and treatment of adverse reactions to them.
 - f. Technical aspects of performing the procedure, including appropriate injection rates and volumes of contrast media, and imaging sequences.

- g. Anatomy, physiology, and pathophysiology of peripheral venous vasculature.
- h. Interpretation of diagnostic venography.
- i. Postprocedural patient management, especially recognition and initial management of complications.

The written substantiation should come from the chief of interventional radiology, director or chief of body imaging or ultrasound, or the chair of the radiology department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional director or chair to solicit 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 Parameter for Continuing Medical Education (CME)</u> [42].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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 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 (CCPM), 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 (CME)</u> [42].

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

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (e.g., 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 (i.e., 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 but should not perform diagnostic

venography independent of supervision by physicians with training, experience, and privileges to perform the relevant procedures. See the <u>ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology</u> [43].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

D. Radiologic Technologist

- 1. 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 [2] the patient for the venographic procedure. The technologist assists the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.
- 2. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
- 3. The technologist should be certified by the American Registry of Radiologic Technologist or have an unrestricted state license with documented training and experience in diagnostic venography procedures.

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, Resolution 12m)

*For the purposes of this guideline, "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.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

E. Other Ancillary Personnel

Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform specific interventional fluoroscopic or other image-guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal and must comply with local, state, and federal regulations. Individuals should be credentialed for specific fluoroscopic and other image-guided interventional procedures and should have received formal training in radiation management and/or application of other imaging modalities as appropriate. See the <u>ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures</u> [44].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

F. Nursing Services

Nursing services are an integral part of the team for preprocedural, intraprocedural, and postprocedural patient management and education and are recommended in monitoring the patient during the procedure when deemed appropriate by the performing physician.

IV. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements to ensure safe and successful diagnostic infusion venography. These include adequate radiographic/fluoroscopic imaging equipment, institutional facilities, and physiologic monitoring equipment.

IV. SPECIFICATIONS OF THE EXAMINATION

A. Venography Equipment and Facilities

1. The following are considered the minimum equipment requirements for performing diagnostic infusion

venography. A radiography suite that is large enough to allow easy transfer of the patient from the bed to the table and to accommodate the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for circulation of technical staff in the room without interfering with the contrast injection [45].

2. A floating table top may be desirable. The fluoroscopy unit should have a sufficiently large field of view to visualize the extent of the contrast agent. Bolus material or wedge filters may help equalize image brightness. For lower extremity venography, a tilt table fluoroscopy unit is desirable [46].

IV. SPECIFICATIONS OF THE EXAMINATION

B. Resuscitation Equipment

There should be ready access to emergency resuscitation equipment, including an emergency defibrillator, an oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available. In fluoroscopy suites where pediatric patients are treated, appropriate pediatric emergency resuscitation equipment and drugs should be available. Resuscitation equipment should be monitored and checked on a routine basis in compliance with institutional policies.

IV. SPECIFICATIONS OF THE EXAMINATION

C. Patient Care

The appropriate anatomic region/site and side(s) should be indicated on the initial examination request.

- 1. Preprocedural care
 - a. The physician performing the procedure must have knowledge of the following:
 - Clinically significant history, including the indications for the procedure.
 - Clinically significant physical examination findings, including an awareness of clinical or medical conditions that may necessitate specific care.
 - Possible alternative imaging modalities, such as ultrasound, MR, or CT, to obtain the desired diagnostic information.
 - b. Informed consent must comply with all state laws and applicable ACR practice parameters and technical standards. See the <u>ACR-SIR-SPR Practice Parameter on Informed Consent for Image-Guided Procedures</u> [47].
 - c. If peripheral venous access for the procedure is obtained by nursing or other support staff, the desired site of access should be discussed with the performing/interpreting physician before obtaining access.

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 non–operating room settings, including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."
- b. During the use of fluoroscopy, the physician should have knowledge of exposure factors, including kVp, mA, frame rate, magnification factor, and dose rate, and should consider additional parameters such as collimation, field of view, and last image hold to decrease radiation dose. See the <u>ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures</u> [44].
- c. Nursing personnel, technologists, and those directly involved in the care of patients undergoing venography should have protocols for use in standardizing care. These should include, but are not limited to:
 - Equipment needed for the procedure.
 - Patient monitoring.
- d. Protocols should be reviewed and updated periodically.

3. Postprocedural care
Patients should be monitored after diagnostic infusion venography per local practice for the evaluation of potential procedural-related complications, particularly allergic reaction to intravenous contrast or access site infiltration.

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> [48].

Documentation of a complete venogram procedure will vary according to the indication for the examination, as outlined in section II. At a minimum, for any indication, the operator should document and archive a sufficient number of images with complete contrast filling of the veins of the anatomic region being studied to answer the clinical question that prompted the examination.

The physician responsible for the performance and interpretation of the study should have full knowledge of the pathophysiology of venous diseases and should tailor the examination appropriately to provide optimal diagnostic information while attempting to minimize the patient's exposure to iodinated contrast and ionizing radiation.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the <u>ACR—AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment</u> and the <u>ACR—AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment</u> [49,50].

These data should be used in conjunction with the thresholds described in section VIII below to assess procedural efficacy and complication rates and to trigger institutional review when these thresholds are exceeded.

VII. 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). 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 (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). 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).

VIII. 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 ACR Position Statement on Quality Control and 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).

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- *Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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