# COMMISSIONS, COMMITTEES & TASK FORCES:

- **Bylaws Committee**
- **Governance Committee**
- **Commission on Quality & Safety**
- **Commission on Radiation Oncology**
- **Commission on International Relations**
- **Commission on Patient & Family Centered Care**
- **Commission on Nuclear Medicine and Molecular Imaging**
- **Task Force on Brand Promise**

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## ACR STAFF:
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- **Moderator:** Pam Platt
- **Recorder:** David O’Brien
- **Assistant to Society Representatives:** Ashraful Azim
- **Attorney:** Gloria Romanelli, JD
RESOLUTION NO. 36

Ten Year Extension of Policy

WHEREAS, the ACR bylaws state that “All official actions and policies of the Council are effective for only ten years unless extended for an additional ten year period by the Council...,” and

WHEREAS, the various components of the College feel that the following policy should be extended for an additional ten year period; therefore

BE IT RESOLVED, that the following policies of the American College of Radiology be extended for an additional ten year period:

(a) J. TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS

14. RADIOLOGIC TECHNOLOGISTS AND RADIATION THERAPISTS

The Radiologic Technologist, Nuclear Medicine Technologist, Radiologist Assistant and Radiation Therapist are qualified by education and the achievement of technical skills to provide patient care in diagnostic radiological and radiation oncologic modalities under the direction of radiologists and radiation oncologists. In the performance of their duties, the application of proper radiologic techniques and radiation protection measures involves both initiative and independent professional judgment by the radiologic technologists and radiation therapists. In as much as it is both desirable and necessary for all disciplines of radiologic technology to be recognized as professionals by government and other agencies, the ACR supports this position and recognizes the radiologic technologist, Nuclear Medicine Technologist, Radiologist Assistant, and radiation therapist as professional members of the health care team; 1980, 1990, 2000, amended 2010 (Res. 1-e).

(b) L. THIRD PARTY CARRIERS AND COMPENSATION

3. APPLICABLE CPT CODES FOR PATIENT EVALUATION AND CLINICAL MANAGEMENT

The American College of Radiology supports the ability of radiologists to use the appropriate CPT-IV or other system codes for patient evaluation and clinical management. The ACR strongly opposes the restrictions of compensation for clinical care solely because that care is rendered by a radiologist; 1990, amended 2000, 2010 (Res. 39-h).

(c) L. THIRD PARTY CARRIERS AND COMPENSATION

4. BALANCE BILLING
The American College of Radiology opposes in principle any limitation on balance billing and the ACR urges its members to set fees carefully, equitably and appropriately. The American College of Radiology urges its members to continue to show compassion and understanding for financially disadvantaged patients, forgiving all or part of any balance due from such patients, as appropriate to the individual patient’s circumstances; in compliance with applicable laws and regulations; 1990, amended 2000, 2010 (Res. 39-i).

(d) L. THIRD PARTY CARRIERS AND COMPENSATION

16. MAMMOGRAPHY SCREENING: INSURANCE COVERAGE

The ACR urges all insurance carriers to cover screening mammography studies at the time schedule recommended by the ACR/ACS and to reimburse for the procedure at a fair and equitable level; adopted 1990, 2000, 2010 (Res. 39-k).

(e) L. THIRD PARTY CARRIERS AND COMPENSATION

28. REIMBURSEMENT FOR RADIOLOGY AND RADIATION ONCOLOGY SERVICES

Reimbursement for radiology and radiation oncology services should appropriately reflect the expertise, time and expenses required for the provision of those services.

Any payor fee schedule for those services should be determined and re-evaluated with input by representatives of those physicians who will perform services for the patients contracting with that payor.

The ACR endorses contractual and legislative provisions that ensure prompt and equitable payment for provision of radiology and radiation oncology services, as well as appropriate appeals processes for claims disputes; adopted 2000, 2010 (Res. 39-m).

Sponsored by: ACR Council Steering Committee
Fiscal Note

Ten Year Extension of Policy

To support the resolution for **Ten Year Extension of Policy**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 37

BE IT RESOLVED,

that the American College of Radiology adopt the ACR Practice Parameter for Communication of Diagnostic Imaging Findings

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2014 (Resolution 11)*

ACR PRACTICE PARAMETER FOR COMMUNICATION OF DIAGNOSTIC IMAGING FINDINGS

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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken. The practice of medicine involves not only the science, but also 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

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1 Iowa 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.
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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

Effective communication is a critical component of diagnostic imaging. Quality patient care can only be achieved when study results are conveyed in a timely fashion to those responsible for treatment decisions. An effective method of communication should 1) promote optimal patient care and support the referring ordering physician/health care provider in this endeavor, 2) be tailored to satisfy the need for timeliness, and 3) minimize the risk of communication errors.

Various factors and circumstances unique to a clinical scenario may influence the methods of communication between interpreting physicians and referring ordering physicians/health care providers. Timely receipt of the report is more important than the method of delivery.

Communication of information is only as effective as the system that conveys the information. There is a reciprocal duty of information exchange. The referring ordering physician or other relevant health care provider also shares in the responsibility for obtaining results of imaging studies he or she has ordered and acting on them in an appropriate manner. Formulating an imaging interpretation requires the commitment and cooperation of administrators, clinicians, and referring physicians, interpreting physicians, and other health care providers. Whenever possible, previous reports and images, should be available for review and comparison with the current study. A request for imaging should include relevant clinical information, and including for pertinent clinical signs and symptoms. In addition, including a specific question to be answered can be helpful. Such information helps tailor the most appropriate imaging study to the clinical scenario and enhances the clinical relevance of the report, thus promoting optimal patient care.

II. DIAGNOSTIC IMAGING REPORTS

An official interpretation (final report) by the interpreting physician must be generated and archived following any examination, procedure, or officially requested consultation regardless of the site of performance (hospital, imaging center, physician office, mobile unit, etc). It is not appropriate for nonphysicians to provide interpretations or generate diagnostic reports (final or preliminary).

A. Components of the Report

The following is a suggested format for reporting:

1. Demographics
   a. The facility or location where the study was performed
   b. Name of patient, age or date of birth, and gender another identifier
   c. Name(s) of referring ordering physician(s) or other health care provider(s). If the patient is self-referred (a patient who seeks medical care without referral from a physician/health care provider), that should be stated.
   d. Name or type of examination
   e. Date of the examination
   f. Time of the examination, if relevant (eg, for patients who are likely to have more than one of a given examination per day)
   g. Inclusion of the following additional items is encouraged:
2. Relevant clinical information

3. Body of the report

a. Procedures and materials
   The report should include a description of the studies and/or procedures performed and any contrast media and/or radiopharmaceuticals (including specific administered activities, concentration, volume, and route of administration when applicable), medications, and catheters or devices used beyond those utilized for routine administration of contrast agents used, if not recorded elsewhere. Any known significant patient reaction or complication should be recorded along with a description of any therapeutic interventions. If related instructions are given to the patient (and/or accompanying responsible parties) these should be documented.

b. Findings
   The report should use appropriate anatomic, pathologic, and radiologic terminology to describe the findings.

c. Potential limitations
   The report should, when appropriate, identify factors that may compromise the sensitivity and specificity of the examination.

d. Clinical issues
   The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical question, these should be stated explicitly.

e. Comparison studies and reports
   Comparison with relevant examinations and reports should be part of the radiologic consultation and report when appropriate and available.

4. Impression (conclusion or diagnosis)

a. Unless the report is brief, each report should contain an “impression” or “conclusion.”

b. A specific diagnosis should be given when possible.

c. A differential diagnosis should be rendered when appropriate.

d. Follow-up or additional diagnostic studies to clarify or confirm the impression should be suggested when appropriate.

   Any significant patient reaction should be reported.

e. Any significant adverse event involving the patient that occurred in relation to performance of the study should be described in the body of the report and/or in the institutional electronic medical record, and briefly noted in the impression.

5. Standardized computer-generated template reports

   a. Standardized computer-generated template reports should may be utilized to fulfill or designed to satisfy the above criteria.
3. The final report should be completed in accordance with appropriate state and federal requirements. Electronic or rubber-stamp signature devices, instead of a written signature, are acceptable unless contrary to state law, if access to such devices is secure.

4. The final report should be transmitted to the referring ordering physician or health care provider in accordance with the appropriate state and federal requirements. The referring ordering physician or other relevant health care provider also shares in the responsibility to obtain results of imaging studies he or she has ordered.

5. When feasible, a copy of the final report should accompany the transmittal of relevant images to other health care professionals when such images are requested.

6. A copy of the final report should be archived by the imaging facility as part of the patient’s medical record and be retrievable for future reference. Retention and distribution of these records must be in accordance with state and federal regulations and facility policies. The final report and images should be available to the patient upon request after obtaining appropriate consent by the patient or other legally authorized person acting on their behalf.

C. Communications Other Than the Final Report

1. Preliminary report

When needed, a preliminary report precedes the final report. It may be rendered for the purpose of directing immediate patient management or to meet the needs of a particular practice environment. It very likely will contain limited or incomplete information. It should not be expected to contain all the information subsequently found in the final report.

Preliminary reports may be communicated in writing, electronically, or verbally, and the method of communication should be documented. These preliminary communications should be reproduced into a permanent format as soon as practical and appropriately labeled as a preliminary report, distinct from the final report, and archived because clinical decisions may have been based on the preliminary report. The archived preliminary report should contain the name of the person or office that received the report, if applicable.

As soon as possible, a significant variation in findings and/or conclusions between the preliminary and final interpretations should be reported in a manner that reasonably reliably ensures receipt by the referring ordering or treating physician/health care provider, particularly when such changes may impact patient care. Documentation of communication of any discrepancy should be incorporated into the final report.

2. Nonroutine communications

Routine reporting of imaging findings is communicated through the usual channels established by the hospital or diagnostic imaging facility. However, in emergent or other nonroutine clinical situations, the interpreting physician should expedite the delivery of a diagnostic imaging report (preliminary or final) in a manner that reasonably ensures timely receipt of the findings. This communication will usually be to the referring ordering physician/health care provider or their his/her designee. When the referring ordering physician/health care provider cannot be contacted expeditiously, it may be appropriate to convey results directly to the patient, depending upon the nature of the imaging findings.

a. Situations that may warrant nonroutine communication include the following:

i. Findings that suggest a need for immediate or urgent intervention:
Generally, these cases may occur in the emergency and surgical departments or critical care units and may include such findings as of pneumothorax, pneumoperitoneum, or a significantly misplaced line or tube and other urgent conditions that may be considered critical to patient care. Other urgent conditions typically included in “critical values” categories in most health care institutions would also be included in this group.

ii. Findings that are discrepant with a preceding interpretation of the same examination and where failure to act may adversely affect patient health:

These cases may occur when the final interpretation is discrepant with a preliminary report or when significant discrepancies are encountered upon subsequent review of a study after a final report has been submitted.

iii. Findings that the interpreting physician reasonably believes are significant and unexpected, may have a reasonable probability of impacting the patient’s health, and may not require immediate attention but, if not acted on, may worsen over time and likely possibly result in an adverse patient outcome.

For example, acute infectious processes, possible malignant lesions, or other unexpected findings that may impact patient care if not treated in a timely fashion would fall into this category. This may be particularly applicable when there is a potential break in the continuity of care (such as can occur in emergency department encounters or the outpatient setting) that is unexpected by the treating or referring physician.

b. Documentation of nonroutine communications

Interpreting physicians should document all nonroutine communications. Documentation is best placed in the radiology report or the patient’s medical record but may be entered in a department log and/or personal journal. Documentation preserves a history for the purpose of substantiating the transmission of certain findings or events. Inclusion of the time, method of communication, and the name of the person to whom the communication was delivered is an example of such documentation.

c. Methods of nonroutine communication

Communication methods are dynamic and varied. It is important however, that nonroutine communications be handled in a manner most likely to reach the attention of the treating or referring ordering physician/health care provider in time to provide the most benefit to the patient. Communication by telephone or in person to the treating or referring ordering physician or a responsible health care provider his/her representative is appropriate and reasonably ensures receipt of the findings. This may be accomplished directly by the interpreting physician or, when judged appropriate, by the interpreting physician’s designee. There are other forms of communication that provide documentation of receipt that may also suffice to demonstrate that the communication has been delivered and acknowledged.

Although other methods of communication may be considered, including texting, facsimile, voice messaging, instant messaging, e-mail, and other nontraditional approaches, these methods may not guarantee receipt of the communication. Such communications must be in compliance with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA) or state laws if more restrictive. Therefore, in these instances, the interpreting physician may consider initiating a system that explicitly requests confirmation of receipt of the report by the clinician. If confirmation or other response is not received within a time appropriate to the diagnosis after the initial communication, a
staff person should notify the clinician to document follow-up. Regardless of the method selected, it must be in compliance with state and federal law.

3. Informal communications

Occasionally, an interpreting physician may be asked to provide an interpretation that does not result in a “formal” report but is used to make treatment decisions. Such communications may take the form of a “curbside consult,” a “wet reading,” or an “informal opinion” that may occur during clinical conferences, interpretations while involved in other activities, or review of an outside the study with the patient or patient’s family. These circumstances may preclude immediate documentation and may occur in suboptimal viewing conditions without comparison studies and their accompanying reports or adequate patient history.

Informal communications carry inherent risk, and frequently the referring ordering physician’s/health care provider’s documentation of the informal consultation may be the only written record of the communication. Interpreting physicians who provide consultations of this nature in the spirit of improving patient care are encouraged to document those interpretations. A system for reporting outside studies is encouraged.

III. SELF-REFERRED AND THIRD-PARTY–REFERRED PATIENTS

Most patients who have imaging procedures are referred by physicians or other health care professionals. Some patients, however, are self-referred, such as for mammography, or are referred by a third party, such as an insurer or employer.

A. Self-Referred Patients

Interpreting physicians should recognize that performing imaging studies on self-referred patients may establishes a doctor-patient relationship that includes responsibility for communicating the results of imaging studies directly to the patient and arranging for appropriate follow-up. It is recommended that radiologists providing imaging services for self-referred patients request such patients to identify a licensed provider to receive their imaging results and oversee any necessary follow-up care. Adopting and implementing protocols for referring patients with suspicious findings who have not identified a provider to receive imaging results may help facilitate appropriate follow-up.

B. Third-Party–Referred Patients

It is not unusual for patients to be referred for imaging studies by insurance companies, employers, federal benefits programs, and, in some instances, lawyers. In such cases, the reports of the studies are frequently communicated through the requesting entity to a clinician licensed provider or directly to the third-party–designated licensed provider clinician. The results of the examinations are then communicated to the patient either directly by the third party or by its designated licensed provider clinician. Regardless of the source of the referral, the interpreting physician should make every possible effort has a ethical responsibility to ensure communication of unexpected or serious findings to the patient. Therefore, in certain situations, the interpreting physician may feel it is appropriate to communicate the findings directly to the patient.

IV. COMMUNICATION POLICIES

If an imaging department has written a policy on communication, it can be an effective tool to promote patient care. The policy can provide guidance on the types of communications that are most critical, the individuals responsible for delivering and receiving communications, and the methods of communication that are most appropriate. To be effective, however, any written policy must be followed and shared with others within the institution in which the interpreting physicians provide their services.
As technology changes and new methods of communication evolve, interpreting physicians may wish to modify their actions to accommodate these changes, but they must also remain in compliance with federal, state, and local statutes and developing legal requirements. HIPAA states that patients have a right to access their personal health information (https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/eaccess.pdf).

In recognition of this legal obligation and in the interest of added value and personalized medicine, the ACR recommends that all imaging reports be made readily available to the patient. This may be achieved in numerous ways. One such technique is the posting of patient imaging reports through the use of a Web-based portal. Any method used should consider the best interests of the patient and the professional relationship between the patient and the referring ordering physician/health care provider. Any Web-based portal must comply with federal, state, and as appropriate, with hospital directives ensuring patient information integrity and security. Any known or suspected breach in the portal should be immediately reported to the appropriate agencies and patients involved.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters of the ACR Commission on General, Small, Emergency, and/or Rural Practice and was based on the Report of The Task Force on Diagnostic Reporting.

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PRACTICE PARAMETER 7 Communication Diagnostic Imaging 2020 Resolution No. 37
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Additional Resources

1. Berlin L. Mock trial at 2009 RSNA annual meeting: jury exonerates radiologist for failure to communicate abnormal finding- but...Radiology 2010;257:836-845.
2. Berlin L. Communicating results of all radiologic examinations directly to patients: has the time come? AJR 2007;189:1275-1282.
3. Berlin L. Communicating results of all outpatient radiologic examinations directly to patients: the time has come. AJR 2009;192:571-573.
12. Lucey LL, Kushner DC. The ACR practice parameter on communication: to be or not to be, that is the question. JACR 2010;7:109-114.

Pertinent Legal Cases Involving Communication:

Williams v Le, 662 S.E. 2d 73 (Va 2008)
Diaz v. New York Downtown Hospital, 784 N.E.2d 68 (N.Y. 2002)
Duckworth v. Lutheran Medical Center, 1995 WL 33070 (Ohio App. 1995)
Daly v. United States, 946 F.2d 1467 (9th Cir. 1991)
Courteau v. Dodd, 773 S.W.2d 436 (Ark. 1989)
Phillips v. Good Samaritan Hospital, 416 N.E.2d 646 (Ohio App. 1979)

*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.

Development Chronology for this Practice parameter
1991 (Resolution 5)
Revised 1995 (Resolution 10)
Revised 1999 (Resolution 27)
Revised 2001 (Resolution 50)
Revised 2005 (Resolution 11)
Revised 2010 (Resolution 11)
Revised 2014 (Resolution 11)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 38

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR Practice Parameter for the Performance of Adult Cystography and Urethrography

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

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Revised 2015 (Resolution 31)

ACR–SAR PRACTICE PARAMETER FOR THE PERFORMANCE OF ADULT CYSTOGRAPHY AND URETHROGRAPHY

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

1 Iowa 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter is intended to assist radiologists performing cystography and urethrography in adult patients. Properly performed urethrography and cystography (either conventional or CT) are diagnostic radiological imaging tests that can provide information about the urethra and bladder, and occasionally the ureters. Application of the following practice parameter will maximize the diagnostic yield of these studies. Magnetic resonance imaging (MRI) or ultrasound may occasionally provide additional diagnostic information when clinically indicated.

The goal of cystography and/or urethrography is to evaluate the anatomy, function, and pathology of the lower urinary tract.

II. INDICATIONS AND CONTRAINDICATIONS, AND CAUTIONS

A. Indications

1. Indications for cystography include, but are not limited to, evaluation of the following:
   a. Recurrent urinary tract infections
   b. Vesicoureteral reflux [1]
   c. Bladder morphology and capacity
   d. Bladder diverticula [2]
   e. Leak from or tear of urinary bladder [3]
   f. Enterovesical, vesicouterine, vesicovaginal, and vesicocutaneous fistulae [4]
   g. Integrity of postoperative anastomoses or suture lines [5,6]
   h. Bladder outlet obstruction [7]
   i. Incontinence [7]
   j. Hematuria
   k. Neoplasia
   l. Evaluation for bladder leak after pelvic surgery
   m. Unexplained free intraperitoneal fluid following surgery or trauma

2. Indications for urethrography include, but are not limited to, evaluation of the following:
   a. Urethral diverticula [8]
   b. Urethral strictures [9]
   c. Bladder outlet or urethral obstruction
   d. Hematuria
   e. Suspected urethral injury following trauma [10]
   f. Recurrent urinary tract infections
   g. Diminished urinary stream
   h. Incomplete voiding
   i. Urethral foreign bodies
   k. Urethral fistula
   l. Postoperative urethral evaluation injury
B. Absolute contraindications: None

C. Relative contraindications

1. Pregnancy is a relative contraindication to cystography/urethrography because of radiation concerns for the fetus.
2. Urinary tract infection. Antibiotic prophylaxis should be considered in patients with a history of urinary tract infection. In patients with active urinary tract infection, consideration may be given to delaying cystography/urethrography until the infection has cleared.
3. Iodinated contrast allergy. The possibility exists for contrast media to be systemically absorbed during cystography or urethrography. This commonly occurs if there is extravasation of contrast media from the urethral or bladder lumen, and it may occur, though uncommonly, in the absence of frank extravasation.

See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [12] and the ACR Manual on Contrast Media [13].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Practice Parameter for General Radiography [14].

IV. SPECIFICATION OF THE EXAMINATION

The written or electronic request for cystography and urethrography should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

Cystography and urethrography consist of imaging the bladder and/or urethra following administration of contrast media. The studies may be combined. These studies include cystography, cystourethrography, voiding cystourethrography, and urethrography (antegrade and retrograde). One or more scout images may be obtained before the infusion or injection of contrast for any of these studies.

Following contrast administration of 300 mL of contrast or to the limit of the patient’s tolerance, images are obtained in various projections appropriate to the indication for the study (eg, oblique, lateral, during rest and strain, and/or during voiding) accompanied by postvoid imaging of the bladder. Abnormalities of the bladder or urethra may be detected, as well as extrinsic effects on them by adjacent abnormalities.
Fluoroscopy during the procedure may enhance diagnostic accuracy and is especially valuable in assessing the urethra, detecting contrast media extravasation from the bladder or urethra, and documenting the presence of vesicoureteral reflux.

CT cystography:
CT cystography consists of imaging the bladder following retrograde filling of the bladder to patient tolerance or a predetermined institutionally approved volume in the setting of trauma or recent surgery (usually 200–300 mL), whichever is achieved first \[12,13\]. Contiguous axial scans through the pelvis are obtained \[15,16\]. Multiplanar reformations may be helpful in identifying leak from or tear of urinary bladder \[5,17\].

A. Appropriate history and preprocedure screening should be performed by personnel familiar with the various risk factors, preparations, and premedication strategies. Either ionic or nonionic contrast media for injection may be used for cystography and urethrography.

B. If a urinary catheter is not in place, the urethra or bladder should be catheterized using aseptic technique. An appropriate volume of contrast should be administered to demonstrate the anatomic structures of interest. The examination should be tailored to the needs of the individual patient. Fluoroscopy can optimize diagnostic yield, especially during voiding studies. If a catheter has already been placed, another smaller catheter can be passed beside it to perform pericatheter urethrography to assess urethral integrity. Combined (simultaneous) voiding cystourethrography and retrograde urethrography can provide valuable treatment planning information in male urethral stricture disease. Clinical judgment should guide decisions about contrast quantity and use of infusion or injection technique.

C. Appropriate images should be produced to demonstrate normal and abnormal findings with the minimum radiation dose necessary to achieve an optimal study. Radiologists and technologists should be trained in the correct positioning of the patient to obtain optimal images. In addition to the anteroposterior projection, bladder imaging is often enhanced by oblique and lateral views. Postvoid imaging of the bladder is helpful in assessing postvoid residual volume and can help in detecting small bladder leaks. If the examination is being performed to evaluate suspected bladder leak, particularly in a patient with pelvic trauma, it is essential to actively distend the bladder until a detrusor contraction occurs. Visualization of the male urethra is often best in a posterior oblique projection with extension of the penis to straighten the natural curve at the penoscrotal junction. Anteroposterior (AP) and lateral views of the anterior urethra may offer better characterization of the extent of an abnormality. Attempt should be made to reflux contrast past the external urinary sphincter to opacify the posterior urethra to the bladder for a complete examination. Imaging over the kidneys facilitates visualization and documentation of vesicoureteral reflux. Fluoroscopic spot films are useful in documenting reflux and of urethral anatomy.

CT cystography:
CT cystography consists of imaging the bladder following drainage of residual urine and retrograde filling of the bladder with at least 250 mL or to the limit of the patient’s tolerance of 5% iodinated contrast material to patient tolerance or a predetermined institutionally approved volume in the setting of trauma or recent surgery (usually 200–300 mL), whichever is achieved first \[12,13\]. Contiguous axial scans through the pelvis from the iliac crests to the lesser trochanter are obtained \[15,16\]. Multiplanar reformations or postdrainage images may be helpful in identifying bladder rupture, fistulae, and small bladder tumors leak from or tear of urinary bladder \[5,17\]. Adjusting the window width and level settings may also be helpful in characterizing bladder injuries and intraluminal filling defects.

See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media \[12\] and the ACR Manual on Contrast Media \[13\].
V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [18].


VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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, and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization, and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

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 ACR Position Statement on Quality Control and Improvement,
ACKNOWLEDGEMENTS

This parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – General, Small and Rural Practice of the Commission on General, Small, and Rural Practice, in collaboration with the SAR.

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REFERENCES


*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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RESOLUTION NO. 39

BE IT RESOLVED, that the American College of Radiology adopt the ACR–SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2015 (Resolution 23) *

ACR–SIR PRACTICE PARAMETER FOR MINIMAL AND/OR MODERATE SEDATION/ANALGESIA

PREAMBLE

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I. INTRODUCTION

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

The goal of this practice parameter is to assist physicians in the safe administration of sedation/analgesia and monitoring of patients receiving sedation/analgesia without the participation of an anesthesiologist or a certified registered nurse anesthetist, outside the operating room. Sedation/analgesia allows patients to better tolerate diagnostic imaging and image-guided procedures by relieving anxiety, discomfort, or pain. It facilitates and may optimize diagnostic imaging, image-guided interventions, and radiation oncology procedures that require patient cooperation.

This document replaces the “ACR–SIR Practice Parameter for Sedation and Analgesia,” approved in 2015. In addition, this document refers to the guidelines published in 2018, “Practice Guidelines for Moderate Procedural Sedation and Analgesia” [1], a document endorsed by the ACR and SIR as well as other nonanesthesiology specialty societies whose members utilize moderate sedation and analgesia.

The monitoring practice parameters in this guidance document apply to patients who receive minimal sedation beyond anxiolysis or moderate sedation. Patients receiving a single, low-dose anxiolytic agent in appropriate doses under usual circumstances do not necessarily require monitoring [1].

The administration of deep sedation/analgesia requires a greater level of skill and experience and more intensive monitoring than is described herein. Deep sedation is within the scope of practice of qualified interventional radiologists but is outside the scope of this document.

Special consideration should be given to patients undergoing sedation in a magnetic resonance imaging (MRI) environment. Relevant issues are addressed by the American Society of Anesthesiologists (ASA) Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [2].

Sedation is a dynamic continuum ranging from minimal sedation/anxiolysis to general anesthesia. Minimal sedation or anxiolysis is defined by the Joint Commission and the ASA as “a drug-induced state during which the patient responds normally to verbal commands.” The ASA further states that “although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected” [1].

Moderate sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains a continuous and independent ability to maintain protective reflexes and a patient airway, and to can be aroused by physical or verbal stimulation. Planned levels of sedation/analgesia beyond moderate sedation are outside the scope of this document.
II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia may be administered by a physician, or by a nurse, or licensed independent practitioner under the supervision of a physician. Appropriately trained medical personnel should be immediately available to treat any sedation-related adverse event, including at least one individual in the procedure room with the knowledge and skills to recognize and treat airway complications.

A. Supervising Physician

The supervising physician should maintain the following:

1. Sufficient knowledge of preprocedural workup, patient monitoring equipment, airway management, sedation medications and their reversal agents, and postsedation management
2. Appropriate continuing education in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [3]
3. Current Basic Life Support (BLS) certification. For pediatric sedation, have personnel certified in Pediatric Advanced Life Support (PALS) certification should be present [4]. For adult sedation, have personnel certified in Advanced Cardiac Life Support (ACLS) certification or an institutionally approved alternative (eg, Advanced Radiology Life Support) must be in the room or immediately available have an individual with ACLS certification or institutionally approved alternative (eg., Advanced Radiology Life Support) available with a response time of less than 5 minutes [1]. [5]
4. Privileges to perform sedation at their health care institution

B. Health Professional Responsible for Monitoring the Patient

There must be a physician, licensed independent practitioner, or nurse other than the practitioner performing the procedure present to monitor the patient during throughout the period of sedation/analgesia. This individual must not be a member of the procedure team [1]. This individual may administer the medications used for sedation/analgesia and may assist with minor, interruptible tasks during the procedure if the patient’s level of sedation analgesia and vital signs are stable [1].

This professional should:

1. Be a physician, licensed independent practitioner, or nurse authorized by the facility, whose primary job is to monitor the patient
2. Be appropriately privileged by the institution
3. Have current certification in ACLS or an institutionally approved alternative (eg, Advanced Radiology Life Support). If children are being sedated, certification in PALS is needed as well
4. Be knowledgeable in the use, side effects, and complications of the sedative agent(s) and reversal agents to be administered
5. Be knowledgeable and experienced in monitoring vital signs, using pulse oximetry, capnography when appropriate, and cardiac monitoring, including the recognition of apnea and airway obstruction, cardiac dysrhythmias, and treating associated complications
6. Meet the credentialing requirements of the facility

III. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation/analgesia outside the operating room; ie, by personnel other than anesthesiologists (see Appendix A). Patients who are ASA class III or IV may require additional consideration. When the patient’s history and comorbidities, current condition, and expected goals and objectives of sedation, either before or during the procedure, exceed the experience or resources of nonanesthesiology sedation personnel, there should be a low threshold for consultation with an experienced anesthesiologist.
These practice parameters specifically exclude the following:

1. Patients whose sedation is managed by the anesthesiology or critical care service
2. Patients on mechanical ventilation
3. Patients who are ASA class V; such patients should be sedated by anesthesiologists

IV. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, physician’s assistant, or other appropriately trained individual for the presence of risk factors that may increase the likelihood of an adverse effect. If risk factors are present, consultation with an anesthesiologist may be considered.

Positive-pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with an airway abnormality. Some airway abnormalities which may increase the likelihood of airway obstruction during spontaneous ventilation (see Appendix B).

Additional risk factors include, but are not limited to, the following:

- **Adverse experience with sedation/analgesia as well as regional or general anesthesia**
- Recent catastrophic event, intensive care unit (ICU) admission, surgery, or interventions
- Sedation or anesthesia within 24 to 48 hours of the planned sedation
- Septicemia
- Polypharmacy and polyintravenous therapy
- Lung disease
- Respiratory impairment
- Cardiovascular disease
- Critical aortic stenosis
- Congestive heart failure
- Congenital heart disease
- Hemodynamic instability
- Neuromuscular and metabolic diseases
- Symptomatic brain stem dysfunction
- Apnea or hypotonia
- **Sleep apnea or snoring**
- **Facial deformity or airway defect (birth defect or from trauma), which would be difficult for bag valve mask (BVM) resuscitation or intubation**
- Liver failure
- Restricted hepatic and renal clearance
- Symptomatic gastroesophageal reflux or poor gastric emptying

V. PATIENT EVALUATION AND MANAGEMENT

Sedation as described in this practice parameter should be performed in accordance with ASA guidelines, as described below [1]; [5]

Adult patients and legal guardians providing consent should be informed of and agree to the administration of sedation/analgesia before the procedure begins. Minor patients should be informed of the procedure and provide their assent as appropriate. The requirement for written informed consent should follow facility policies and procedures and state and local laws and regulations.
A. Patient Preparation Before Sedation

Hospital guidelines for preprocedure fasting should be followed. A suggested pediatric fasting protocol is given in Appendix C.

B. Evaluation Before Sedation

1. Electrocardiogram tracings and relevant laboratory values, when appropriate, should be available for review.

2. A focused history and physical examination should be performed and recorded. It should include the patient’s previous experience with sedation/analgesia, current medical problems, current medications, drug allergies, and history of a difficult airway, frequent or repeated exposure to sedation/analgesic agents, any significant comorbidities, and pregnancy, as appropriate. A physician, nurse practitioner, or physician assistant or advanced practice provider should perform the presedation evaluation.

3. Prior to initiating sedation, an assessment of recent oral intake (see Appendix C), recent illness, pulmonary status (including upper airway), cardiac status, baseline vital signs, level of consciousness, pulse oximetry, capnography (if available), and electrocardiogram (when applicable) should be performed and recorded.

4. A responsible adult must accompany outpatients after discharge. This adult will provide contact information and receive clear postprocedure instructions including methods by which to contact medical personnel if needed. For all outpatient procedures, the person responsible for accompanying the patient after discharge and who will be receiving postprocedure instructions must be clearly identified and contact information obtained.

C. Management during Sedation

1. Qualitative clinical signs, such as chest excursion, and auscultation of breath sounds are may be useful.

2. During moderate or deep sedation, the adequacy of ventilation should be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment [2]. [5]

3. Intravenous access must be maintained.

4. Homeothermia Normothermia should be preserved.

5. Patients should be protected from pressure-related and position-related injuries.

6. All patients should be continuously monitored throughout the procedure by physiologic measurements that should be recorded (at least every 5 minutes). These measurements include, but are not limited to, level of consciousness, respiratory rate, pulse oximetry, capnography (if possible), blood pressure (as indicated), heart rate, and cardiac rhythm. The types of measurements taken should comply with facility policies.

7. Supplemental oxygen with size-appropriate equipment should be immediately available and administered as needed.

8. Suction equipment should be immediately available.

9. A Defibrillator with backup emergency power and an emergency cart, including equipment for intubation and ventilation, should be immediately available.

10. The route, dosage, and time of all sedation and reversal agents should be documented on the sedation record by the health professional responsible for monitoring the patient.

11. Drug antagonists and intravenous fluids should be available; their use should be based on the clinical circumstances.

12. For pediatric patients, intravenous sedative/analgesic drugs should be given based on the patient’s weight in incremental doses that are titrated to the desired endpoints of sedation and analgesia. Weight-based dosing should operate within the maximum dose limit guidelines for each medication. For all patients, sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (eg, oral, rectal, intramuscular,
inhaled), allowance should be made for the time required for drug absorption before supplementation is considered.

13. In adult patients, intravenous sedative/analgesic drugs are given in incremental doses that are titrated to the desired endpoints of sedation and analgesia. In smaller adults, weight-based dosing may be considered.

14. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the medical condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (eg, additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The combinations of sedative and analgesic agents may potentiate respiratory depression. This underscores the need to dose each agent appropriately as well as the need to monitor respiratory function.

D. Recovery Following Sedation

1. The patient must recover in an area where continuous monitoring and resuscitative equipment (eg, suction, oxygen) are immediately available. A code cart must be immediately available. Monitoring should include, but is not limited to, the level of consciousness, respiratory rate, pulse oximetry, blood pressure, and heart rate and rhythm and should comply with facility requirements.

2. Levels of consciousness and vital signs must be monitored at intervals consistent with recovery status until all return to presedation levels and/or the patient meets established discharge criteria. A patient may not leave the recovery area without accompanying monitoring personnel until vital signs and level of consciousness are at acceptable levels as determined by facility policy.

3. If intravenous access is used during the procedure, it should be maintained until the patient is ready for discharge.

4. If use of reversal agents was required, the level of consciousness and vital signs should return to acceptable levels for a period of 2 hours from the time of administration of the reversal agent before monitoring ends. (Use of reversal agents may be associated with relapse into a deeper level of sedation than intended after successful rescue, and repeated doses may be required.)

5. The monitoring personnel will notify a supervising physician (who should remain available until recovery is complete) of any significant change in the patient’s clinical status.

6. Qualified monitoring personnel (as described in Section IV) must be immediately available to the patient from the initiation of sedation until the patient has adequately recovered or has been turned over to the appropriate personnel delivering recovery care.

VI. SEDATION-RELATED DOCUMENTATION

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [5].

Adequate documentation of all aspects of patient evaluation and monitoring is essential for high-quality patient care. This documentation should include, but is not limited to, the following:

1. Presedation assessment, including ASA criteria and airway assessment (such as Mallampati score) and pregnancy

2. Preprocedure timeout documentation

3. Dose, route, site, and time of administered drugs must be part of the permanent medical record.

4. Patient’s response to medication and the procedure

5. Inspired concentrations of medical gases, such as oxygen and nitrous oxide, their rate and duration, and method of administration

6. Physiological data from monitoring

7. Any rescue interventions, including ventilatory support, or use of reversal agents as well as the patient’s response
8. Any significant adverse reactions and their management

A record should be kept for all patients receiving sedation, indicating sedation failure and adverse effects (eg, vomiting, hypoxic events, resuscitation, and 24-hour follow-up when possible) and possible explanations for adverse outcomes. Patient care areas using sedation and analgesia should have policies and procedures for reporting complications encountered during sedation and analgesia to the quality assurance committee.

VII. DISCHARGE CRITERIA

A. The patient should not be discharged until vital signs, level of consciousness, and motor function have returned to the patient’s preprocedure baseline, as determined by the health care professional responsible for monitoring the patient and dependent on the patient’s destination. Recovery according a standardized scoring system (such as the Aldrete score) should be documented [6,7].

B. When discharge is to home For outpatients, discharge instructions must be given to the patient or accompanying responsible adult. The discharge instructions should include, but not necessarily be limited to, the following:

1. Physician contact information, including after-hours contact information, in the event of postprocedure problems
2. Advice against driving or operating machinery for a minimum of 12 hours
3. Advice against alcohol intake for 24 hours
4. Advice regarding diet and activity
5. Advice regarding follow-up instructions
6. The patient should be advised of possible Advice regarding sedation-related adverse effects and when to seek medical attention
7. Instructions regarding preexisting and/or new medications

VIII. EQUIPMENT

Facility policies for monitoring and evaluating the function of all equipment should be followed. Any location where sedation is administered and recovery from sedation is provided must have equipment and drugs for emergency resuscitation readily available [2] [8]. It is critical that a complete range of sizes of emergency and monitoring equipment be available in the immediate area for all ages and sizes of patients treated at the facility. The equipment should include the following:

1. Oxygen supply from a portable or fixed source, with a backup oxygen supply.
2. Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannulae, face masks, and oral airways and resuscitation equipment (eg, an Ambu bag manual resuscitator, laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (eg, a nonrebreather mask).
3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mmHg that is regularly checked for adequacy according to facility policies. Suction catheters appropriate for patients’ airways must be available.
4. Appropriate emergency medications and equipment, including a defibrillator, must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored according to facility policies. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Equipment function should be checked on a regular basis according to facility policies. Equipment checks should be documented in accordance with facility policies.
5. Monitors
a. Pulse oximeter with probes appropriate for the patient’s size. Pulse oximeter should have both visual and audible outputs
b. Blood pressure measuring device with cuffs appropriate for the patient’s size
c. Multilead electrocardiographic monitors as appropriate for the patient’s medical history
d. A means of monitoring ventilation, either visually or through a device
e. Capnography (if available)

6. A stethoscope
7. A telephone
8. An emergency light source, such as a flashlight
9. Emergency electrical power (or battery backup) for all electrical equipment listed above

For sedation performed in the MR suite, special equipment requirements apply, as indicated in the Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging: An Updated Report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging.

IX. 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).

ACKNOWLEDGEMENTS

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REFERENCES


2. Practice advisory on anesthetic care for magnetic resonance imaging: an updated report by the American society of anesthesiologists task force on anesthetic care for magnetic resonance imaging. Anesthesiology 2015;122:495-520.


OLD REFERENCES


American Society of Anesthesiologists (ASA) Physical Status Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A normal healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
</tr>
<tr>
<td>VI</td>
<td>A declared brain-dead patient whose organs are being removed for donor purposes</td>
</tr>
</tbody>
</table>

Factors that may be associated with difficulty in airway management include, but are not limited to, the following:

- Previous problems with anesthesia or sedation
- Stridor
- Snoring or apnea
- Dysmorphic facial features (eg, Pierre Robin syndrome, trisomy 21)
- Craniocervical abnormalities
- Significant obesity (especially involving the neck and facial structures)
- Short neck, limited neck extension, neck mass
- Tracheal deviation
- Small mouth, protruding incisors, loose or capped teeth, high-arched palate
- Macroglossia
- Tonsillar hypertrophy
- Nonvisible uvula
- Micrognathia
- Retrognathia
- Trismus

Suggested Fasting Protocol

Summary of ASA Recommendations for Preoperative Fasting and Use of Pharmacologic Agents to Reduce Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures [1].

Ingested material

<table>
<thead>
<tr>
<th>Material</th>
<th>Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids†</td>
<td>2-h minimum fasting period*</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4-h minimum fasting period*</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6-h minimum fasting period*</td>
</tr>
<tr>
<td>Nonhuman milk‡</td>
<td>6-h minimum fasting period*</td>
</tr>
<tr>
<td>Light meal§</td>
<td>6-h minimum fasting period*</td>
</tr>
</tbody>
</table>
- Fried foods, fatty foods, or meat  Additional fasting time (eg, 8 h or more) may be needed

**Pharmacologic**

- **Recommendations (medication type and common examples)**

  **Gastrointestinal stimulants**
  - Metoclopramide  May be used/no routine use

  **Gastric acid secretion blockers**
  - Cimetidine  May be used/no routine use
  - Famotidine  May be used/no routine use
  - Ranitidine  May be used/no routine use
  - Omeprazole  May be used/no routine use
  - Lansoprazole  May be used/no routine use

  **Antacids**
  - Sodium citrate  May be used/no routine use
  - Sodium bicarbonate  May be used/no routine use
  - Magnesium trisilicate  May be used/no routine use

  **Antiemetics**
  - Ondansetron  May be used/no routine use

  **Anticholinergics**
  - Atropine  No use
  - Scopolamine  No use
  - Glycopyrrolate  No use

  **Combinations of the medications above**  No routine use

---

**These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee complete gastric emptying.**

*The fasting periods noted above apply to all ages. †Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. ‡Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period. §A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (eg, 8 h or more) may be needed in these cases. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period. In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone [1].

*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.

**Development Chronology for this Practice Parameter**

1995 (Resolution 13)
Revised 2000 (Resolution 17)
Revised 2005 (Resolution 43)
Revised 2010 (Resolution 45)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 23)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SIR Practice Parameter for the Performance of Angiography, Angioplasty, and Stenting for the Diagnosis and Treatment of Renal Artery Stenosis in Adults

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2015 (Resolution 22)*

ACR–SIR PRACTICE PARAMETER FOR THE PERFORMANCE OF ANGIOGRAPHY, ANGIOPLASTY, AND STENTING FOR THE DIAGNOSIS AND TREATMENT OF RENAL ARTERY STENOSIS IN ADULTS

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication.

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1 Iowa 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.
of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Hypertension (HTN) is a common problem, affecting 29.1% of the adult adults in the United States population [1]. If poorly controlled, HTN causes significant morbidity and mortality. This can be in the form of end-organ damage frequently affecting the kidneys as well as the cerebrovascular and cardiovascular systems. Although HTN is most often essential or idiopathic in origin, renovascular disease is an important and potentially remediable secondary cause of HTN and progressive renal insufficiency. The definition of renovascular hypertension (RVH) is still being elucidated, so the incidence of RVH varies in the literature from 0% to 29% with a weighted mean of 4% in an analysis of 8,899 patients in 12 studies [2]. The prevalence of RVH increases with age and coexisting atherosclerotic disease in other vascular beds.

Not all renal artery stenosis (RAS) is symptomatic. The incidence of incidental renal artery atherosclerotic disease increases with age [3]. In an asymptomatic 65-year-old, the incidence of RAS is 2%, but in an elderly patient with cardiovascular disease, the prevalence may be as high as 40% [4,5]. Few patients with RAS, even many with severe HTN or chronic renal failure, will have RVH. Certain clinical scenarios may significantly increase the likelihood that HTN is truly RVH (eg, abrupt onset of HTN before the age of 30); but however, identifying RVH in an older population with a high prevalence of RAS is challenging [6]. Performing an effective vascular consultation for HTN, renal insufficiency, or incidental RAS requires an understanding of the physiology of renal vascular disease, the most appropriate screening examinations, and the indications for renal angiography. Renal vascular consultation also requires mastery of the indications, contraindications, outcomes, risks, and alternatives to endovascular renal vascular intervention.

This document reviews those circumstances that should prompt evaluation for RVH or renal ischemia. It also discusses both the noninvasive imaging and the angiographic evaluation of such patients. Practice parameters for the performance of renal artery angiography and percutaneous renal artery angioplasty and stenting (PTRAS) are reviewed, as well as considerations of what constitutes a successful intervention. Practice parameters for the training and ongoing credentialing of practitioners performing these interventions are also presented.

For additional information on Definitions, see Appendix A, and for Methods, see Appendix B.

II. INDICATIONS/CONTRAINDICATIONS FOR RENAL VASCULAR IMAGING OR ANGIOGRAPHY

Although recent randomized trials have raised doubts about the clinical efficacy of renal angioplasty and stenting for RAS, noninvasive imaging still has an important role in clinical diagnosis and management. Clinical features suggestive of RVH were first enumerated by the Cooperative Study of Renovascular Hypertension in 1972 [7] and
have been regularly updated through the time of the American College of Cardiology (ACC) guidelines in 2005 [8-12]. The indications for screening for RAS historically include the following:

- Onset of HTN before the age of 30, especially without a family history, or recent onset of significant HTN after the age of 55
- An abdominal bruit, particularly if it continues into diastole and is lateralized
- Accelerated or resistant HTN (RHTN)
- Recurrent (flash) pulmonary edema
- Renal failure of uncertain cause, especially with a normal urinary sediment and less than 1 g of protein per daily urinary output
- Coexisting, diffuse atherosclerotic vascular disease, especially in heavy smokers
- Acute renal failure precipitated by antihypertensive therapy, particularly angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers
- Malignant HTN with a unilateral small kidney
- HTN associated with medication intolerance

As doubts about the clinical efficacy of renal artery intervention have evolved, the seventh report of the Joint National Committee (JNC 7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure published in 2004 more generally listed clinical signs of secondary HTN that may require further testing: young age, physical examination findings, RHTN, abnormal laboratory values, sudden onset of HTN, or worsening of previously well-controlled HTN [13]. The JNC 7 report recommends duplex ultrasound or MR angiography (MRA) for evaluation of the renal arteries [14]. **Depending on institutional bias, CT angiography (CTA) is also an option for noninvasive imaging of the renal arteries.** Indications for renal vascular imaging have not been updated by the ACC or JNC since that time [15].

The ideal timing for imaging evaluation is not well defined. Any antihypertensive treatment regimen that effectively lowers blood pressure is associated with slowed progression of renal failure and improved cardiovascular survival [16]. Prior to referral for RAS imaging, appropriate diligence is needed in reviewing the blood pressure history and what medication combinations have been tried to control HTN [15]. In particular, the history of ACE inhibitor usage and clinical response to ACE inhibitors is used in determining whether renal artery imaging is needed. The use of ACE inhibitors or angiotensin receptor blockers (ARBs) in the setting of a significant RAS may cause a decrease in renal function [17,18]. Renal artery imaging should be performed to exclude stenosis as the etiology of unexplained new renal failure associated with initiating ACE inhibitors or ARBs.

Diagnostic angiography remains the gold standard for identifying a RAS [19]. Angiography may be indicated, in the appropriate clinical setting, following the discovery of a RAS by noninvasive imaging or in settings in which RVH or ischemic nephropathy (IN) is suspected clinically but noninvasive imaging is equivocal. Renal angiography provides not only better quantification of the degree of stenosis but also an opportunity to determine the physiologic significance of a stenosis.

Although a stenosis results from pathology of the arterial wall, it is clinically important only when that process reduces the vessel lumen to the point of hemodynamic significance. Although a 50% diameter reduction is associated with hemodynamic significance, rising renin excretion is clinically the marker that suggests a RAS is potentially causing RVH [20]. **Excess increased renin excretion probably only reliably usually** occurs when the luminal diameter is reduced by 80% or more [21]. This number will vary depending on characteristics of the stenosis, such as its length, irregularity, and multiplicity, the resistance of the distal vascular bed, and the available collateral blood supply [22,23].

The physiologic significance of a stenosis depends on the resistance of the peripheral renal vasculature and the condition of the renal autoregulatory system [24-26]. Doppler ultrasonography and nuclear renography may be useful in assessing the significance of a RAS, but the gold standard for measuring the physiologic significance of a stenosis is simultaneously measuring the gradient between the aortic pressure via a guiding catheter near the ostium.
and a pressure wire distal to the RAS [20,27,28]. The use of a low-profile pressure-sensing wire or microcatheter
to obtain the measurement distal to the stenosis prevents false elevation of the gradient that could occur if a larger
catheter were used, as this might obtrude the artery and lower the pressure distal to the stenosis.

Several standards have been proposed for determining hemodynamic significance, and there is no consensus as to
whether an absolute systolic, peak systolic, or mean pressure should be used, whether the pressure should be
measured during a resting or hyperemic state, or at what level the criterion for hemodynamic significance should
be set. Different investigators have variously defined a significant pressure gradient as 10% of the systolic pressure,
a 10, 15, or 20 mm Hg systolic pressure gradient, or a 10 mm mean gradient. Given the variable clinical response
to renal angioplasty and stent placement, a more conservative approach to systolic gradients probably requires a
systolic gradient of 20 mm Hg to be considered clinically significant (that which activates the renin-angiotensin
system) [29]. Measurement of renin levels in humans with balloon inflation used to create variable stenoses revealed
that a 10% mean pressure gradient raises renin levels. The use of mean pressure gradient is now a widely accepted
measure of clinical significance [30]. Other authors have found that a dopamine-stimulated mean pressure compared
to an unstimulated mean pressure gradient of 20 mm Hg indicates a significant gradient [31]. Extrapolating from the
coronary literature, the determination of renal fractional flow reserve (FFR), following the intra-arterial
administration of 30 mg papaverine, has also been shown to predict physiologic significance through measurements
of renal vein renin levels better than systolic pressure gradients [20,32]. A FFR of 0.9 or less, which corresponds to
a stimulated (hyperemic) systolic gradient of 21 mm Hg, is physiologically significant. Other tests that can lend
support to the clinical significance of a RAS of borderline hemodynamic significance include intravascular
ultrasound, optical coherence tomography (OCT), or selective renal vein renin sampling [23,33-36].

Prior to leaving the topic of the indications for renal angiography, it is worth discussing potential prerequisites for
performing angiography. Additional laboratory testing that may be useful in determining whether or not to proceed
to angiography include low urine protein levels, high plasma renin levels (which have low sensitivity and high
specificity for response to renal revascularization), and elevated brain natriuretic peptide (BNP) [37]. Angiotensin
II, a potent vasoconstrictor that stimulates cellular hypertrophy and proliferation, likely contributes to vascular and
ventricular hypertrophy, accelerates atherosclerosis, and causes progressive glomerular sclerosis independent of
their hemodynamic effect [38]. Whenever possible, an ACE inhibitor or ARB should be part of the treatment of
HTN associated with chronic kidney disease because these drugs have been shown to be organ-protective beyond
their antihypertensive effect in certain renal disease categories [15].

III. SUCCESS RATES FOR RENAL ARTERY INTERVENTION

Although a hemodynamically significant RAS may stimulate the renin-angiotensin system and result in systemic
HTN or renal ischemia, there are other factors that may influence the clinical response to treating a RAS. The
etiology of the stenosis and the age of the patient are important factors in determining clinical success. Additional
factors that are important in older patients include the level of blood pressure control that can be attained medically,
the patient’s ability to tolerate and comply with the prescribed medical regimen, any impairment in renal function
or evidence of progressive nephron loss, and comorbid medical conditions. Therefore, in most cases, the clinical
significance of a RAS and the likelihood that the clinical syndrome can be improved should guide the decision to
revascularize a kidney rather than the morphologic or hemodynamic characteristics of the renal artery stenotic lesion
alone. The majority of patients with hemodynamically significant RAS associated with HTN or reduced renal
function can be managed medically without a risk of increased mortality or progression to end-stage renal disease
[16,39-41]. However, there are patient subpopulations in whom RAS may produce RVH, IN, or cardiac disturbance
syndromes (ie, recurrent “flash” pulmonary edema not felt to be secondary to impaired left ventricular systolic
function) and in whom intervention may therefore be helpful. Thus, the benefits of revascularization need to be
individually determined based on the underlying clinical condition prompting intervention.

A. Clinical Success Following Renal Revascularization

1. Atherosclerotic renovascular disease and HTN
a. HTN in the patient with atherosclerotic RAS

Although a distinguishing advantage for revascularization compared with medical therapy alone is the potential for an HTN cure, only a small percentage of patients with atherosclerotic RAS (ARAS) are reported as cured following revascularization [16,39-45]. The clinical profile of the atherosclerotic patient, who is most likely to be cured, has not been defined [7,46-54]. There are findings that may help determine the outcomes of renal revascularization for ARAS, including the severity of the RAS, if the RAS is unilateral or bilateral, the diameter of the narrowed vessels, location of the narrowing, if there is involvement of branch points, the patency of small arteries and arterioles distal to a RAS, the renal mass available for revascularization (usually a measurement of kidney length or cortical thickness), function of the involved kidney as demonstrated by nuclear scintigraphy, and the presence of intrinsic renal disease on the affected side (measured by duplex ultrasound determinations of resistive index) [55-58]. Randomized controlled trials (RCTs) [16,39-43,45,59,60] and multiple case series [49,51,61,62] report that renal revascularization results in only modest decrease in doses of medications or blood pressure. More recent studies have focused on the risk of cardiovascular events in patients with possible RVH and have failed to demonstrate an advantage to of renal artery angioplasty and stent placement [16,40]. Whether controlling blood pressure on less medication or a potential reduction in blood pressure on the same medications outweighs the risks of the procedure can should still be considered on an individual patient basis [63-65]. Despite the findings of these RCTs, there may be patients with high blood pressure, refractory HTN, or severe bilateral RAS who will have a positive clinical response to revascularization [61,66]. In the following sections, the clinical evidence regarding revascularization is discussed for specific indications.

b. In the patient with RHTN

Although RHTN is uncommon, the incidence of RAS, by angiography, in RHTN is high (24.1%) [6]. True RHTN (excluding noncompliant patients and white-coat syndrome) involves represents only a small percentage of hypertensive patients [67], and the available randomized clinical trials have often been cited for underrepresenting this population. In 2000, van Jaarsveld et al published one of the first RCTs focused on atherosclerotic RHTN. The study of 106 RHTN patients with RAS found no difference between medical management and balloon angioplasty [40]. The trial has been criticized for not including renal artery stents, but a meta-analysis of all of the RCTs also fails to demonstrate a benefit in RHTN. There are more recent case-controlled series indicating that a carefully selected population of patients with RHTN and hemodynamically significant stenosis respond favorably to angioplasty and stenting stent placement [29,66,68,69]. Although several RCTs suggest that RHTN is not an indication for PTRAS, the study populations are potentially biased, and the incongruity between these randomized trial studies and multiple case series leave questions on this indication for revascularization [70]. The clinical efficacy of treating RHTN, particularly in the setting of severe, bilateral RAS, remains potentially unproven.

c. Renal revascularization in the setting of hypertensive crisis

The literature on renal revascularization in patients with a hypertensive crisis is limited [71]. The risks of stroke and access site complications are higher if blood pressure is not well controlled. There is general agreement that blood pressure must be well controlled, with intravenous (IV) medications if necessary, prior to angiography. On the other hand, patients with severe HTN requiring hospitalization should be considered for intervention.
2. **HTN in the patient with fibromuscular RAS**

There is strong evidence that when HTN is associated with hemodynamically significant renal artery fibromuscular dysplasia (FMD), it is an indication for angiography and PTRA [72,73]. The mean cure rate in this population, following renal revascularization, is 44% to 46% in meta-analysis [62,73]. Using logistic regression, Davidson et al found that younger age, milder severity, and shorter duration of HTN were statistically significant independent variables predicting a cure following PTRA in FMD [74]. The type of FMD may be important in predicting technical success and clinical response. Medial type affects 60% to 70% of patients with FMD [75]. Medial fibroplastic disease is similarly the most commonly reported type of FMD treated with angioplasty. The rate of cure of renovascular HTN due to the medial fibroplastic type of FMD is sufficiently high to recommend PTRA as a first-line treatment.

FMD most often involves the distal main and branch renal arteries. Fortunately, the technical and clinical response of FMD involving renal artery branches to angioplasty is as good as in cases in which FMD is limited to the main renal artery [76,77]. The operator must understand that treatment should not be limited to main renal artery lesions because the best chance for a cure is achieved when all of the hemodynamically significant lesions are treated.

Renal artery FMD can be found by CTA in 2.6% of potential kidney donors [78]. There is a strong association between renal FMD and carotid FMD, so a thorough screening, usually with CTA, is recommended whenever renal FMD is diagnosed. FMD can also be found in 7.3% of first-degree or second-degree relatives, so consulting with the family is an important part of the evaluation process in patients with FMD [79].

3. **Takayasu arteritis (TA)**

TA is a rare, large-vessel arteritis. TA primarily affects large vessels originating from the aorta, causing wall inflammation, fibrosis, and stenosis [80]. The reported incidence of TA in North American patients was found to be 2.6 per million per year [81]. Detection of RVH can be difficult to delineate because these patients can have bilateral subclavian artery stenosis causing misleadingly low blood pressure measurements [82]. Glucocorticoids are first-line agents and the gold standard in treatment for TA. After being prescribed glucocorticoids, most patients show improved quality of life. Prednisone can reverse stenotic lesions of the aorta and renal arteries and concomitantly reduce blood pressure [83]. Treatment of this disease entity can be challenging because it is often resistant to medical therapy [84]. Endovascular treatment with PTRA remains crucial to the treatment of RVH TA. A recent retrospective analysis demonstrated increased restenosis rate with stent placement compared with angioplasty [85]. Multiple retrospective analyses have confirmed these findings [86,87] and demonstrated better long-term patency of angioplasty compared with both surgery and stent placement [86]. Angioplasty alone should therefore be the mainstay treatment of RVH in TA with stent placement reserved for cases of clear angioplasty failure. Elevated erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are indicators of the acute inflammatory stage of the disease. Care should be made not to perform angioplasty during the acute phase of the disease because it has been shown to have a higher risk of complications [88].

4. **Renal artery dissection**

Spontaneous, isolated, renal artery dissection may be detected as part of a hypertensive or renal failure evaluation. It may also be first detected because of new flank pain or hematuria. It is often idiopathic but is often frequently associated with HTN, FMD, and connective tissue disease, and trauma. Acute dissection may cause new or accelerated HTN, renal failure, or flank pain. A case series of patients with acute symptomatic idiopathic renal artery dissection (no connective tissue disorders or other associated pathology) demonstrated clinical benefit to intervention [89].

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PRACTICE PARAMETER 6 Renal Artery Stenosis

2020 Resolution No. 40
5. Atherosclerotic renal artery disease and IN

There is ongoing controversy concerning the degree of benefit that can be expected from revascularization of the patient with IN. It is well recognized that there is progressive nephron loss with aging. The loss is accelerated by many disease states, including IN in which, in addition to the loss of nephron tissue, there can be functional loss resulting from hypoperfusion and loss of renal autoregulation secondary to RAS. Measurement of estimated glomerular filtration rate (eGFR) remains the best measure of functional outcomes [90]. The slope of the linear relationship between the reciprocal of creatinine concentration (a surrogate for the calculation of eGFR) and time can be used to delineate the rate of change in renal function [91]. If the slope of this curve can be altered with PTRAS, then the consequences of chronic renal failure (CRF) and renal replacement therapy may be deferred. Altering the progression along the slope of decline in renal function may indicate a benefit from intervention despite a lack of improvement in baseline serum creatinine.

Several case series of renal revascularization for IN have demonstrated statistically significant improvement in renal function at follow-up [92-94]. On the other hand, in three recent prospective randomized studies of renal revascularization, no improvement in renal function was reported [16,40,45]. However, other markers including baseline kidney size and resistive indices were not included in these trials [95,96]. There are three indications that continue to be debated regarding renal revascularization for ischemia: acute renal failure, renal failure associated with prior artery manipulations, and renal angioplasty for preservation of renal mass.

a. Acute IN

Although all the RCTs of IN failed to demonstrate clinical benefit of revascularization, these trials enrolled patients with chronic renal insufficiency [16,39,40,45]. Renal revascularization can result in improvement of GFR in selected patients with acute IN [66,97]. Signs that a patient with acute IN is likely to benefit from revascularization include 1) normal appearance of the arterioles distal to the RAS, 2) bilateral severe RAS or RAS involving a single functioning kidney, 3) a near-normal volume of renal mass available for revascularization, 4) renogram demonstrating adequate function of the involved kidney, 5) renal biopsy demonstrating well-preserved glomeruli and tubules with minimal arteriolar sclerosis, 6) severe, difficult to control HTN, 7) abrupt onset of renal insufficiency [39,41,57,58,66,98,99], and 8) renal artery fractional flow reserve over 0.80 [100]. Delay in revascularization in these settings has been associated with a reduction in clinical benefit [7].

b. Renal failure associated with prior arterial interventions

None of the randomized trials of renal artery interventions for CRF address the management of patients with prior renal artery interventions. Acute renal failure in the setting of RAS related to prior renal artery bypass, aortic endograft encroachment, or prior renal artery stent placement should be treated aggressively [101-103]. In these clinical scenarios, there is often a significant temporal relationship between serial imaging changes and deterioration in renal function that indicates a strong association between recurrent RAS and renal failure. This recommendation for treatment is also based on the natural history of rapid progression to renal artery occlusion in previously treated renal arteries [104-106].

c. Prophylactic treatment for renal mass preservation

There is no known benefit to prophylactic treatment to preserve renal mass [107]. Nevertheless, it is recommended that renal mass and function be followed in the setting of severe RAS. This is especially true for patients with either bilateral severe RAS or a severe stenosis of the renal artery supplying a
solitary kidney because there is twice the risk of mortality and 1.5 times the risk of significant deterioration of renal function compared with patients who have a unilateral RAS and two kidneys [108]. Patients should also be followed for changing or emerging clinical indicators that may prompt a re-evaluation of the need for renal revascularization (eg, precipitant heart failure or sudden loss of renal function without medical explanation).

6. Cardiac disturbance syndromes
RAS may worsen angina or congestive heart failure in patients with coronary artery disease, left ventricular dysfunction, or cardiomyopathy as a result of complex pathophysiologic alterations, such as changes in the renin-angiotensin axis that lead to volume overload and peripheral arterial vasoconstriction [109-112]. Renal revascularization may relieve these cardiac syndromes, particularly in patients with bilateral RAS [66,111,113-115]. Over 70% of patients remain free of congestive heart failure and unstable angina at the 12-month mean follow-up after PTRAS [109,114]. In particular, there are multiple case series suggesting that PTRAS in the setting of flash pulmonary edema may be beneficial [66,70,116-118]. Restoring unobstructed renal blood flow has the additional potential benefit of allowing safe usage of ACE inhibitors without the risk of worsening renal failure.

7. Prevention of cardiovascular mortality
Renal artery stenting was associated with a 43% reduction in mortality in patients with 0 or 1 mortality risk factor(s) (defined as Left Ventricular Ejection Fraction LVEF ≤35%, previous Myocardial infarction (MI), and GFR ≤45 mL/min/1.73 m²) but had no effect on mortality in patients with 2 or 3 mortality risk factors [119].

The most recent RCTs indicate renal revascularization does not reduce the risk of cardiovascular mortality [16].

8. Summary
There is no consensus on the indications for renal intervention in the general population with ARAS with HTN or renal ischemia. There are several important subpopulations that will need further clinical investigation before global recommendations can be made regarding renal intervention, eg, patients with hemodynamically significant atherosclerotic stenosis (as determined by a minimum 10% mean translesion pressure gradient) and poorly controlled HTN, global ischemia with renal insufficiency, and/or cardiac disturbance syndromes. The following table lists common indications for PTRAS, evidence-based management recommendations, and the level of evidence to support that recommendation.

<table>
<thead>
<tr>
<th>Indication For RAS Intervention</th>
<th>Renal Angioplasty Treatment</th>
<th>Quality of Evidence [170]</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTN with ARAS</td>
<td>Medical therapy is equivalent to PTRAS [16,40,41,43]</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>RHTN with hemodynamically significant bilateral ARAS</td>
<td>PTRAS may be of benefit, particularly in young patients [66]</td>
<td>Low</td>
<td>Weak</td>
</tr>
<tr>
<td>HTN crisis with hemodynamically significant ARAS</td>
<td>PTRAS may be of benefit</td>
<td>Low</td>
<td>Weak</td>
</tr>
<tr>
<td>HTN with fibromuscular dysplasia</td>
<td>PTRA (avoid stent) is indicated</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>TA</td>
<td>PTRA is indicated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1

PRACTICE PARAMETER

Renal Artery Stenosis

2020 Resolution No. 40
### Symptomatic renal artery dissection
PTRAS may be of benefit [89]

<table>
<thead>
<tr>
<th>Symptom/Condition</th>
<th>Treatment Description</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic renal failure with ARAS</td>
<td>Medical therapy is equivalent to PTRAS [16,39,45,72,73,79,120,121]</td>
<td>High</td>
</tr>
<tr>
<td>Acute renal failure with hemodynamically significant bilateral ARAS and low resistive index, or ARAS to a single functioning kidney</td>
<td>PTRAS may be of benefit [66,97]</td>
<td>Low</td>
</tr>
<tr>
<td>Renal failure with prior intervention (in-stent stenosis, endograft, or open surgery)</td>
<td>Repeat intervention may be beneficial [103]</td>
<td>Very Low</td>
</tr>
<tr>
<td>Renal mass preservation with ARAS</td>
<td>Medical therapy preferred (PTRAS not indicated) [16,39,45]</td>
<td>Moderate</td>
</tr>
<tr>
<td>Cardiac disturbance syndromes with ARAS</td>
<td>PTRAS may be beneficial in flash pulmonary edema [66,113,116-118]</td>
<td>Low</td>
</tr>
<tr>
<td>Prevention of cardiovascular mortality with ARAS</td>
<td>Medical therapy is equivalent to PTRAS [16]</td>
<td>High</td>
</tr>
</tbody>
</table>

The technical success rates, long-term patency, and complications must also factor into the decision to proceed with revascularization.

#### B. Technical Success and Long-Term Patency of Renal Revascularization Procedures

Intravascular stent placement is the standard of care for revascularization of atherosclerotic ostial RAS [16,61]. Stents dilated to less than 6 mm, female sex, age greater than 65 years, and smoking are statistically significant risk factors for restenosis [122,123]. In the US Multicenter Renal Artery Stent Trial, the lowest risk group was men with renal arteries 6 mm or greater, in whom there was a restenosis rate of 10.5%. There are very little data regarding stent use in nonostial RAS; however, there are studies suggesting that these lesions may respond favorably to balloon angioplasty alone [124]. Stent fracture is associated with early restenosis [105]. Increased technical success and improved long-term patency would be expected if the reference vessel diameter is 6 mm or greater. The evidence for the use of drug-eluting stents (DESs) is limited, but there does appear to be enough evidence of early restenosis in accessory arteries that after balloon Percutaneous transluminal angioplasty (PTA) alone or DES are preferred to placement of conventional bare-metal stents that DES may be preferred for small arteries [125-127].

There is an ongoing investigation on the use of covered stents. At present, their use as a first-line device cannot be recommended, although there is mounting evidence that they are appropriate for the management of in-stent stenosis (ISS).

Not all stent placements allow an the opportunity for repeat intervention and assisted patency. The use of stents in ostial and nonostial locations is are relatively contraindicated if the stent traverses renal artery branches or if restenosis would likely make surgical revascularization difficult or impossible.

Long-term stent patency and clinical outcomes in most trials include noninvasive monitoring of the stent. Follow-up of stents placed for atherosclerosis should include regular duplex ultrasound which, with appropriate baseline evaluation, provides a highly sensitive marker of ISS [128,129]. CTA has limited use in follow-up after renal artery stent placement [130,131].

Repeat intervention for ISS has twice the failure rate than primary stent placement (20% versus 11%; P = 0.003) [106]. The methods for management of ISS are varied and include PTA, PTRAS, atherectomy, brachytherapy, and DES placement [132-134].
Technical success for treatment of renal FMD should be 95% or greater. There is increasing emphasis on measures of technical success other than angiographic appearance for FMD. Pressure-wire manometry and intravascular ultrasound should be available and their use considered when treating FMD. Appropriate treatment of FMD includes dilatation of the entire diseased segment, even if it involves a branch point. The operator must be comfortable with the use of dual-wire access and kissing balloons. If a satisfactory technical result is achieved, the long-term patency of the treated segment should be nearly 100%. Renal artery stents have no role in the primary treatment of FMD. Stents may be indicated in technical failures due to vessel dissection, but the remodeling capabilities of a post-PTA renal artery with mild dissection should not be underestimated by the operator.

IV. RENAL DENERVATION THERAPY

Renal denervation therapy has been established to decrease renal and sympathetic vascular tone. Early studies, however, did not demonstrate consistent efficacy in decreasing blood pressure. Post hoc analyses of the early trial, SYMPLICITY HTN-3, demonstrated inconsistencies in renal artery denervation, medication compliance, and inclusion of patients with isolated systolic HTN [135]. Two new clinical trials, the SPYRAL HTN-OFF MED and RADIANCE-HTN SOLO, have now demonstrated decreased ambulatory blood pressures. Despite using different devices with resulting different techniques (radiofrequency in SPYRAL HTN-OFF MED and sonication in RADIANCE-HTN SOLO), both studies demonstrated reduced ambulatory blood pressures without antihypertensive medications when compared with a sham procedure [136,137]. There are several case reports of RAS following renal denervation [138-142].

V. COMPLICATIONS – RISKS OF ENDOVASCULAR VASCULARIZATION

The rates of complications related to endovascular renal artery revascularization have shown improvement over time.

There are two large series [143,144] and two meta-analyses [51,77] in which there is with no overlap of data among them that provide complication data on 2,994 revascularizations (980 stented vessels in 2,474 patients). The total complication rate ranged from 12% [51] to 36% [144], with a mean complication rate of 14%, excluding events that occur during catheterization or stent deployment that have no clinical consequences but lead to an increase in procedural time or cost [144]. Groin hematoma and puncture site trauma were the most common complications reported, with a rate of approximately 3% to 5%. Major complications (and their incidence rates) include worsening of renal function (4%), occlusion of the renal artery (2% to 3%), segmental infarction (1% to 2%), requirement for surgical intervention for either nephrectomy or salvage (2%), and death (1%). Thirty-day mortality was 1%, usually related to renal artery perforation, cholesterol embolization, acute renal failure, and arterial access puncture above the inguinal ligament. A surgical salvage operation was necessary in 1% to 2.5% [51,77]. Symptomatic embolization occurred in 1% to 8% of the patients [51,144]. Occlusion of the main renal artery was reported in 0.8% to 2.5% and occlusion of a renal artery branch causing a segmental infarction in 1.1% to 1.7% [51,77].

Operator experience is important in minimizing the complication rate. A trend toward reduced complications was demonstrated in an earlier investigation by Martin et al, which found that the total complication rate fell from 20% in the first 100 cases to 13% in the second 100 cases. The authors attributed the change to increased experience and improvement in technology and devices [145].

Cholesterol embolization resulting in decreased renal function or visceral or peripheral symptoms is expected in less than 3% of cases [51,77,143,144]. A “no-touch” technique of positioning a guide catheter in the renal ostium with a second wire extending to the suprarenal aorta may potentially reduce cholesterol embolization, but the technique is unsubstantiated [146]. The rate of cholesterol embolization may be related to the clinical outcomes of renal stent placement for renal ischemia. The postprocedural worsening of renal function that occurs in roughly one-third of renal artery stents placed for renal insufficiency may be related to distal microemboli. The use of a distal embolic protection device may reduce cholesterol embolization rates and this may subsequently reduce the incidence of postprocedural worsening of renal function [147-150]. There is some evidence that antplatelet therapy
and distal embolic protection may further reduce the risk of worsening renal failure after renal artery stent placement for renal ischemia [147,151]. However, the routine use of distal protection has not been proven to be of benefit in reducing renal failure or in preserving renal mass so and therefore is not a practice parameter recommendation.

A thorough understanding of both the appropriate medical management of RVH and the natural history of the disease without revascularization is essential in providing consultation on the risks and benefits of endovascular therapy. The long-term effects of poorly controlled HTN or progressive renal insufficiency are the most important sequelae that should be considered if a stenotic renal artery is not revascularized in a case of apparent RVH [152]. The systematic review of early angiographic studies showed an average RAS progression rate of 49% with total occlusion resulting in 14% in 237 patients with follow-up ranging between 6 and 180 months [153]. However, more recent data show that the long-term risk of a missed opportunity to revascularize the kidney because a stenosis progressed to an occlusion appears to be small [154,155].

VI. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The physician performing renal angioplasty/stenting must have a broad perspective on the benefits, alternatives, and risks of the procedure. He or she The physician must have a thorough understanding of renal vascular physiology, medical management of HTN and renal ischemia, vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety considerations, and physiologic monitoring equipment. The physician must have access to and familiarity with an adequate supply of diagnostic catheters, guiding catheters guide sheaths, and guidewires. The physician must also have awareness of the skills and numbers of ancillary personnel needed to perform the procedure safely.

Renal angioplasty/stenting procedures must be performed under the supervision of and interpreted by a physician who meets the qualifications has the following qualifications pertinent to the scope of services as stated in the ACR-SIR-SPR Practice Parameter for the Performance of Arteriography [156] and perform a sufficient number of renal arteriograms, renal angioplasty, or renal stenting procedures (bilateral procedures may count as two cases).

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, 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 renal angioplasty/stenting procedures to demonstrate competency as attested by the supervising physician(s).

or

2. Completion of a radiology residency training program and/or interventional/vascular radiology fellowship 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), and has performed (with supervision) a sufficient number of renal angioplasty/stenting procedures to demonstrate competency as attested by the supervising physician(s).

or

3. Completion of an ACGME-approved nonradiology residency or fellowship training and a minimum of 12 months of training on a service that is primarily responsible for performing 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 the following procedures:

a. Meets the requirements of the ACR-SIR-SPR Practice Parameter for the Performance of Arteriography [143]. At least 10 of the cases performed should be renal arteriograms.

and

b. Performance of at least 30 successful systemic (eg, noncardiac and non-neurologic) arterial
interventions as the primary operator, with acceptable complication rates as defined in section V of this document. At least 10 of these should be renal angioplasty or stenting (bilateral may count as 2 cases):

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. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications
   c. Where applicable, pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications
   d. Fluoroscopic and radiographic equipment, mechanical injectors, digital image capture devices, digital subtraction systems, and other electronic imaging systems
   e. Where applicable, principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel
   f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions
   g. Percutaneous needle and catheter introduction techniques
   h. Technical aspects of performing the procedure, including the use of alternative catheter and guidewire systems, selective angiographic methods, appropriate injection rates and volumes of contrast media, and filming sequences
   i. Recognition of periprocedural complications and knowledge of treatment options for these complications (e.g., stenting, embolization, thrombolysis, suction embolectomy, surgery)
   j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature
   k. Interpretation of peripheral and visceral arteriographic studies

The written substantiation should come from the chief of interventional radiology, director or chief of body imaging or ultrasound, or the chair of the 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 who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education (CME)

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [157].

B. Qualified Medical Physicist

For qualifications of the Qualified Medical Physicist, see the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment [158].

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an
advanced academic program encompassing an ACR/American Society of Radiologic Technologists (ASRT) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006 – revised in 2016, Resolution 1-c).

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 the patient for the procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. If IV contrast material is to be administered, qualifications for technologists performing IV injection should be in compliance with the current ACR policy and existing operating procedures or manuals at the facility. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

2. Technologists should be certified by the ARRT or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided percutaneous procedure.

E. Nursing Services

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

F. Other Licensed Independent Practitioners

Licensed independent practitioners may be involved in renal artery angioplasty and stenting procedures in accordance with their societal and local regulatory scope of practice under the supervision of the physician operator. Typically, they will be involved with patient preparation, patient monitoring, and patient education, and in some cases they may serve as “scrub” assistants.

VII. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements that are necessary in order to ensure safe and successful renal angiography, angioplasty, and stenting. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel. These recommendations are adapted from the Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL) trial [78] and the intersociety paper on optimum resources for endovascular treatment [159].

A. Angiographic Equipment and Facilities

The following are considered the minimum equipment requirements for performing renal procedures. In planning facilities for these procedures, equipment and facilities more advanced than those outlined below may be desired in

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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. (1987, 1997, 2007 - ACR Resolution 12-n)

*For the purposes of this parameter, “personally and immediately available” is defined in the 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)

3 See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media.
order to produce higher-quality studies with reduced risk and examination time. The facility should include the following, at a minimum:

1. A high-resolution image receptor (preferably with a 28-cm to 40-cm field of view [FOV]) and imaging chain are recommended with dose-reducing capabilities, such as pulsed fluoroscopy, dose reduction software, and last-image-hold capabilities, are recommended. Digital subtraction angiographic (DSA) systems with high spatial resolution are strongly recommended because they allow for reduced volumes of contrast material, reduced examination times, and avoidance of complications related to the use of low radiopacity stents. In accordance with the “as low as reasonably achievable” (ALARA) principle, a radiation dose measurement package to provide operator and patient feedback is recommended.

2. Adequate angiographic supplies such as catheters, guidewires, stents, balloons, needles, and introducer sheaths. In particular, pressure wires are advisable in order to provide objective evidence of hemodynamic significance in cases of angiographically equivocal stenoses.

3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection.

4. An angiography suite large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware, such as IV pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.

5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. At this location, there should be personnel to provide care as outlined in the Patient Care section below, and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the angiography suite to allow for monitoring the patient’s heart rate, cardiac rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available (see the ACR–SIR Practice Parameter for Sedation/Analgesia [160]).

2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages or sizes in the patient population.

3. Equipment for invasive pressure monitoring.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the diagnostic imaging equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, adjunctive supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive moderate sedation, one of the staff assisting in the procedure should be assigned to periodically assess the patient’s status. In cases in which moderate sedation is used or the patient is critically ill, an experienced licensed provider should be present whose sole responsibility is monitoring of the patient’s vital signs, sedation state, and level of comfort/pain. This person should maintain a record of the patient’s vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer moderate sedation (see the ACR–SIR Practice Parameter for Sedation/Analgesia [160]).

3. For unstable patients, additional support may be necessary to ensure the safe performance of renal interventional procedures. The primary operator may be engaged in the details of the renal interventional procedures. Therefore, appropriate personnel should be available to attend to the ongoing care and resuscitation of critically ill patients. Such personnel might include anesthesiologists; operating room (OR), intensive care unit (ICU), and/or emergency department (ED) trained nurses; or other physicians. The nurses may be radiology nurses and/or the same personnel responsible for monitoring and maintaining moderate sedation as discussed immediately above. Alternatively, the nurses may be supplied from other patient care units in the facility.

All such additional personnel should work in concert with and under the overall supervision of the primary operator performing the renal interventional procedures but within the scopes of service as defined by their professions, state regulations, and institutional guidelines.

D. Acute Care Support

Although surgical or other emergency treatment is needed infrequently for serious complications after renal interventional procedures, there should be prompt access to surgical and interventional equipment and specialists familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

E. Patient Care

1. Preprocedure care
   a. The physician performing the procedure must have knowledge of the following:
      i. Clinically significant history, including indications for the procedure
      ii. Clinically significant physical or diagnostic examination, including knowledge and awareness of other clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures
      iii. Possible alternative methods, such as surgical or medical treatments, to obtain the desired therapeutic result
   b. Informed consent must be in compliance with all state laws and the ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures [161].

2. Procedural care
   a. Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the timeout.
   b. The physician performing fluoroscopy should have knowledge of exposure factors, fluoroscopic pulse rate, magnification factor, and fluoroscopic dose rate, and should consider additional parameters such as collimation, FOV, distance from the patient to the image receptor, distance from the x-ray source to the patient, and last image-hold.
   c. Nursing personnel, technologists, and those directly involved in the care of patients undergoing renal interventional procedures should have protocols for use in standardizing care. These should include, but are not limited to, the following:
i. Equipment needed for the procedure

ii. Patient monitoring

Protocols should be reviewed and updated periodically.

During the use of fluoroscopy, the physician should use exposure factors consistent with the ALARA radiation safety guidelines.

3. Postprocedure care

a. A procedure note should be entered in the patient’s chart summarizing the major findings of the study and any immediate complications. This note may be brief if a formal report will be available within a few hours. However, if the formal report is not likely to be available on the same day, a more detailed summary of the study should be entered in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the patient’s medical condition. Orthostasis and even hypotension can be encountered after renal artery revascularization.

c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the patient.

d. The patient should be monitored for urinary output, cardiac symptoms, pain, changes in blood pressure, and other indicators of systemic complications that may necessitate overnight care.

e. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, recovery from the 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 or a nurse.

VIII. DOCUMENTATION

Documentation should be in accordance with the ACR–SIR–SPR Practice Parameter for Reporting and Archiving of Interventional Radiology Procedures [162].

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.
Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution adopted in 2006 – revised in 2009, 2013, Resolution 52)

X. 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).

These practice parameters are to be used in quality improvement (QI) programs to assess the diagnosis and treatment of RAS. The most important processes of care are 1) patient selection, 2) performance of the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Participation by the radiologist in patient follow-up is an integral part of the evaluation and treatment of RAS and will increase the success rate of the procedure.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds.

When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of symptomatic cholesterol embolization of the kidney is one measure of the quality of renal angioplasty or stenting of RAS, then values in excess of the defined threshold of 6% should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication.

Thresholds for imaging and angiography have become less clear for atherosclerosis. Table 1 provides qualitative appropriateness criteria. However, technical success and complication thresholds have been well defined. In addition, the appropriate indications for performing angiography in the setting of FMD remain well defined as listed below:

A. Indications for Angioplasty in FMD (Threshold – 95%)

1. An angiographic appearance of a hemodynamically significant RAS

PRACTICE PARAMETER 17 Renal Artery Stenosis 2020 Resolution No. 40
2. A hemodynamically significant stenosis as determined by:
   • A 10% mean pressure gradient across the RAS or
   • A dopamine stimulation–induced 20 mm Hg mean pressure gradient with dopamine stimulation across the RAS

B. Indications for Angioplasty and Stenting in ARAS ASVD (atherosclerotic vascular disease)
   1. Greater than 50% diameter stenosis or greater than 75% reduction in cross-sectional area
   2. A hemodynamically significant stenosis as determined by:
      • A 10% mean pressure gradient across the RAS or
      • A dopamine stimulation–induced 20 mm Hg mean pressure gradient across the RAS

C. Relative Contraindications for Renal Artery Stent Deployment (Threshold – 5%)
   1. Angioplasty for FMD should not require the use of stents unless used to treat a flow-limiting complication of angioplasty
   2. An atherosclerotic renal bifurcation lesion in which more than 50% of a kidney will be jailed by a stent
   3. Presence of sepsis
   4. Renal artery measuring 4 mm or less; use of DESs in these instances may prove to be useful [127]

D. Technical Success of Percutaneous Renal Revascularization (Threshold – 90%)
   1. Defined by minimal thresholds of <30% residual diameter stenosis or <10 mm Hg systolic gradient
   2. Early bifurcation lesions are excluded from this analysis

E. Complications

Complications are stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight). For further information, see the Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee. See Appendix A.

The complication rates and thresholds below refer to major complications.

### Specific Major Complications From Percutaneous Renal Revascularization

<table>
<thead>
<tr>
<th></th>
<th>Reported Rate</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Secondary nephrectomy</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
<tr>
<td>Surgical salvage operation</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Symptomatic embolization</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Main renal artery occlusion</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Branch renal artery occlusion</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Access site hematoma requiring surgery, transfusion, or prolonged hospital stay</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Worsening of CRF requiring an increase in the level of care</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Renal artery rupture [163]</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Perinephric hematoma [163]</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Overall threshold for major complications from percutaneous renal revascularization – 14%
Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (e.g., early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program. In the above table, all values were supported by the weight of literature evidence and panel consensus.

**ACKNOWLEDGEMENTS**

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website ([https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards](https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards)) by the ACR Specialty Commission by the Committee on Practice Parameters – Interventional and Cardiovascular Radiology of the ACR Commission on Interventional and Cardiovascular Radiology in collaboration with the SIR.

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REFERENCES


For the purpose of this practice parameter, the following definitions apply:

Hypertension: HTN is defined by the 1999 2003 World Health Organization’s International Society of Hypertension as the “diastolic blood pressure of 90 mm Hg or greater.” Systolic blood pressure of 140 mm Hg or greater and/or a diastolic blood pressure of 90 mm Hg or greater in subjects who are not taking antihypertensive medication” [164]. The sixth In 2014, the eighth [15] report of The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defined HTN as “systolic blood pressure 140 mm Hg or greater, diastolic blood pressure 90 mm Hg or greater, or taking antihypertensive medication” [165]. However, in 2018 recommendations by the American College of Cardiology and the American Heart Association now define stage 1 hypertension as a systolic blood pressure of 130 to 139 mm Hg or a diastolic blood pressure of 80 to 89 mm Hg [166]. Any of these definitions would be appropriate.

Accelerated hypertension: Sudden worsening of previously controlled HTN, which may indicate the development of a secondary cause of HTN.

Resistant hypertension: HTN should be considered resistant if the systolic blood pressure (SBP) cannot be reduced to below 140/90 mm Hg in patients who are adhering to an adequate and appropriate triple-drug regimen that includes a diuretic, with all three drugs prescribed in near maximal doses. For patients older than
age 60 with isolated systolic HTN, resistance is defined as failure of an adequate triple-drug regimen to reduce the SBP to below 160 mm Hg.

Cardiac disturbance syndrome: Recurrent “flash” pulmonary edema, not felt to be secondary to impaired cardiac function. This can be seen in the setting of bilateral RAS or unilateral stenosis of the renal artery to a solitary kidney [109,114,165].

Hypertensive crisis: According to AHA guidelines, “Hypertensive crises can present as hypertensive urgency or as a hypertensive emergency.”

Hypertensive urgency: SBP of 180 mm Hg or greater, or diastolic blood pressure of 100 mm Hg or greater. There may be associated headache, shortness of breath, nosebleeds, or anxiety.

Hypertensive emergency: Hypertensive urgency plus the coexistence of end-organ damage, which may include retinal hemorrhage, stroke, angina, myocardial infarction, aortic dissection, or pulmonary edema.

Malignant hypertension: HTN with end-organ damage including left ventricular hypertrophy (LVH), congestive heart failure (CHF), visual or neurologic disturbance, or advanced retinopathy.

RAS: Anatomic narrowing of the renal artery lumen diameter by 50% or greater, expressed in this practice parameter as a percentage of the diameter of a normal renal vessel, ie, \( \% \text{RAS} = 100 \times (1 - \frac{\text{the narrowed lumen diameter}}{\text{the normal vessel diameter}}) \).

Ostial RAS: Anatomic narrowing within the proximal 5 mm of the artery. Lesions within 10 mm of the aorta may also be considered ostial, when atheromatous plaque increases the distance between the extra-aortic renal artery and the aortic lumen on cross-sectional imaging [167].

Truncal RAS: Nonostial RAS occurring proximal to renal artery branching.

Renovascular hypertension: RVH is a secondary HTN due to activation of the renin-angiotensin system by a hemodynamically significant RAS [168].

IN: Renal vascular compromise leading to decreased estimated glomerular filtration rate (eGFR) without evidence of a medical cause. There may or may not be evidence of decreasing renal parenchyma mass [61].

Renal revascularization: Any procedure that restores unobstructed arterial blood flow to the kidney.

Technically successful endovascular renal revascularization: Less than 30% residual stenosis measured at the narrowest point of the vascular lumen and pressure gradient less than the selected threshold for intervention. In the presence of an angiographically visible dissection at the treatment site, the residual lumen is measured from the widest opacified lumen regardless of luminal dissections, knowing that the true lumen is difficult to measure accurately in this situation [169].

Clinical Success in the Endovascular Treatment of Renal Vascular Hypertension or Ischemia:

Cure: Restoration of blood pressure below 140/90 mm Hg and no longer taking antihypertensive medications. For renal insufficiency, a cure would be return of eGFR to normal baseline levels.

Partial response: Reduced blood pressure by 10 mm Hg systolic or diastolic on the same medications, or a comparable blood pressure on a reduced number or dose of medications after renal intervention. For renal insufficiency, improvement, or stabilization of eGFR is a partial response [61].
The goal of the authors for this review was to produce a practice parameter for the indications, methods, and quality improvement measures for diagnostic angiography and arterial interventions in renal artery occlusive disease. A process for developing a systematic approach to guideline development was published by the Institute of Medicine in 2011.

A Medline literature search was performed for English language articles published through February 2014 January 2018 with the following keywords: renovascular hypertension, renal artery stent, RAS, renal artery denervation, DES, paclitaxel or renal artery angioplasty complications. Randomized trials in adult populations, except those relating to congenital or inherited disorders, were selected for review. In developing a consensus document, the authors also reviewed case series, case reports, and expert opinion titles for relevance in answering the following questions: indications for renal artery imaging and renal angiography, indications for percutaneous renal artery intervention, procedure techniques, patient management, outcomes of renal artery angioplasty and stenting, quality thresholds, qualifications for operators, and facilities required to safely perform these procedures. The quality of evidence and the strength of recommendation was assessed according to the GRADE system [170]. Those standards form the basis for the process used in creating this practice parameter. The level of evidence is defined as strong, moderate, weak, or very weak. The strength of the recommendation is categorized as strong or weak.

APPENDIX A

Society of Interventional Radiology
Standards of Practice Committee
Classification of Complications by Outcome

**Minor Complications**
A. No therapy, no consequence
B. Nominal therapy, no consequence; includes overnight admission for observation only

**Major Complications**
C. Require therapy, minor hospitalization (<48 hours)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
E. Permanent adverse sequelae

*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.*

**Development Chronology for this Practice Parameter**

- 2004 (Resolution 26)
- Amended 2006 (Resolution 16g, 17, 34, 35, 36)
- Amended 2007 (Resolution 12m, 38)
- Revised 2009 (Resolution 26)
- Amended 2014 (Resolution 39)
- Revised 2015 (Resolution 22)
RESOLUTION NO. 41

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–ASNR–SNMMI Practice Parameter for Brain PET-CT Imaging in Dementia

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

2015 (Resolution 21)*

ACR–ACNM–ASNR–SNMMI PRACTICE PARAMETER FOR BRAIN PET-CT IMAGING IN DEMENTIA

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

1 Iowa 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Neuroradiology (ASNR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

It is estimated that the number of people with dementia, 36.5 million worldwide in 2010, will increase to 65.7 million in 2030 and to 115 million in 2050, a result of changed demographics and increased longevity [1]. This poses great challenges for both society and health care systems [2]. Four primary neurodegenerative etiologies of dementia have been defined: Alzheimer disease (AD), vascular dementia, frontotemporal dementia (FTD), and dementia with Lewy bodies (DLB) [3]. AD is the most common form of dementia, accounting for approximately 60% – 80% of all cases [4].

The most prominent clinical feature of AD is an early impairment of episodic memory [5], which manifests as memory impairment for recent events, unusual repeated omissions, and difficulty learning new information. As the disease progresses, the symptoms often manifest in more persistent language disturbance and difficulties completing more complex tasks of daily living. The early stage of cognitive decline, namely, mild cognitive impairment (MCI), is the intermediate phase between normality and dementia, during which patients show cognitive decline confirmed on objective cognitive testing but do not meet criteria for dementia because independent function is generally preserved [6]. Those with MCI convert to AD at a rate of about 10% to 25% annually compared with healthy elders who convert at a rate of about 1% to 2% annually [3]. About 20% of MCI patients progress to other dementia types, and 30% to 40% of cases do not progress to dementia [7].

The original diagnostic criteria for AD rested on the notion that AD is a clinical-pathological entity. The diagnosis is was classified as definite (clinical diagnosis with histologic confirmation), probable (typical clinical syndrome without histologic confirmation), or possible AD (atypical clinical features but no alternative diagnosis apparent; no histologic confirmation). Note that Possible AD may can be identified when there is an by unusual course or atypical features but also by the presence versus concomitant evidence of an alternative or contributory pathology, such as prior significant head trauma, alcohol-substance abuse, cerebrovascular disease, etc. A diagnosis of definite AD is was made only made according to criteria of the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer’s Disease and Related Disorders Association (NINCDS-ADRDA) criteria when there is was histopathologic confirmation of the clinical diagnosis [8].

With research progress, distinctive biomarkers of the disease are now recognized, including structural brain changes visible on magnetic resonance imaging (MRI), molecular neuroimaging changes seen with positron emission tomography (PET), and changes in cerebrospinal fluid (CSF) biomarkers. These distinctive biomarkers have been incorporated into revised diagnostic criteria for the AD pathophysiological process. These biomarkers can be divided into 2 major categories: 1) the biomarkers of A-beta (Aß) amyloid accumulation: abnormal radiopharmaceutical retention on amyloid PET imaging and low CSF Aß-42 peptide and 2) the biomarkers of neuronal degeneration or injury: elevated CSF tau protein (both total and phosphorylated tau); decreased 18F fluorodeoxyglucose (FDG) uptake on PET in a specific topographic pattern involving posterior cingulate/precuneus and temporoparietal cortex; and atrophy on structural MR, again in a specific topographic pattern involving medial,
basal, and lateral temporal lobes and medial and lateral parietal cortices [9]. Biomarkers of Aβ amyloid are indicative of initiating upstream events that may deviate from normal before clinical symptoms manifest. Biomarkers of neuronal injury and neuronal dysfunction are indicative of downstream pathophysiological processes that temporally follow [9]. Current evidence suggests that amyloid biomarkers may become abnormal approximately 10 to 20 years before noticeable clinical symptoms. Progression of clinical symptoms closely parallels progressive worsening of neurodegenerative biomarkers [6,10,11]. Biomarkers of neurodegeneration are now being incorporated into clinical diagnostic criteria for specific disorders, in particular for AD [12-14].

In 2004, the Centers for Medicare and Medicaid Services (CMS) issued a positive coverage decision (NCD 220.6.13) for the use of FDG-PET to distinguish AD versus FTD [15]. It was determined that FDG-PET was reasonable and necessary only in patients with recent development of dementia who met diagnostic criteria for AD and FTD. The National Coverage Determination also contained a second and broader element for FDG-PET in the diagnosis of dementia under coverage with evidence development. In 2012, the FDA subsequently approved the first three amyloid PET radiopharmaceuticals (18F-florbetapir [2012], 18F-Flutemetamol [2013], 18F-Florbetaben [2014]) for imaging of the brain for Aβ-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline.

A negative scan indicates sparse to no amyloid neuritic plaques and thus is not consistent with a neuropathological diagnosis of AD at the time of the scan. A negative scan reduces the likelihood that a patient’s cognitive impairment is due to AD. A positive amyloid scan indicates moderate to severe amyloid neuritic plaques and can be seen in AD and DLB. Positive scans may be obtained also be seen in patients with mild cognitive impairment and in older people with normal cognition who are at increased risk for progressing to MCI and AD [16].

This ACR practice parameter is for both FDG and amyloid brain PET or PET/computed tomography (CT) for patients with cognitive decline.

For additional information on Definitions, see Appendix A.

II. INDICATIONS

A. FDG-PET

Imaging of regional glucose metabolism with the radiopharmaceutical 18F FDG can provide unique neuronal metabolism information in patients with cognitive decline and dementia. Symptoms and signs of cognitive disorders are manifestations of synaptic and neuronal dysfunction and losses in neurodegenerative diseases. Regional patterns of altered glucose metabolism, as imaged with FDG-PET, can indicate the presence of a neurodegenerative process and can characterize involvement of individual cerebral structures and pathways. FDG-PET studies should be performed at the request of physicians knowledgeable in clinical diagnosis and management of dementia and under circumstances in which the results of the examination are likely to have an impact on patient care. Examples of indications for FDG-PET imaging in cognitive decline and dementia include, but are not limited to, the following:

1. Assessment of progressive dementia: Although AD is the most common cause of dementia in the elderly, several other neurodegenerative conditions exist that may be responsible for progressive dementia in the individual patient. FDG-PET can identify the underlying characteristic brain regional patterns of cerebral hypometabolism and can thereby distinguish AD from other degenerative processes such as FTD [17].

2. Assessment of neurodegeneration in subjects with MCI: Several studies support the utility of FDG-PET to identify patients with a course of progressive cognitive decline attributable to a neurodegenerative condition before the onset of clinically diagnosed dementia. Although the use of FDG-PET has not been determined to be useful for screening of asymptomatic patients who may ultimately be at risk of developing dementia, the modality can be useful in patients who meet the criteria for MCI [18-20].
B. Amyloid-PET

Clinical molecular imaging of cerebral fibrillar Aβ-amyloid deposition is based in large part on results obtained with the use of the research radiopharmaceutical 11C-Pittsburgh Compound-B (PiB; [11C] 6-HO-BTA-1). The FDA has recently approved radiofluorinated radiopharmaceuticals (florbetapir, flutemetamol, and florbetaben) for clinical use. The FDA approvals were based on the demonstration that in vivo tracer imaging correlated with the extent or severity of postmortem neuritic plaques in end-of-life patients [21-24]. The biodistribution and imaging characteristics of these newer radiopharmaceuticals, and the indications below, are predicated in part on the basis of findings with PiB, with the expectation that the clinical radiopharmaceuticals have similar discriminatory properties [7]. Pathological depositions of fibrillar Aβ-amyloid are requisite for the pathological diagnosis of AD [25] and are also found in many instances of related neurodegenerative disorders, most frequently in cases of DLB.

Deposition of fibrillar Aβ-amyloid is also found in cognitively normal elderly individuals, increasing in prevalence with age. Nonneurodegenerative disorders, such as primary cerebral amyloid angiopathy, may be amyloid PET-positive [26]. Evolving understanding of the relationships among amyloid deposition, synaptic dysfunction, and losses of neurons and synapses in AD suggest that the amyloid-driven aspects of the pathophysiology occur prior to losses of neurons and synapses, perhaps by many years [27]. Thus, it is anticipated that Aβ-amyloid imaging may be more specific than FDG-PET in differentiating among degenerative dementias, but it may not necessarily provide evidence of a specific neurodegenerative cause of early cognitive complaints in nondemented patients.

The use of amyloid imaging is recommended to determine presence (or absence) of pathological fibrillar Aβ-amyloid deposition in patients with progressive cognitive decline or dementia of uncertain etiology in whom AD is a possibility. Amyloid-PET studies should be performed at the request of physicians knowledgeable in clinical diagnosis and management of dementia and under circumstances in which the results of the examination are likely to impact patient care. Indications for amyloid-PET imaging in cognitive decline and dementia include, but are not limited to, the following: detection of Alzheimer pathology amyloid plaques in cognitively impaired adults. Subjects with progressive cognitive decline who demonstrate features atypical of AD and suggestive of another neurodegenerative process, such as FTD (eg, early age of onset, prominent behavioral dysregulation, or primary progressive aphasia), may have atypical AD presentations or may have FTD. Patients with FTD do not demonstrate abnormal levels of amyloid deposition at pathology evaluation and do not have increased binding of amyloid radiopharmaceuticals in PET imaging. A negative amyloid PET scan is inconsistent with Alzheimer pathology and suggests that AD does not account for symptoms and signs of progressive cognitive decline.

Recently published primary analysis of the Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) study included 11,409 participants with MCI or dementia of uncertain cause. The patient management 90 days after amyloid PET changed (compared with the pre-PET plan) in 60.2% of patients with MCI and 63.5% of patients with dementia. Hence, amyloid PET was associated with changes in the subsequent management of diagnostically challenging patient cognitive disorders [28].

At the present time, clinical amyloid-PET imaging has not been validated for screening asymptomatic subjects with genetic or other risk factors for developing AD or in subjects without a clinical diagnosis of a progressive cognitive decline or dementia as established by a clinician expert in the assessment and management of dementing disorders. In addition, amyloid PET cannot be used to establish the diagnosis of AD or monitor the response to therapy for AD in terms of disease progression or improvement, except as part of an approved clinical research trial of anti-amyloid therapy. A negative amyloid-PET study indicates absence of significant β-amyloid plaques at the time of the study and does not exclude the future development of these plaques.
III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

PET/CT examinations of the brain should be performed under the supervision of and interpreted by a physician who meets qualifications outlined in the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [29]:

and

Initial Education and Experience

For brain FDG PET/CT:
1. Six hours of CME in brain FDG PET/CT interpretation for dementia
2. Thirty proctored or over-read brain FDG PET/CT scans performed for investigation of dementia prior to beginning unsupervised interpretation
3. Live or online education programs may be used to fulfill these requirements

For brain amyloid PET/CT:
1. Three hours of CME in brain amyloid PET/CT interpretation. Live or online educational programs may be used to fulfill this requirement.
2. Interpretation of brain PET images to estimate β-amyloid neuritic plaque density should be performed only by readers who successfully complete a special training program such as one sponsored by the manufacturer of one of the FDA-approved radiopharmaceuticals. Live or online educational programs may be used to fulfill this requirement.

Continuing Education and Experience

For continuing education and experience, please see the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [29] and ACR Practice Parameter for Continuing Medical Education (CME) [30].

B. Qualified Medical Physicist

For qualified medical physicist qualifications, see the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment [31].

C. Radiologic and Nuclear Medicine Technologist

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [32] and the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [29].

Representatives of the SNMMI and the American Society of Radiologic Technologists (ASRT) met in 2002 to discuss training technologists for PET/CT. The recommendations from that consensus conference for training technologists for PET/CT are outlined in the subsequent article published [33]. As a consequence of this conference and ensuing educational recommendations, cross-training and continuing educational programs have been developed to educate radiologic, radiation therapy, and nuclear medicine technologists in PET/CT fusion imaging.

The Nuclear Medicine Technology Certification Board (NMTCB) has developed a PET specialty examination that is open to appropriately educated and trained, certified, or registered nuclear medicine technologists, registered radiologic technologists, CT technologists, and registered radiation therapists, as defined on the NMTCB website (www.nmtcb.org). The American Registry of Radiologic Technologists (ARRT) offers a CT certification.
examination for qualified radiologic technologists and allows certified or registered nuclear medicine technologists who meet the educational and training requirements to take this examination. Eligibility criteria are located on the ARRT website (www.arrt.org).

D. Radiation Safety Officer

The radiation safety officer must meet applicable requirements of the Nuclear Regulatory Commission (NRC) for training as specified in 10 CFR 35.50 or equivalent state regulations.

IV. EXAMINATION FOR THE SPECIFICATIONS

The written or electronic request for PET/CT of the brain should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination. Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

A. Patient Preparation

1. For FDG PET/CT, the major goal of preparation is to minimize radiopharmaceutical uptake in normal tissues, such as the myocardium and skeletal muscle, while maintaining high FDG uptake in the brain. The preparation should include, but not be limited to, the following:
   a. Pregnancy testing when appropriate
   b. Fasting instruction (a minimum of 4 hours) and no oral or intravenous (IV) fluids containing sugar or dextrose
   c. Serum glucose analysis performed immediately prior to FDG administration (an acceptable range is up to 450-200 mg/dL)
   d. Oral hydration to enhance renal excretion of FDG
   e. Focused history regarding the reason for examination (symptoms, diagnoses, and recent imaging examinations), treatments and medications, diabetes and recent exercise. Specific details and dates should be obtained when possible.
   f. Patients should be injected in the awake resting state with eyes open while sitting or lying comfortably in a dimly lit and quiet room. The uptake of FDG when the patient’s eyes are closed may cause hypometabolism in the occipital lobe, possibly leading to a misdiagnosis of DLB [34].
   g. Patients should void prior to being positioned on the PET/CT table. Patients can also be advised to void after completion of imaging to minimize radiation dose to the bladder and internal organs.

2. For a 18F-amyloid binding radiopharmaceutical PET/CT scan, the preparation should include, but not limited to, the following:
   a. Pregnancy testing when appropriate
   b. Focused history regarding the reason for examination (symptoms, diagnoses, and recent imaging examinations) and treatments and medications. Specific details and dates should be obtained when possible.
   c. Oral hydration to enhance renal excretion of the radiopharmaceutical
d. Patients should be injected in the resting state while sitting or lying comfortably in a dimly lit and quiet room.
e. Patients should void prior to being positioned on the PET/CT table.

B. Radiopharmaceutical

1. For FDG, the amount of administered activity should be 185 to 444 MBq (5-12 mCi) IV.
2. For $^{18}$F-amyloid binding radiopharmaceuticals, the amount of administered activity should be 185 to 444 MBq (5-1210 mCi) IV. The recommended doses are 10 mCi, 5 mCi, and 8.1 mCi for flurbetapir, flumetamol, and flurbetaben, respectively [35-37].

Note: With PET/CT, the radiation dose to the patient is the combination of the administered activity from the PET radiopharmaceutical and the dose from the CT portion of the examination. Lower administered activities may be appropriate with longer imaging times and advances in PET/CT technology.

C. Patient Positioning

1. Careful positioning of the patient’s head in the center of the camera’s field of view is critical.
2. The patient should be informed of the need to remain still throughout the scan, and a head holder may diminish movement artifacts. With dementia patients, a comfortable head position, rather than straight, may reduce motion artifacts.
3. Continuous supervision of the patient during the whole scanning procedure is necessary. This is especially important for patients with cognitive impairment.
4. Conscious sedation using a short-acting benzodiazepine for agitation may be needed in selected patients. Sedating medications should be given at least 20 minutes after radiopharmaceutical injection, preferably close to PET/CT acquisition.

D. Protocol for CT Imaging

The CT performed as part of a PET/CT examination provides diagnostic information that may be relevant to both PET interpretation and overall patient care. A variety of protocols exist for performing the CT scan in the context of PET/CT scanning. In most cases, low-dose CT scans are utilized to provide attenuation correction and anatomic localization because the patient will often have an existing MR of the head. In patients in which an MR is contraindicated, the CT portion of the examination can be performed as an optimized brain CT with standard brain CT imaging parameters if ordered by the referring physician. Regardless of the CT technique used, a careful review of CT images is necessary for comprehensive interpretation of the PET/CT examination. Patient positioning should be optimized to minimize radiation dose to the lens.

E. Protocol for PET Imaging

1. A standardized acquisition protocol with a fixed acquisition start time is useful so that comparable data are obtained each time, whether from different patients or repeat scans in the same patient. PET emission acquisition should commence 35 to 60 minutes after FDG administration and 30 to 60 90 minutes after administration of $^{18}$F-amyloid binding radiopharmaceutical. More specific details about the imaging protocol for individual amyloid PET radiopharmaceuticals can be found in the respective package inserts [35-37].
2. The duration of emission acquisition will depend on the performance characteristics of the individual scanner system, but a minimum of 10 minutes in 3-D mode is recommended.
3. PET data should be normalized for detector/geometric effects and corrected for random coincidences, dead time, scatter, and attenuation. Non–attenuation-corrected (NAC) images should also be reconstructed to assess patient motion.
4. If patient movement is a particular concern, the PET/CT scan can be performed as a dynamic acquisition (e.g., five 2-minute frames). The dynamic images may be evaluated for motion and the intact data added...
together prior to final reconstruction. List-mode acquisitions can be used for the same purpose.

5. Images should be reconstructed so as to have a pixel size less than 2 mm in the transverse plane.

6. Iterative or analytic reconstruction methods are acceptable, although consistent technique is important.

7. Reconstruction parameters will depend on injected activity, scanner, acquisition parameters, available software, and the interpreting physician’s preference.

F. Interpretation

1. With an integrated PET/CT system, the software packages typically provide a comprehensive platform for image review.

2. A standard brain image review is recommended to ensure rapid, accurate, and reproducible interpretations. Internal landmark reorientation should be used to achieve standardized image display.

3. The images should be critically examined prior to interpretation for technical quality, especially evidence of movement. NAC PET images should be used to assess motion between CT and PET acquisitions.

4. Fused PET/CT images are helpful to identify motion and evaluate functional-structural findings simultaneously. Fusion of PET with MRI is desirable in select individuals.

5. Review of coronal and sagittal images is highly recommended.

6. Known morphological changes, such as atrophy, must be factored into interpretation of PET data.

7. Three-dimensional display of the data set (eg, by volume rendering or surface projections, such as 3-D stereotactic surface projection (SSP), can be helpful for detection of disease patterns.

8. Comparison to an appropriately appropriate normative database obtained under similar acquisition settings may improve diagnostic accuracy.

9. For amyloid PET/CT, interpretation guidance from special training programs sponsored by the manufacturer of the FDA-approved radiopharmaceuticals need to be followed because they vary between amyloid PET radiopharmaceuticals.

V. EQUIPMENT SPECIFICATIONS

See the ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Brain [38] and the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment [31].

A. Performance Parameters

For patient imaging, the PET/CT scanner should meet or exceed the following specifications:

1. For the PET scanner
   a. In-plane spatial resolution: <6.5 mm
   b. Axial resolution: <6.5 mm
   c. Sensitivity (3-D): >4.0 cps/kBq
   d. Sensitivity (2-D): >1.0 cps/kBq
   e. Uniformity: <5%

2. For the CT scanner (if applicable)
   a. Helical (spiral) scan time: <5 sec (<2 sec is preferable)
   b. Slice thickness and collimation: <5 mm (<2 mm is preferable)
   c. Limiting spatial resolution: >8 lp/cm for >32 cm display field of view (DFOV) and >10 lp/cm for <24 cm DFOV

B. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and
drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. A fusion workstation with the capability to display PET, CT, and fused images with different percentages of PET and CT blending should also be available. The workstation should ideally have the capability to fuse the PET brain images to MR. Quantification software can be a useful adjunct to visual interpretation.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [39].

VII. EQUIPMENT QUALITY CONTROL

PET/CT performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment [31].

Administered activity calibrator performance monitoring should be in accordance with the ACR–SPR Technical Standards for Diagnostic Procedures Using Radiopharmaceuticals [29]. The accuracy of administered activity calibrators used for $^{18}$F should ideally be measured using Germanium-68 ($^{68}$Ge) standards, cross-calibrated for $^{18}$F and traceable to a national metrology lab.

Specific requirements for PET/CT brain imaging include quarterly testing with an $^{18}$F fillable phantom, such as the ACR-approved PET phantom. Phantom images should be analyzed using the appropriate clinical workstations wherever possible. Qualitative assessment should include confirmation that PET and CT images are free from artifacts, particularly side-to-side gradients in intensity. The accuracy of the spatial registration of the PET and CT images should ideally be assessed quantitatively, although qualitative assessment is acceptable. The centers of the phantom inserts should be closely aligned on PET and CT with no systematic differences across the images. The uniform region of the PET images should have a standard uptake value in the range 0.9 to 1.1, with a target range of 0.95 to 1.05. Resolution recovery of the phantom inserts should be stable over time, and current measurements should be consistent with previous data, eg, mean ± 2 SD of prior measurements.

A check of the performance of both the PET and CT components is required every day that the scanner is to be used and should be performed prior to patient imaging. The nature of these procedures will vary between scanner systems, and manufacturer recommendations should be followed. For PET, such tests should include verification of PET detector integrity, which involves a quantitative comparison of various detector parameters to reference values. Daily CT quality control should include a scan of a standard CT water phantom. The accuracy of the resulting CT numbers and image noise should be recorded.

When not indicated by the manufacturer’s daily recommendations, a $^{68}$Ge cylinder phantom is recommended for periodic assessment of PET/CT system stability. Additional use of this phantom is recommended after scanner maintenance or scheduled scanner recalibration and should be performed prior to patient imaging.

The dates and results of all quality control procedures should be recorded.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

IX. RADIOPHARMACEUTICALS QUALITY CONTROL

A. FDG

\[ \text{FDG} \]

\(^{18}\text{F}\) FDG refers to a positron-emitting radiopharmaceutical containing radioactive 2-deoxy-2-(\(^{18}\text{F}\)) fluoro-d-glucose, which is used for diagnostic purposes in conjunction with PET. It is administered by IV injection. The active ingredient, 2-deoxy-2-(\(^{18}\text{F}\)) fluoro-D-glucose, abbreviated \(^{18}\text{F}\) FDG, has a molecular formula of \(\text{C}_6\text{H}_11\text{F}_6\text{O}_5\) with a molecular weight of 181.26 Da. \(^{18}\text{F}\) decays by positron (\(\beta^+\)) emission and has a half-life of 109.7 minutes. The principal photons useful for diagnostic imaging are the 511 keV gamma photons, resulting from the annihilation of the emitted positron with an electron.

\(^{18}\text{F}\) FDG is taken up by cells and phosphorylated to \(^{18}\text{F}\)-FDG-6-phosphate (\(^{18}\text{F}\)-FDG-6P) at a rate proportional to the rate of glucose utilization within a given tissue. \(^{18}\text{F}\)-FDG-6-phosphate is not metabolized further in the glycolytic pathway (it is not a substrate for hexose phosphate isomerase) and is relatively trapped in the cell. In some cells, \(^{18}\text{F}\)-FDG-6-phosphate may be dephosphorylated back to \(^{18}\text{F}\)-FDG via glucose-6-phosphatase. This pathway is relatively minor in brain, skeletal muscle, and cardiac muscle, which permits PET imaging of the accumulated \(^{18}\text{F}\)-FDG-6P in these target tissues. Many neoplasms have similar high phosphorylation to
dephosphorylation rates, resulting in trapping of $^{18}$F FDG and retention of $^{18}$F-FDG-6P. $^{18}$F FDG that is not involved in glucose metabolism is excreted unchanged in the urine.

B. Amyloid-avid Radiotracers

As of June 2014, the US FDA has approved the use of three amyloid-avid radiotracers for human imaging of fibrillar amyloid deposition in the brain. Each of the tracers has the fundamental property of binding to fibrillar Aβ amyloid aggregates, and a given tracer results in highly similar brain images in subjects with and without pathologic amyloid deposition [7].

$^{18}$F florbetapir is described as (E)-4-(2-(6-(2-(2-[18F]fluoroethoxy)ethoxy)ethoxy)pyridine-3-yl(vinyl)-N-methylbenzamine. The molecular weight is 359 and the structural formula is as follows [35]:

![Florbetapir Structural Formula](image)

$^{18}$F flutemetamol is described as 2-[3-[18F]fluoro-4-(methylamino)phenyl]-6-benzothiazolol. It has the molecular formula C14H1118FN2OS, molecular weight 273.32, and the following structural formula [36]:

![Flutemetamol Structural Formula](image)

$^{18}$F florbetaben is described as 4-[(E)-2-(4-(2-[18F]fluoroethoxy)ethoxy)phenyl]vinyl]-N-methylaniline. The molecular weight is 358.45, and the structural formula is [37]:

![Florbetaben Structural Formula](image)

The time-activity curves for the amyloid tracers in the brains of subjects with positive scans are similar across the individual agents, showing continual signal increases from time zero through 30 approximately 30 minutes post administration with stable values thereafter up to at least 90 minutes post injection. Differences in the signal intensity between portions of the brain that specifically retain the amyloid tracer and the portions of the brain with nonspecific retention form the basis of image interpretation. The specific binding of the radiotracers to Aβ-amyloid aggregates was demonstrated in postmortem human brain sections using autoradiographic methods, thioflavin S, and traditional silver-staining correlation studies as well as monoclonal antibody Aβ-amyloid–specific correlation studies. Radiotracer binding to tau protein aggregates and alpha-synuclein aggregates and a battery of neuroreceptors was not detected in in vitro studies. Tracer-specific binding to fibrillar Aβ-amyloid aggregates in vivo was confirmed for each of the tracers in comparison to autopsy measures of amyloid burden.

Amyvid® contains florbetapir $^{18}$F and is described as (E)-4-(2-(6-(2-(2-[18F]fluoroethoxy)ethoxy)ethoxy)pyridine-3-yl(vinyl)-N-methylbenzamine. The molecular weight is 359 and the structural formula is:

Vizamyl® contains flutemetamol F18 and is described as 2-[3-[18F]fluoro-4-(methylamino)phenyl]-6-benzothiazolol. It has the molecular formula C14H1118FN2OS, molecular weight 273.32, and the following structural formula:

Neuraceq® contains florbetaben F-18 and is described as 4-[(E)-2-(4-(2-[18F]fluoroethoxy)ethoxy)ethoxy]phenyl] vinyl]-N-methylaniline. The molecular weight is 358.45 and the structural formula is:
X. 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).

For specific issues regarding CT quality control, see the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [32].

For specific issues regarding PET and PET/CT quality control, see Section VIII on Equipment Quality Control.

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [40].

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36. GE Healthcare. Highlights of Prescribing Information: These highlights do not include all the information needed to use VIZAMYL safely and effectively. See full prescribing information for VIZAMYL. VIZAMYL (flutemetamol F 18 injection) for intravenous use. ; Initial U.S. Approval: 2013.

37. Piramal Imaging. Highlights of Prescribing Information: These highlights do not include all the information needed to use NEURACEQ safely and effectively. See full prescribing information for NEURACEQ. NEURACEQ (florbetaben F 18 injection), for intravenous use. ; Initial U.S. Approval: 2014.


APPENDIX A
DEFINITIONS

For the purpose of this practice parameter, the following definitions apply:

PET/CT scanner: A device that includes a single patient table for obtaining a PET scan, a CT scan, or both. If the patient stays reasonably immobile between the scans, the PET and CT data are aligned and can be accurately fused.

PET/CT acquisition: The process of collecting PET/CT data. In the context of brain imaging, data will be acquired from the vertex to the base of the skull. Typically this range will be encompassed by the axial field-of-view of the PET system, ie, no bed translation during PET data acquisition.

PET/CT registration: The process of taking PET and CT image sets that represent the same brain volume and aligning them such that there is a voxel-by-voxel match for the purpose of combined image display (fusion) or image analysis.

PET/CT fusion: The simultaneous display (superimposed or not) of registered PET and CT image sets. When superimposed, the image sets are typically displayed with the PET data color-coded onto the grayscale CT data.

PET/MRI scanner: A device that includes a single patient table for obtaining a PET scan and an MRI scan.
in a simultaneous manner.

*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.

Development Chronology for this Practice Parameter
2015 (Resolution 21)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Cervicocerebral Computed Tomography Angiography (CTA)

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2015 (Resolution 19)*

ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF CERVICOCEREBRAL COMPUTED TOMOGRAPHY ANGIOGRAPHY (CTA)

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

1 Iowa 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Cervicocerebral computed tomography angiography (CTA) is a proven and useful procedure for the detection and characterization of vascular diseases and of vascular anatomy relevant to the treatment of extravascular disorders [1]. CTA may be used as the primary modality for detecting disease or as an adjunctive tool for characterizing known disease or assessing changes over time. With the goal of reducing radiation exposure to children, magnetic resonance angiography (MRA) should be the first line of imaging in the pediatric and other vulnerable populations given the appropriate clinical setting. Whenever possible, magnetic resonance angiography (MRA) should be considered as an alternative to CTA to reduce radiation exposure, especially in the pediatric and vulnerable populations [2,3]. Although it is not possible to detect all cerebrovascular abnormalities using CTA, adherence to the following practice parameter will maximize the probability of their detection and optimize patient safety.

CTA is a medical imaging technology that exposes patients to ionizing radiation. It should only be performed under the supervision of a physician with the necessary training in radiation biology and protection to optimize patient safety. Medical physicists and trained technical staff must be available.

CTA should be performed only for a valid medical indication and with the minimum exposure that provides the image quality necessary for adequate diagnostic information.

CTA is primarily performed to assess the heart, arteries, or veins. It requires, at a minimum, a thin-section helical (spiral) CT acquisition coupled with a power injection of intravenous (IV) iodinated contrast medium. Three-dimensional rendering and multiplanar reformations are important components of many CTA examinations.

II. INDICATIONS

Indications for CTA of the head and neck vessels include, but are not limited to, the diagnosis, characterization, and/or surveillance of:

1. Arterial aneurysms or pseudoaneurysms, and venous varices, and dissections [2-10]
2. Ischemic stroke, transient ischemic attacks, vasospasm, and thromboembolism, including collateral assessment [9,11-24]
3. Intracranial Acute neurologic, head and neck, and cervical spine hemorrhage and intraspinal hemorrhage [25-29]
4. Vasculitis and collagen vascular diseases. Atherosclerotic steno-occlusive disease, including atherosclerotic plaque localization and characterization [1,30-39]
5. Nonatherosclerotic, noninflammatory vasculopathy, including radiation vasculopathy
6. Vasculitis and collagen vascular diseases [40]
8. Venous and dural sinus thrombosis and stenosis when performed as a dedicated CT venogram (CTV) [50-52]
9. Vascular malformations and fistulas [53]

**10. Pulsatile tinnitus [54]**
11. Vascular anatomic variants [35,55]
12. Evaluation for vascular intervention and follow-up (percutaneous and surgical) [56-70]
13. Tumors of vascular origin, with rich vascular supply or involving vascular structures [68,71-75].

**14. Surgical and radiation therapy localization, planning, and neuronavigation [70,76]** of arterial and venous structures for surgical planning
15. Dynamic/positional CTA to assess for vascular compression vertebrobasilar insufficiency (bowhunter’s syndrome and Eagle syndrome) [77,78]
16. Brain death [79]
17. Cervical and upper thoracic spine injuries in the setting of trauma
18. Postsurgical/posttreatment vascular complications

For certain indications, such as cerebral aneurysms and vasospasm, it may be appropriate to limit CTA to include only the head to avoid unnecessary radiation to the patient.

For the pregnant or potentially pregnant patient, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [80].

**III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [81].

**A. Physician**

Examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

The physician should meet the criteria listed in the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) and in the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media and should be trained in radiation safety [81,82].

1. The physician is responsible for reviewing indications for the examination and for specifying the parameters of image acquisition; the route, volume, timing, type, and rate of contrast injection; and the method of image reconstruction and archival. The physician should monitor the quality of the images, be aware of potential artifacts [83], and interpret the study. Interpreting physicians must have knowledge of the benefits and risks of the procedures. Knowledge of the head and neck anatomy, including the vascular anatomy, and diseases of the intracranial and extracranial cerebrovascular system and their treatment is required.

2. Non-radiologist Physicians meeting the aforementioned criteria additionally must have knowledge of the spectrum of nonvascular abnormalities presenting on CT scans. They should be capable of identifying and characterizing important nonvascular abnormalities that may be included visualized on CTA, such as neoplasia, sequelae of infection, trauma, noninfectious inflammatory diseases, congenital anomalies, and normal anatomic variants, and any other abnormalities that may affect patient care and might necessitate treatment or further characterization through additional diagnostic testing.
Not for publication, quotation, or citation

3. The physician should be familiar with the use of 3-D processing workstations and be capable of performing or directing creation of 3-D renderings, multiplanar reformations, and measurements of vessel dimensions.

4. The physician should work with a Qualified Medical Physicist to optimize site-specific CTA scan protocols, including minimizing the field of view, when possible.

B. Technologist

The technologist should have the responsibility of patient comfort, preparing and positioning the patients for the CT examination, monitoring the patient during the examination, and obtaining the CT data in a manner prescribed by the supervising physician. For the IV administration of contrast material for CTA, qualifications for technologists performing IV injections should be in compliance with current ACR policy and existing operating procedures or manuals at the imaging facility. The technologist should perform the regular quality control testing of the CT system under the supervision of a medical physicist (ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media) [82].

1. The technologist performing CT examinations should be certified by the American Registry of Radiologic Technologists or have an unrestricted state license with documented training and experience in CT.

IV. SPECIFICATIONS OF THE EXAMINATION

CTA is a broad term that may refer to evaluation of arterial vessels, known as CTA, or evaluation of venous structures, known as CT venography (CTV). The equipment and contrast used for these examinations is the same. The scan protocols differ in the time delay to scanning following the injection of contrast.

The written or electronic request for a cervicocerebral CTA should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

A. Patient Selection and Preparation

Patients without absolute contraindication to the administration of iodinated contrast media are candidates for cervicocerebral CTA. In cases of relative contraindication to the administration of iodinated contrast medium, measures to reduce the possibility of contrast medium reactions or nephrotoxicity should be followed to the extent that the patient’s condition allows, as defined in the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media, or an alternative vascular imaging modality should be considered, eg, magnetic resonance angiography (MRA) [82,84].

When possible, patients should be well hydrated, and IV access should be established. A 20-gauge or larger antecubital IV catheter should be placed ideally on the right side to accommodate an optimal rate of 4 or 5 mL/s of iodinated contrast media. Smaller catheters that can withstand the prescribed injection rates can be used, and lower
injection rates may be used for pediatric patients. All catheters used for the CTA examination should first be tested with a rapidly injected bolus of sterile saline to ensure that the venous access is secure and can accommodate the rapid bolus, minimizing the risk of contrast medium extravasations. The injection site should be monitored by medical personnel trained in the rapid recognition of IV extravasations. Department procedures for care of IV extravasations should be documented and applied if necessary.

B. CT Equipment

The use of a multidetector-row CT scanner is preferred for CTA. Helical CT acquisition is mandatory for CTA. A complete gantry rotation should be no greater than 1 second, and preferably less. The scanner must be capable of detecting and reliably diagnosing pathology in the adjacent structures and end organs of the vessels.

A contrast medium power injector that allows programming of both the volume and flow rate must be used for head and neck CTA examinations.

Capability of creating multiplanar reformations, curved planar reformations, maximum-intensity projections, and volume renderings, and/or shaded surface displays should be available for CTAs and applied to the appropriate study. A method of bone removal for intracranial vessels is desirable. The direct measurement of vascular diameters and, when appropriate, path lengths should also be available.

C. Examination Technique

Prior to acquiring the CTA, an unenhanced helical CT acquisition a noncontrast head CT (NECT) may be obtained, depending on the clinical suspicion, presentation, and acuity, for detecting mural or extravascular hemorrhage, mapping of arterial calcification, or localization of the anatomy of interest. Similarly, once contrast has already been administered for the CTA, a delayed contrast-enhanced head CT (CECT) can be of value to detect areas of delayed/parenchymal enhancement, slow-flow lesions, and/or spot sign not captured on the CTA. The section thickness for this preliminary these additional CT acquisitions is application dependent but should not exceed 5 mm. The radiation exposure to the patient should be minimized within the limits of acceptable image quality, including optimization of peak kilovoltage (kVp) and mAs [85,86]. In infants and children, any being imaged, there weight- or age-appropriate guidelines should be written guidelines used for acceptable CT radiation exposure, including weight-appropriate or age-appropriate guidelines to reflect the “as low as reasonably achievable” (ALARA) principle. If available, dose modulation and iterative reconstruction approaches should be used, with appropriate targeted signal-to-noise ratio [87,88].

Because of substantial variations in the time required for an IV contrast medium injection of nonionic contrast medium (iodine, 300-370 mg/mL) to reach the target vascular anatomy, an assessment of patient-specific circulation time is frequently required, especially for arterial imaging, although not mandatory. Circulation timing can be performed using one of the following techniques [89]:

1. Intravenous injection of a small test bolus (eg, 10-15 mL) of contrast medium at the same rate and through the same access that will be used for the CTA followed by acquisition of sequential cine CT images at the level of the artery or vein of interest. The rate and intensity of enhancement of the lumen of interest are then used to create a time density curve. The peak of the curve is used to calculate the scanning delay postinjection. A perfusion CT series performed before the CTA can be used similarly to a test bolus for determining the timing of the CTA acquisition.

2. The use of automated or semiautomated triggering software based on monitoring of the attenuation within the vessel of interest (or a great vessel such as the aorta) by the CT scanner following initiation of the full dose of contrast media injection. The CTA is automatically started when the enhancement in the vessel reaches a predetermined operator-selected level.
3. For CTV, administration of nonionic contrast medium (iodine, 300 to 370 mg/mL) at a rate of 3 mL/sec with a 40-50 second prescanning delay, or a 30 second delay after the arterial bolus time, should allow adequate opacification of the venous structures minimizing flow artifacts.

Ideally the administration of iodinated contrast media for the CTA should be performed with a minimum flow rate of 4 mL/s in any patient weighing 50 kg or more. Higher flow rates up to 6 mL/s or greater are frequently required for larger patients, and in general, higher flow rates are required for shorter acquisitions. In children, contrast medium dosing should be scaled to body weight. Injection rate should be scaled similarly and preferably delivered via powered injection. For young children and infants, a 22- or 24-gauge IV catheter may be the only option, and a 2 mL/s injection rate may be reasonable for these patients. For patients under 50 kg, a dose of 2 mL/kg should be considered, with an option for increase in the very young patient. In summary, contrast injection parameters should be modified on an individual patient basis, and the volume of contrast medium should be selected with consideration of the patient’s weight and comorbidities that might increase the risk of nephrotoxicity. When performing cervicocerebral CTA, a right-arm injection is preferable to a left-arm injection to avoid artifacts from undiluted contrast medium in the left brachiocephalic vein. When possible, a bolus of saline following the iodinated contrast medium injection may reduce the volume of contrast medium required to achieve adequate vascular opacification.

The cervicocerebral CTA acquisition should be performed with a section thickness of 1.5 mm or less, depending on the vascular territory to be assessed. The scan should be reconstructed with overlapping sections, at a maximum increment of 50% of the effective section thickness. For many indications, such as intracranial aneurysms, vasospasm, and venous/dural sinus thrombosis, CTA imaging only needs to include the head. When CTA imaging of the neck is performed, such as in the setting of trauma/cervical fractures, the acquisition should at least cover the aortic arch, the origin and cervical course of the subclavian and carotid arteries, and proximal subclavian arteries, through the skull base (e.g., the floor of the Sella). For many indications, such as stroke imaging, the acquisition should be extended through the Circle of Willis and may be extended up to the cranial vertex. For examinations not limited to the head (such as intracranial aneurysms, vasospasm, and venous/dural sinus thrombosis), the acquisition should at least cover the aortic arch, the origin and cervical course of the subclavian and carotid arteries, the Circle of Willis, and may be extended up to the cranial vertex. In some patients, coverage can extend to include the heart, complete aortic arch, the left atrium, the distal intracranial arteries, and the venous sinuses. In the pediatric population, anatomic coverage should be strictly limited to the vascular segments of interest, and variable mA is important in order to keep the radiation dose as low as possible. Automated tube voltage selection can also be employed in conjunction with tube current modulation when available.

Postprocessing of the CTA by either physicians, radiologic technologists, or appropriately trained staff to provide multiplanar reformations and/or 3-D renderings is recommended. Volume renderings, maximum-intensity projections, shaded surface displays, and curved planar reformations must be created by a person with knowledge of both cervicocerebral vascular anatomy and pathology to avoid misrepresenting normal regions as diseased and vice versa. Segmentation of the CT data through a variety of manual and automated means may facilitate vascular visualization and measurement of stenosis, but it must be performed with care to avoid excluding key regions of the anatomy or creating pseudolesions. Pertinent measurements of vascular dimensions should be performed.

When applying the North American Symptomatic Carotid Endarterectomy Trial (NASCET) method for evaluation of cervical internal carotid artery stenosis, it is important for the interpreting physician to take into consideration that the denominator measurement needs to be done well beyond the tapering bulb, which tapers over a long distance, and should only be done where the vessel walls are parallel. An alternate method uses the residual lumen diameter measured in millimeters. This approach has been validated against the NASCET methodology and has been shown to be reproducible, to be easy to implement, and to provide similar information equivalent data. When faced with near occlusion, the NASCET methodology does not apply.
D. Interpretation

Cervicocerebral CTAs are preferentially interpreted on equipment that allows stacked dynamic paging of the primary transverse and the reformatted CTA sections. A complete interpretation includes review of all images, including the scout and the transverse CT sections (source images) and, as indicated, multiplanar/curved reformations, volume renderings, maximum-intensity projections, and other images produced during postprocessing. On occasion, the interpreting physician will personally create postprocessed images documenting important findings that are essential to the interpretation of the study [98]. These images should be archived with the patient’s original study or other postprocessed images. Interpretation of the cervicocerebral CTA includes an assessment of the patency and caliber of the carotid and vertebral arteries, their origins, the carotid bifurcations, the intracranial arteries, possible occlusion, dissection, stenosis, and aneurysmal dilatation. To the extent that venous structures are adequately opacified on CTA images, as opposed to a dedicated delayed CT venogram (CTV), evaluation of images for venous pathology is also necessary. The visible and adequately opacified veins should be commented on when appropriate. Interpretation of dedicated cervicocerebral CTV includes an assessment of the patency and caliber of the dural venous sinuses, cortical veins, and internal jugular veins. The visible and adequately opacified arteries should be commented on when appropriate.

The visible regional anatomy and pathology should be commented on when appropriate. In the setting of suspected traumatic injury, the soft issues surrounding the vasculature and adjacent bony structures in the cervical region should be assessed. Comparison with prior studies should be performed when appropriate.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [99].

In addition to examining the cervicocerebral vascular structures of interest, the CTA sections should be examined for clinically relevant extravascular abnormalities bearing clinical relevance. These abnormalities should be described in the formal report of the examination.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [100].

For diagnostic quality CTA, the CT scanner should meet or exceed the following specifications:

1. Cervicocerebral CTA should be performed on a multidetector CT (MDCT) scanner, preferably with greater than or equal to four active detector rows.
2. Gantry rotation: 1 second or less for cervicocerebral CTA.
3. Tube heat capacity that allows for a single ≥10-second acquisition.
4. Minimum Section thickness: no greater than 3 mm, preferably no greater than 1.5 mm.

To maximize information available from the CT scan and thus derive the full diagnostic benefit for the patient following x-ray irradiation, any CT scanner used for CTA must allow display and interpretation of the full 12 bits (from −1,000 to 3,095 Hounsfield units) of attenuation information. Additionally, the display field of view must be sufficient to allow an assessment of the vasculature of interest, the end-organ, and adjacent tissues. Dual-energy CTA can be obtained when available to decrease total patient radiation dose, lower contrast administration, distinguish contrast from hemorrhage and calcium, and reduce hardware artifacts [101-104].
Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

Utilization of iterative image reconstruction techniques, when available, is recommended to reduce image noise and artifacts, thereby allowing significant dose reduction.

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).
This practice parameter was developed according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Neuroradiology of the ACR Commission on Neuroradiology and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ASNR, and the SPR.

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PRACTICE PARAMETER

Cervicocerebral CTA

2020 Resolution No. 42


*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.

Development Chronology for this Practice Parameter
2010 (Resolution 20)
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BE IT RESOLVED,
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Revised 2015 (Resolution 10)*

ACR–ASNR–SNIS–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF CERVICOCEREBRAL MAGNETIC RESONANCE ANGIOGRAPHY (MRA)

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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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

1 Iowa 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the Society of NeuroInterventional Surgery (SNIS), and the Society for Pediatric Radiology (SPR).

Cervicocerebral Magnetic resonance angiography (MRA) is a general term that refers to various MRA techniques used for the diagnostic evaluation, quantitative or qualitative severity assessment, of severity and follow-up and surveillance of arterial and venous vascular diseases of the brain, head, and neck. Cervicocerebral system MRA is a rapidly evolving technology; and consequently only therefore, general recommendations can be made regarding imaging techniques. Detailed imaging protocols have been omitted here to avoid promoting obsolete methodology. The practitioner should periodically review the imaging protocols and update the protocols them as needed using resources from the literature, major MR manufacturers, and professional imaging society meetings and their websites (eg, ASNR, International Society for Magnetic Resonance in Medicine, Society of Cardiovascular Magnetic Resonance, MR Angiography Club, Society for Magnetic Resonance Angiography, and other similar resources).

MRA has important valuable attributes that make it valuable in assessing for the imaging assessment of a wide spectrum of vascular diseases [1,2]. Compared with radiographic catheter-based angiography, it is noninvasive without any risk of vascular injury, ischemic neurological complications, deficit, circulatory compromise due to vascular injury or adverse effects of or iodinated contrast reactions. material Compared with vascular ultrasound, it is less operator dependent, has greater freedom from interference by body habitus, and has provides greater three-dimensional (3-D) capability. These benefits must be balanced against the limitations and technical artifacts of MRA, which include such as degraded image quality due to patient motion, artifacts generated by vascular slow or turbulent flow, patient motion and metal and/or susceptibility effects, which can lead to degraded imaging. In general, MRA has lower spatial resolution in comparison with computed tomography (CT) or digital subtraction angiography, but emerging high-resolution MRA techniques have the potential for to replace current examination techniques nephrogenic systemic fibrosis (NSF) in at-risk populations undergoing gadolinium contrast-enhanced (CE) MRA also needs to be considered [3-9]. The ACR Manual on Contrast Media provides detailed recommendations for the use of gadolinium contrast agents in at-risk groups [10].

Children typically demonstrate a different spectrum of neurovascular conditions. Imaging protocols tailored for adult patients may not be optimal or even appropriate in the pediatric setting. Cervicocerebral MRA can provide valuable information regarding flow conditions, congenital/developmental vascular anomalies/abnormalities, and acquired pathologic processes pathology that may involve the pediatric brain and spine without the concern for radiation to the developing central nervous system. Performing successful MRA evaluation in pediatric patients is more complex and poses unique technical and safety issues [11]. In general, the fast intracranial flow in pediatric patients makes can be leveraged for time-of-flight (TOF) MRA sequences a useful choice in most cases, avoiding contrast administration and reducing the need for the more technically challenging contrast enhanced (CE)-MRA. The smaller size of the pediatric patient requires MRA scanning with a decreased field of view (FOV) to delineate smaller structures. Higher-resolution sequences Finally, sedation is frequently may be necessary in order to limit motion artifacts and obtain a diagnostic-quality examination.
Application of this practice parameter should be in accordance with the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [12] and the ACR–SIR Practice Parameter for Sedation/Analgesia [13].

Cervicocerebral MRA should be performed only for valid medical reasons. Additional or specialized pulse sequences are frequently required to optimize the examination. Although it is not possible to detect all abnormalities by using cervicocerebral MRA, adherence to the following practice parameter will enhance the probability of their detection.

II. INDICATIONS

A. Adult and Pediatric Indications for Cervicocerebral MRA

MRI/MRA is typically the imaging modality of choice for the initial evaluation of the cervicocerebral vasculature in children [14]. It is a noninvasive and low-risk examination free of ionizing radiation as compared with conventional endovascular (catheter) or CT angiographic procedures. Studies of pediatric stroke that compared MRA with conventional angiography found MRA to be accurate in delineating stenosis and/or occlusion and able to demonstrate vascular anatomy in a variety of pathologic conditions [15-22]. In some clinical instances, follow-up computed tomographic angiography (CTA) CT or catheter angiography may be necessary to further characterize the abnormality.

Indications for cervicocerebral MRA in the pediatric population include, but are not limited to, the definition detection and evaluation of the following:

1. Atherosclerotic or nonatherosclerotic steno-occlusive disease, thromboembolism or vasospasm in the setting of cerebral ischemia, and infarction [23-27]
2. Traumatic injury to cervicocerebral vessels, including dissection [28-30]
3. Intracranial or extracranial aneurysms, pseudoaneurysms, and venous varices [24,25,27,31-35]
4. Cerebral intracranial or extracranial, congenital or acquired arteriovenous malformations (AVMs), vein of Galen malformations, dural venous malformations, arteriovenous fistulas, proliferative angiopathy, hemangiomas, venous malformations, lymphatic malformations, or other low-flow vascular malformations [24,25,27,36-40]
5. Etiology of intracranial/intraspinal hemorrhage
6. Vasculitis and vasculopathy including, but not limited to, collagen vascular disease [41,42]; flow-mediated dilatation; sickle cell [43]; moyamoya disease or steno-occlusive vasculopathy [44]; and nonatherosclerotic, noninflammatory vasculopathy
7. Tumor vascular supply, tumor invasion, encasement, or constriction of vasculature
8. Localization of relevant vascular anatomy/pathology for preoperative and/or radiation treatment planning
9. Relevant vascular anatomy/pathology for preprocedural and/or postprocedural evaluation and determining the effect of therapeutic interventions, including endovascular embolization and/or stent placement in treatment of stenosis, dissections, aneurysms, AVMs, tumor embolization [25], and/or posttreatment changes following interventional/surgical procedures or radiation therapy [45,46]
10. Soft-tissue vascular anomalies in the head and neck [47]
11. Vascular status following extracorporeal membrane oxygenation (ECMO)
12. Pulsatile tinnitus, bruits, and neuralgia that might result from vascular etiology
13. Dural venous sinus thrombosis and intracranial venous steno-occlusive disease [36,37,40]

B. Evaluation of the aortic arch and subclavian arteries in adults and children may require separate techniques and sequences. Indications include, but are not limited to, the detection and evaluation of the following [48-50]:

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1. Dissection of the aorta and/or great vessels to the brain
2. Aneurysm of the aorta and/or great vessels its branches
3. Presence and extent of Atherosclerotic occlusive disease of the great vessels and subclavian steal
4. Identification of Congenital abnormalities of the aorta, such as including coarctation, double aortic arch, and aberrant subclavian artery
5. Evaluation of Superior vena cava syndrome or unilateral upper-extremity edema
6. Normal vascular anatomy versus aneurysms/masses for preoperative planning

13. Evaluation of etiology of intracranial/intraspinal hemorrhage hemorrhage and
14. Sickle cell vasculopathy [43]
15. Vasculitis and collagen vascular disease [41,42]
16. Moyamoya disease [44]
17. Detection and evaluation of aneurysms, or pseudoaneurysms, and venous varices [32,34]
18. Cerebral arteriovenous malformations (AVMs), arteriovenous fistulas, and venous–vascular malformations [33,34]
19. Vascular status following extracorporeal membrane oxygenation.
20. Blood supply to vascular neoplasms for operative planning
21. Acute ischemic stroke, vasospasm, and thromboembolism [27]
22. Traumatic injury to cervicocerebral vessels, including dissection [28]
23. Localization of arterial and venous structures for operative planning
24. Invasion, encasement, and constriction of blood vessels by neoplasm
25. Soft-tissue vascular anomalies in the head and neck region [33]
26. Dural sinus thrombosis and intracranial venous occlusive disease
27. Atherosclerotic steno-occlusive disease
28. Nonatherosclerotic, noninflammatory vasculopathy

B. Indications for cervicocerebral MRA for adults include, but are not limited to, the definition and evaluation of the following:
1. Etiology of intracranial/intraspinal hemorrhage hemorrhage and
2. Dural sinus thrombosis and intracranial venous occlusive disease [36,37,40]
3. Presence and extent of atherosclerotic occlusive disease and thromboembolic phenomena in the setting of patients presenting with symptoms of cerebral ischemia and infarction [34-36]
4. Relevant vascular anatomy for preprocedural evaluation and determining the effect of therapeutic measures, including the endovascular coil embolization treatment of aneurysms and AVM embolization [36,36]
5. Presence, location, and anatomy of extracranial and intracranial aneurysms and vascular malformations [35-37]
6. Presence, nature, and extent of traumatic injury to cervicocerebral vessels, including dissection [38,39]
7. Vascular supply to tumors and vessel encasement and narrowing by tumors
8. Nature and extent of other congenital or acquired AVM (soft tissue) vascular anomalies (eg, hemangioma, venous malformation, AVM, lymphatic malformation) [43-45]
9. Extent of disease in vasculitis and vasculopathy
10. Operative planning for tumor resection
11. Differentiation of aneurysms and masses
12. Definition of the relationship of masses to nearby vascular structures
13. As a measuring tool for treatment of occlusive disease of the extracranial vessel (ie, subclavian, innominate, common carotid)
III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [12].

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [12] and the ACR Guidance Document on MR Safe Practices: 2013 [51].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [1,21].

V. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for Cervicocerebral MRA should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

The supervising physician must have complete understanding of the indications, benefits, and risks of the examination as well as alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI, including incompatible devices and potential adverse reactions to contrast media. The physician should be familiar with relevant ancillary studies that the patient may have undergone (see the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [52]). The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

A. Patient Selection

The physician responsible for the examination should supervise patient selection and preparation and be available in person or by phone for consultation. Patients must be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment (eg, incompatible metallic implants surgical devices, etc). See the ACR MR Guidance Document on MR Safe Practices: 2013 [51].

Certain indications require administration of intravenous (IV) contrast media. IV contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution’s policy on IV contrast used. Patients receiving gadolinium contrast agents should be evaluated for potential risk of nephrogenic systemic fibrosis (NSF) according to the recommendations in the chapter on NSF in the ACR Manual on Contrast Media [10].
Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate sedation may enable achievement of a successful examination. If moderate sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [13]. Additional considerations and equipment may be required in critically ill or intubated patients under general anesthesia.

B. Facility Requirements

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of age and sizes in the patient population.

C. Examination Technique

MRA is a general term that refers to a diverse group of MR pulse sequences. Multiple methods can be used to generate signal from flowing blood, and each method may be performed with a variety of coils, acquisition sequences, and display techniques. TOF gradient recall echo (GRE) techniques rely on flow-related enhancement to generate images of blood flow within the vascular lumen. Flow Anatomic vascular images and quantitative measurements of flow velocity can be obtained using phase-contrast (PC) MRA techniques in which the image contrast is generated by velocity-induced phase shifts. CE MRA relies on enhancement of the blood signal by paramagnetic contrast agents and typically uses rapid, 3-D T1-weighted gradient-echo acquisitions. CE MRA can provide higher spatial resolution with the first-pass techniques or provide temporal resolution with time-resolved 4-D techniques [53-56]. Vascular images can also be generated by arterial spin-labeling (ASL), and blood can be directly imaged using methods such as inflow inversion recovery [57-59]. Individuals Practitioners using MRA must understand the artifacts and limitations of each imaging technique. The most commonly used techniques are common MRA sequences utilize non-contrast 2-D and 3-D TOF, and CE 3-D PC, 3-D CE, and 4-D CE time-resolved techniques.

1. Noncontrast TOF MRA

In 2-D TOF MRA acquisitions, contrast between flowing blood and stationary surrounding tissue is generated by acquiring multiple thin slices oriented perpendicular to the direction of blood flow to maximize the signal enhancement due to inflow of blood within vascular structures. These 2-D slices are obtained and combined to form a 3-D volume data set. Vascular structures are isolated from the surrounding tissue by projecting the pixels with maximum intensity into multiple planar views called maximum intensity projection (MIP) images. 3-D TOF techniques directly acquire a 3-D volume. Multiple 3-D volumes using short echo time/repetition time (TE/TR) sequences are typically obtained with overlapping edges to provide coverage of the region of interest. Focused assessment of the vascular structures from the 3-D volume set data can also be displayed with planar- and volume-rendered MIP imaging [60-63].

MRA data sets can also be displayed as 2-D source images. The supervising physician should always review the source images in an effort to improve diagnostic accuracy. Review of the source images can reduce possible confusion of high signal material T1 shortening related to proteinaceous cysts, fat, or thrombus with flow-related enhancement; assist in diagnosis by differentiating overlapping structures, differentiate artifacts caused by tissue motion due to swallowing, cardiac pulsation, or respiration between sequential 2-D slices, and identify artifacts that can cause spurious increase or decrease in flow-related signal [64]. (eg, fat or thrombus) with flow signal, aid diagnosis by eliminating overlapping structures, and identify artifacts that can cause spurious increase or decrease in flow-related signal.

Rotating displays of 3-D volumetric MIP images allow separation of vessels that are superimposed on routine planar projections. The supervising physician should be familiar not only with MIP displays but
also with surface displays, volume displays, and multiplanar reformatting techniques, including their strengths and limitations. The type and frequency of artifacts will vary with the display technique; thus, the supervising physician must understand the potential errors with each display method [65].

2. CE MRA

CE 3-D MRA combines a fast T1-weighted gradient-echo acquisition with an IV-administered paramagnetic contrast agent [66]. Such contrast-based agents reduce the T1 relaxation time of blood and nearly eliminate the loss of signal related to saturation effects, thus leading to a more accurate assessment of vascular stenosis. CE MRA has been evaluated for use in assessing the cervical carotid and vertebral arteries, arterial system, the intracranial arterial circulation, the dural venous sinuses, and the ascending and arteries as well as the aortic arch, ascending great vessels, and descending thoracic aorta. CE MRA has been successful in demonstrating atherosclerotic occlusive diseases, of the aorta, aortic dissections, aneurysms, congenital anomalies of the aortic arch, vascular malformations, and vascular involvement by tumor. It does not routinely require cardiac gating, which makes it a more widely applicable technique in patients with irregular cardiac rhythms arrhythmias. Furthermore, respiratory artifacts are can be reduced by breath-holding, and artifacts seen in TOF MRA due to slow or turbulent flow-related enhancement or in-plane dephasing encountered with vascular tortuosity are much markedly reduced. These advantages make CE MRA extremely very useful for imaging of the aortic arch, great vessels, and cervical vasculature but can also improve visualization of the intracranial circulation. intracranial circulation

Rapid cervical and intracranial circulation (typically 8-10 seconds) makes CE MRA of the cervicocerebral vasculature particularly challenging. Arch and cervicocerebral MRA studies require very accurate timing of the acquisition in relation to the contrast bolus; this may be performed with the utilization of one of the bolus-timing sequences outlined below. If the images are obtained too early, the arterial structures may not be visualized. Late acquisition will result in reduced arterial signal, venous opacification/contamination, and soft-tissue enhancement. Ideally, the center of the k-space is scanned during the first pass of the bolus [67].

Contrast-enhanced cervicocerebral MRA CE MRA is optimized when the center of the k-space is sampled near the peak arterial concentration of the gadolinium contrast chelate. Centric encoding is an example of a vascular imaging technique that improves capture of the arterial phase of the bolus and reduces venous contamination. Many other Three basic CE MRA techniques have been developed to improve arterial phase k-space filling: test bolus timing, fluoroscopic triggering, and time-resolved imaging in order to better evaluate vascular pathology [27,68-73]. For test bolus timing, an initial small test dose is first administered, and continuous 2-D imaging is performed to determine the optimal imaging time interval. For fluoroscopic triggering, a rapid real-time 2-D gradient echo is acquired during the injection of the entire bolus, allowing the MR technologist or an automatic trigger based on a preplaced region of interest to initiate the acquisition such that the center of the k-space is sampled during maximum arterial enhancement. Time-resolved MRA imaging is performed with rapid scanning repeatedly over the region of interest, with oversampling of the central lines of the k-space every few seconds. Increased temporal resolution of time-resolved MRA imaging allows delineation of the arterial and venous phases, arteriovenous shunting, and early venous drainage for the assessment of cervical spinal or intracranial AVMs and fistulas.

Contrast injection rates of 2 to 4 mL/sec generate a bolus profile with a 5-7-second arterial phase. This is desirable because most techniques require several seconds to sample the center of the k-space. The contrast injection volume may vary based on the size and condition of the patient [70]. For example, very large patients or those with poor cardiac output may require a timing bolus and a larger volume of contrast in order to offset the effects of contrast dilution in the blood pool. The use of a power injector facilitates control of the injection rate and helps to standardize the protocol.
Following contrast injection, the power injector can rapidly switch and inject a saline flush to optimize the bolus. In pediatric patients, the combined demands of smaller bolus volume and rapid circulation time require that the injection rate be adjusted to the patient body habitus. The size and location of the IV also needs special consideration in young children.

Finally, saturation (SAT) bands are less effective when the intravascular T1 signal of blood is significantly reduced. In CE MRA, a poorly timed contrast bolus can result in undesirable venous enhancement which cannot be eliminated by the selective placement of SAT bands, and the relevant arterial anatomy may be obscured [74-76]. Similarly, arterial structures cannot be selectively eliminated by saturation techniques when contrast material is administered. The type and frequency of artifacts will vary with the technique; thus, the supervising physician must understand the potential limitations of each acquisition method.

3. PC MRA

PC MRA techniques are based on the protons that move through a magnetic field, and they acquire a phase shift directly proportional to their velocity. As protons move through a magnetic field, they acquire a phase shift directly proportional to their velocity. The magnitude of the phase shift can be measured, and an image of the flowing blood can be generated. Display of the vessels is similar to that obtained with the TOF technique although dependent on the protons' directional flow velocity. Flow can also be indicated when the proper velocity encoding is selected, 2-D PC MRA imaging data can also be used to measure flow velocity or flow volume. Flow quantification with 2-D PC MRA techniques across intracranial vertebrobasilar stenoses has shown promise as a predictor of ischemic stroke in the posterior intracranial circulation [77]. Contrast enhancement may also be used to increase the signal obtained from blood flow in PC MRA acquisitions. In some instances, it is necessary to gate the PC MRA acquisition to the cardiac cycle for optimum flow assessment. When the proper velocity encoding is selected, the image data can be used to measure flow velocity or flow volume. When phase contrast 3-D PC MRA is utilized for flow quantification with time-resolved volumetric acquisitions, used in this manner it is frequently called 4-D flow MRI/MRA; its utilization in the hemodynamic characterization of intracranial aneurysms and AVMs is a topic of ongoing research [57,78-82].

4. ASL MRA

Initial results from recently developed clinically investigations with continuous, pseudocontinuous, and inflow inversion recovery ASL methods have demonstrated clinical feasibility for MRA but are more commonly utilized for perfusion imaging [58,59]. ASL has significant limitations with respect to MRA imaging, including the requirement of reasonably high arterial velocities and knowledge of flow direction and therefore is not widely used in clinical practice. MRA techniques such as continuous and pseudocontinuous ASL and inflow inversion recovery have shown clinical utility.

5. MR Vessel Wall Imaging

The previously described MRA techniques display images of the vessel lumen. High-field (>3T), high-resolution (<1 mm voxels) MR vessel wall imaging (VWI) protocols are optimized to image cervical and intracranial arterial wall pathology with 2-D or 3-D black-blood MRI (BB MRI) using multiple tissue weightings (pre- and postcontrast T1-, proton density, and/or T2-weighted sequences). Depending on 2-D versus 3-D scan protocols and vendor-specific sequences, various blood, fat, and cerebrospinal fluid (CSF) suppression techniques have been described, including spin echo, spatial pre-saturation (or SAT) band, double inversion recovery, intravoxel phase dispersion, diffusion sensitizing gradients, flow-sensitive dephasing (FSD), or delay alternating with modulation of tailored excitation (DANTE). Although carotid MR VWI protocols are typically 2-D BB MRI sequences, isotropic 3-D BB MRI sequences are often employed for intracranial MR VWI for volumetric coverage and multiplanar reformatted reconstructions of this tortuous vasculature, but with increased scanning times [83]. Despite BB MRI sequences being developed to evaluate vessel wall
pathology, the vessel lumen is also well delineated with higher sensitivity for stenosis and higher specificity for vessel occlusions than TOF MRA, with near equivalent accuracy to CT angiography (CTA)/digital subtraction angiography methodologies [84-86].

Cervical MR VWI may be valuable in the diagnostic assessment of dissections and high-risk carotid and vertebral atherosclerotic disease. Specific biomarkers of carotid atherosclerosis with histopathological correlation have been shown to be associated with cerebrovascular ischemic events, including plaque volume/thickness, thin/ruptured fibrous cap, lipid-rich necrotic core, intraplaque, hemorrhage, and/or adventitial enhancement. Preliminary evidence suggests that high-risk plaque features on MR VWI are associated with ischemic stroke risk that may be independent to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria for symptomatic carotid stenosis, although further investigation is warranted [87-93].

Intracranial MR VWI has been an evolving adjunctive technique to better characterize various neurovascular pathologies over standard luminal imaging. Multiple studies have proposed high-risk or culprit intracranial atherosclerotic plaque features associated with symptomatic ischemia, including eccentric plaque thickness/irregularity, positive (adaptive) vessel wall remodeling, intraplaque hemorrhage, and plaque enhancement. Other intracranial MR VWI findings, such as the concentric pattern and presence/absence of vessel wall enhancement, may assist in diagnosing and differentiating inflammatory vasculitis, steno-occlusive vasculopathy/moya moya disease, and reversible cerebral vasoconstriction syndrome [83,94,95].

Early evidence suggests the value of MR VWI in the assessment of intracranial aneurysms, due to suspected pathology of neovascularization and inflammation of the vessel wall in the setting of an unstable atherosclerotic plaque or intracranial aneurysm. Thick, circumferential, or pronounced aneurysm wall enhancement may be associated with ruptured aneurysms or unstable (symptomatic or enlarging) unruptured aneurysms with moderately high specificity [96-99]. However, few longitudinal and prospective studies have evaluated unruptured aneurysm wall enhancement as a predictor of aneurysm growth/rupture, independent of other known anatomic risk factors. Further studies are warranted to assess the role of MR VWI in the differentiatation and risk stratification of neurovascular diseases, standardization of protocols, and technical considerations of contrast injection delays and turbulent flow artifacts [100,101].

6. MR Venography
Cervicocerebral MR venography (MRV) is useful in the evaluation of the intracranial and extracranial venous anatomy and its variants and developmental, structural, or flow abnormalities. Flow-related enhancement or contrast enhancement of the cervical and intracranial veins enables the assessment of venous patency, congenital or acquired stenosis, focal wall thickening, annulus, abnormal valves, webs, septa and flaps, dural venous sinus and cortical vein thrombosis, jugular vein thrombosis, idiopathic intracranial hypertension (IIH), and intracranial hypotension. Venous pathology has also been implicated in a number of other neurological diseases, such as exertional headache, cough headache, and transient global amnesia [102]. Dural venous sinus thrombosis accounts for 0.5% to 1% of all strokes and can be seen in a number of conditions—including dehydration, hypercoagulable states, infection, tumor invasion—in conjunction with oral contraceptives, and pregnancy, especially in the third trimester and during puerperium [102-104].

MRV offers several advantages to CT venography (CTV), including lack of ionizing radiation, improved thrombus visualization, and greater sensitivity for detecting parenchymal lesions, and venous infarcts. Additionally, specific MRV techniques can provide functional flow information that is reproducible and allows assessment of flow impairment, hemodynamically significant venous stenosis, presence/absence of collateral venous drainage, and venous reflux [105,106].
Analogous to MRA, MRV sequences employ either 2-D TOF, 3-D PC, or 3-D CE techniques. Although ASL perfusion-weighted imaging (PWI) can identify hyperintense signal or a “bright sinus” appearance in the setting of dural venous sinus thrombosis with increased sensitivity compared with the susceptibility vessel sign or empty delta sign, it does not offer significant advantages to standard MRV techniques. Newer techniques, such as 2-D Cine PC MRV and 4-D MRA, have been studied for various quantitative flow applications [102,103,105-107]. MRV display protocols should be modified to focus on the cervicocerebral venous structures, utilizing planar- and volume-rendered MIP imaging as well as multiplanar reformatting techniques for 3-D CE MRV.

Noncontrast 2-D TOF MRV relies on flow-related enhancement to produce vascular images by manipulating the magnitude of magnetization (longitudinal magnetization vector), differentiating stationary tissue (low signal intensity) from blood flow (high signal intensity). In imaging the cervicocerebral venous system, an inferior saturation pulse is placed to eliminate arterial inflow signal. Advantages include operator independence, reproducibility, and a large FOV to visualize venous anatomy and pathology. Disadvantages of 2-D TOF MRV include stair-step artifact with 3-D MIP reconstructions, in-plane dephasing resulting in signal loss or “flow gaps” due to saturation, and flow parallel to the scan plane. T1 hyperintense signal or “T1 shine through” from intracellular or extracellular methemoglobin/thrombus may falsely simulate normal blood flow, and arachnoid granulations or hypoplastic dural sinuses may mimic venous thrombosis. 2-D TOF is also more sensitive to image degradation due to patient motion and misregistration, magnetic field inhomogeneities, and susceptibility artifact from air, calcium, or metal. 3-D TOF techniques are not typically used because of severe in-plane saturation effects and signal loss [102,106,107].

PC MRV (2-D or 3-D) uses velocity-induced phase shifts imparted on moving spins to distinguish flowing blood from the surrounding tissues. The signal from stationary tissue is suppressed by a bipolar gradient pulse of equal magnitude and opposite direction. Using a transverse magnetization vector, signal in flowing blood is linearly proportional to the velocity of the spins. Spins in blood moving toward the heart are assigned a hyperintense “bright” signal, and spins in blood moving away from the heart are assigned a hypointense “dark” signal. As opposed to high-velocity encoding (40-70 cm/sec) for arterial inflow, low velocity encoding (10-20 cm/sec) is required for venous flow. PC MRV offers the advantages of improved background tissue suppression, slow flow detection with smaller voxel sizes, flow direction, and quantification. Disadvantages include operator dependence on correct velocity encoding, long acquisition times as a result of applying multidirectional gradients, increased susceptibility to motion artifacts, and intravoxel dephasing/signal loss with turbulent flow. The acquisition time can be reduced by using high field strengths, parallel imaging, and optimized k-0 space sampling [102,103,106,108]. 2-D Cine PC sequences can also be utilized for accurate flow quantification in the cervicocerebral veins, preferably with cardiac gating and recommended velocity encoding of 50 cm/sec. At various levels (C2-3, C5-6, and C7-T1), a slice of interest is placed perpendicular to the vessel’s longitudinal axis (flow direction) and flow rate is calculated from a flow velocity curve as a function of time [102]. Time-resolved 3-D PC MRA or 4-D flow MRI are evolving sequences to assess quantitative flow dynamics of the arteries and veins throughout the cardiac cycle, potentially allowing measurements of pressure gradients in the dural sinuses and jugular veins. However, longer acquisition and postprocessing times as well as lower spatial resolution limit clinical application in the smaller intracranial vasculature [102].

Utilizing 3-D CE MRV techniques to evaluate the superficial and deep intracranial veins and dural sinuses. It relies on T1 shortening of enhanced venous blood rather than flow-related enhancement, overcoming in-plane saturation artifacts seen with TOF techniques. Several other advantages of 3-D CE MRV techniques include a large FOV, isotropic volumetric imaging for multiplanar reformatting, higher spatial resolution, faster scan times, higher signal-to-noise ratios (SNR), and higher contrast-to-noise ratios (CNR). It may help differentiate acute from chronic venous thrombosis, with intense periadventitial enhancement seen with acute thrombosis. Intravascular...
webs/septa and arachnoid granulations are better delineated with 3-D CE MRV techniques. It is also less susceptible to quality degradation by patient motion, magnetic field inhomogeneity, and susceptibility artifacts from air or metal [102]. Time-resolved CE MRA techniques provide dynamic visualization of both the arterial and venous phases and can be leveraged for assessment of arteriovenous shunts, albeit at a lower spatial resolution than standard 3-D CE MRA/MRV studies.

In addition, volumetric T1 postcontrast techniques (where flow suppression techniques are not utilized) with enhancement of the venous sinuses are also a useful technique in evaluating the venous sinuses, including to exclude venous thrombosis and identify stenosis as well as venous vascular variants.

MR angiography of the venous system, also called MR venography (MRV), can be performed using TOF, PC, and CE imaging techniques. Display protocols should be modified to focus on the venous structures as clinically indicated. A contrast medium injection rate of 2 to 4 mL/sec generates a bolus profile with a 5-second to 7-second arterial phase. This is desirable because most techniques require several seconds to sample the center of k-space. The contrast injection volume may vary based on the size and condition of the patient [70]. For example, very large patients or those with known poor cardiac output may require a timing bolus and a larger volume of contrast in order to offset the effects of contrast dilution in the blood pool. The use of a power injector facilitates control of the injection rate and helps to standardize the protocol. Following injection of the contrast material, the power injector can rapidly switch to inject the saline flush dose and injection rate of contrast material will need to be adjusted accordingly for pediatric patients who typically have a faster circulation times. The size and location of the IV also needs special consideration in young children.

Rapid intracranial circulation, (typically on the order of 8 to 10 seconds) makes CE-MRA of the cervicocerebral vascular system particularly challenging. Arch and carotid cervicocerebral MRA studies require very accurate timing of the acquisition in relation to the contrast medium injection. If the images are obtained too early, the arterial structures may not be visualized. Late acquisition will result in reduced arterial signal, venous opacification, and soft-tissue enhancement. Ideally, the center of k-space is scanned during the first pass of the bolus [67].

A limitation of CE MRA is that the extracellular gadolinium chelates are nonspecific MR contrast agents normal and pathologic tissues will enhance. Many This makes repeat imaging more problematic. Subtraction techniques may help, but often there is incomplete subtraction of the background, and artifacts generated by misregistration of the datasets can occur. Increased signal intensity of the enhanced adjacent soft tissues can obscure vessels on the MIP images and may simulate flow-related signal or degrade vascular detail. Blood-pool contrast agents (e.g., gadofosveset trisodium) are available and may be of utility in dynamic CE MRA studies.

Techniques are emerging that permit imaging of the cervical/intracranial arterial wall and may be of clinical value in the setting of subintimal and intramural dissections and atherosclerotic disease. For example, the detection of a thin fibrous cap, lipid/necrotic core, intraplaque hemorrhage, and neovascularity have been reported to be associated with a higher risk of ischemic events [84-89]. Detection and characterization of vessel wall enhancement can suggest the diagnosis of vasculitis, vasoconstriction, or symptomatic atherosclerotic disease [93].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [52].

In addition to examining the vascular structures of interest, the MRA source images should be examined for extravascular abnormalities that may have clinical relevance. These abnormalities should be described in the formal
report of the examination. When MRA/MRV techniques are used for determining carotid stenosis, the report should reflect the methodology and reference the criteria for percent stenosis outlined in the NASCET or based on methods validated against NASCET measurement [109-112]. Also, the percent stenosis must be calculated using the distal cervical ICA (internal carotid artery) diameter, where the walls are parallel, for the denominator. Similar to CTA, MRA with attention to the acquisition parameters and postprocessing techniques can provide cross-sectional measurements of stenosis that correlate with properly performed NASCET estimates of percent stenosis obtained with catheter angiography [113]. In the setting of near occlusion, it may not be accurate to calculate percent stenosis ratios in the presence of poststenotic arterial dilatation. diameter decrease Some MRA techniques may not be amenable to quantitative measurements, in which case qualitative assessment of stenosis should be provided.

Specific policies and procedures related to MRI safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines that deal with potential hazards associated with the MRI examination of the patient as well as to others in the immediate area should be provided. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [114-116].

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [117].

The MR equipment specifications and performance must meet all state and federal requirements. These requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of the magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

A 3-D postprocessing workstation capable of creating multiplanar reformations, MIP images, and 3-D volume renderings or shaded surface displays is required. for MR angiograms The workstation should also allow the direct measurement of vascular diameters and, when appropriate, path lengths and branch angles, either from source images or from reformatted images.

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.

Development Chronology for this Practice Parameter

- Revised 2005 (Resolution 7)
- Amended 2006 (Resolution 35)
- Revised 2010 (Resolution 21)
- Amended 2012 (Resolution 8 – title)
- Amended 2014 (Resolution 39)
- Revised 2015 (Resolution 10)
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RESOLUTION NO. 44

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Head Brain

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2015 (Resolution 20)*

ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF COMPUTED TOMOGRAPHY (CT) OF THE HEAD BRAIN

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 care1. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

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1 Iowa 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.

PRACTICE PARAMETER 1

2020 Resolution No. 44

CT Head Brain
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Computed tomography (CT) is a technology that produces cross-sectional images of the body using x-rays. CT is utilized extensively in imaging of the head brain. This practice parameter outlines the principles for performing high-quality CT imaging of the head brain in pediatric and adult patients. There should be an effort to minimize radiation exposure, particularly in children. An alternate modality should be considered when possible.

CT of the head brain is superior to magnetic resonance imaging (MRI) for the evaluation of osseous structures, acute intracranial hemorrhage, and the detection of calcification, which can be important for the identification of an abnormality or for refinement of a differential diagnosis. CT of the brain is sufficient and diagnostic in many clinical circumstances, such as in acute trauma, nontraumatic intracranial hemorrhage, evaluation of shunt malfunction, and selected postoperative follow-up. However, CT is less useful for certain conditions such as subtle neoplastic, infectious, or inflammatory conditions affecting the cranial nerves, brain parenchyma, and meninges. In combination with the clinical history and physical examination findings, CT of the brain is a useful screening tool for indications such as acute mental status change, seizure, acute neurologic deficit, acute headache, and nonacute headache with neurologic findings. CT is useful as a screening modality for the presence of neoplasm and mass effect, particularly in conjunction with to which the addition of intravenous (IV) contrast may provide added sensitivity in selected circumstances. For further information see the ACR Manual on Contrast Media [1].

II. INDICATIONS

Indications for CT of the brain include, but are not limited to, the following:

A. Primary Indications

1. Acute head trauma [2-6]
2. Suspected acute intracranial hemorrhage [7-9] [4]
3. Follow-up for known intracranial hemorrhages
4. Detection or evaluation of calcification [10]
6. Mental status change [12], including drug toxicity [12-15]
7. Headache [16,17] [15,16]
8. Acute neurologic deficits [18], including cranial nerve dysfunction [19-21] and ataxia [22] [18,22]
9. Suspected Intracranial infection [23-27] [29,31]
10. Suspected Hydrocephalus [28,29], [33] including shunt malfunctions or shunt revisions in the adult population [28]
11. Certain Congenital skull and brain lesions (such as, but not limited to, craniosynostosis, macrocephaly, and microcephaly) [7,30,31]
12. Suspected mass or tumor [32-36], including brain herniation syndromes [3,4] and increased intracranial pressure [4,5].

13. CT guidance, image integration, and 3-D planning [37-45] [49].

14. Certain skull lesions (such as, but not limited to, fibrous dysplasia, Paget disease, histiocytosis, osteolytic lesions, and skeletal tumors).

15. Abusive head trauma and postmortem forensic investigations [15,46-49].

16. Seizures [50-54].

4. Vascular occlusive disease (acute and chronic) or vasculitis (including use of CT angiography and/or venography) [9-25].

5. Aneurysm evaluation [26-28].

6. Detection or evaluation of calcification [29].

7. Treated or untreated vascular lesions [31,32].

8. Increased intracranial pressure.

9. Evaluating psychiatric disorders [37].

10. Brain herniation [2,3].

11. CT guidance and image integration for neurosurgical, neurointerventional, and other therapeutic procedures [55-61].

B. Secondary Indications (when MRI is unavailable or contraindicated, or if the supervising physician determines CT to be appropriate [54]) [28,60].

1. Seizures Epilepsy [50-54].

2. Suspicion of Neurodegenerative disease [55-58].

3. Developmental delay [29,59].

4. Evaluating psychiatric disorder [60].

2. Diplopia [68].

3. Cranial nerve dysfunction [69-72].

4. Apnea [77].

5. Neuroendocrine dysfunction [78].

6. Abusive head trauma and postmortem forensic investigations [14,15,71,74,76].

7. Syncope [78].

8. Ataxia [79].

11. Drug toxicity [33, 85-87].

12. Congenital morphologic brain abnormalities [88].


15. Suspected shunt malfunctions or shunt revisions [44].

For the pregnant or potentially pregnant patient, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [61].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [62].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for CT of the brain should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a
provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

The supervising physician must have complete understanding of the indications, risks, and benefits of the examination, as well as alternative imaging procedures. The physician should be familiar with relevant ancillary studies that the patient may have undergone (See the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [80]). The physician performing CT interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the examination.

A. General Considerations

CT protocols for brain imaging should be designed to answer the specific clinical question. The supervising physician should be familiar with the indications for each examination, relevant patient history, and potential adverse reactions to contrast media. The supervising physician should be familiar with how individual CT settings affect radiation dose and image quality, including field of view (FOV), collimation, pitch, automated exposure control, and image reconstruction algorithms such as iterative reconstruction [63]. The goal of CT scanning is to obtain diagnostic information from images of sufficient quality. Protocols should be optimized to deliver the lowest dose required to achieve appropriate image quality and should be reviewed and updated at least periodically to optimize the examination as needed in light of new clinically applicable developments [64-72], exposure factors, window and center settings, field of view, collimation, slice intervals, slice spacing (table increment) or pitch, dose reduction (eg, iterative reconstruction), and image reconstruction algorithms [99,104].

B. Brain Imaging

CT brain imaging is performed for the evaluation of a variety of pathologies that require appropriate techniques for acquisition and viewing. CT brain imaging may be performed with a sequential single-slice technique, multislice helical (spiral) protocol, or multidetector multislice algorithm [73,74]. Use of these techniques is dependent on clinical indication, scanner capability, and image quality requirements. For CT of the brain, contiguous or overlapping axial slices should be acquired with a slice thickness of no greater than 5 mm. In addition to directly acquired axial images, reformatted images in coronal, sagittal, true axial, or other more complex planes may be constructed from the axial data set to answer specific clinical questions. Additionally, axial reconstructed images should be presented with at least two different kernels, utilizing both a brain/soft tissue and bone kernel. In the setting of trauma Brain images should be obtained and/or reviewed at dedicated workstations and with window settings appropriate for demonstrating brain, and bone, and soft-tissue abnormalities as well as hemorrhage, small subdural hematomas or other sites of hemorrhage and soft-tissue lesions (subdural windows). For imaging of the cranial base, an axial slice thickness as thin as possible, but no greater than 3 mm with spiral techniques and 2 mm with multidetector and nonspiral techniques, should be used for 2-D reformatting or for 3-D reconstruction. Specially tailored protocols may also be considered, however, if clinical circumstances warrant, and under the direction of the supervising physician.

For further information, see the American Association of Physicists in Medicine Routine (AAPM) Adult Head (Brain) Protocols [75].

PRACTICE PARAMETER 4

CT Head (Brain)

2020 Resolution No. 44
C. Contrast Studies

Certain indications require administration of IV contrast media or intrathecal contrast (eg, cisternography) during imaging of the brain. Contrast enhancement should be performed using appropriate injection protocols and be in accordance with the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [76]. Cerebrospinal fluid (CSF) contrast administration requires the use of nonionic agents approved appropriate for intrathecal use and should be performed using appropriate protocols as outlined in the ACR–ASNR–SPR Practice Parameter for the Performance of Myelography and Cisternography [77].

D. Advanced Applications

Postprocessing by either physicians, radiologic technologists, or appropriately trained staff is recommended. Furthermore, images may be manipulated to allow selective visualization of specific tissues, such as in CT perfusion, CT volumetry, CT angiography/venography, multimodality image fusion, and mapping techniques. Such applications are better performed with helical, volume, or dual-energy data sets rather than routine axial sequential data [37,43,66,78-94]. [53,118,124,132-134] Also see the ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging [95] and the ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Cervicocerebral Computed Tomography Angiography (CTA) [96]. Pre- and postcontrast imaging is not recommended in pediatric patients for most indications. In addition to directly acquired axial images, reformatted images in coronal, sagittal, or other more complex planes may be constructed from the axial dataset to answer specific clinical questions or the

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [97].

VI. EQUIPMENT SPECIFICATIONS

For specific issues regarding CT quality control, see the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [62].

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [98].

A. Performance Standards

To achieve acceptable clinical CT scans of the brain, the CT scanner should meet or exceed the following specifications:

1. Scan times: per slice or image not more than 2 seconds

2. Slice thickness: minimum acquired slice thickness should be 2 mm or less, whereas reconstructed slice thickness should be 5 mm or less

3. Interscan delay: no more than 4 seconds; however, this may be longer if intravascular contrast media is not used (not applicable with helical scanners)
4. Limiting spatial resolution: must be measured to verify that it meets the unit manufacturer’s specifications. Limiting spatial resolution should be >10 lp/cm for a display field of view <24 cm (DFOV).

5. Table pitch: no greater than $2:1$ for most CT scanners, pitch may be increased for dual-energy scanners for sole evaluation of bone anatomy (craniofacial).

6. For advanced applications (eg, perfusion imaging or CT angiography (CTA), cine-capable scanners are preferable with tube rotation $\leq 1$ second and continuous cine imaging $\geq 60$ seconds. See the ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging [95].

B. Patient monitoring equipment and facilities for cardiopulmonary resuscitation, including vital signs monitoring equipment and support equipment, should be immediately available.

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages or sizes in the patient populations.

Radiologists, technologists, and staff members should be able to assist with procedures, patient monitoring, and patient support. A written policy should be in place for dealing with emergencies, such as cardiopulmonary arrest.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s
dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution
17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

When possible, CT imaging of the head should consider the following to minimize radiation dose and
maintain image quality:

1. Center the patient in the gantry [99]
2. Remove unnecessary objects from the patient
3. Use of iterative reconstruction technique, if available

Dose-minimization CT techniques should be used for imaging scenarios in which comprehensive information
is not required, such as in the evaluation of shunt placement/malfunction, routine paranasal sinus evaluation,
and craniostenosis in the pediatric population [100].

Diagnostic Reference Levels (DRL) and Achievable Doses (AD) are national benchmarks for radiation
protection and optimization that provide a comparison for facilities in order to review techniques and
determine whether acceptable image quality can be achieved at lower doses. Published levels are available
[101]. For further information, see the ACR–AAPM–SPR Practice Parameter for Diagnostic Reference
Levels and Achievable Doses in Medical X-Ray Imaging [102].

Attention to dose is particularly important but also particularly challenging in the pediatric population,
when age and size specific protocols should be considered [103]. MRI may be an alternative to CT in
monitoring the size of intracranial fluid collections, such as the ventricles in shunted hydrocephalus, size of
arachnoid cysts, or size of nonacute subdural collections. Rapid-MRI to include susceptibility and diffusion-
weighted imaging (DWI) sequences has not yet been proven in the literature to be an equivalent examination
to CT for the detection of acute intracranial hemorrhage or exclusion of a skull fracture in the acute clinical
setting. MRI is useful in detecting areas of parenchymal brain injury that may not be apparent on CT [104].

The use of shields for radiation protection of superficial organs, such as the lens of the eye or the thyroid
gland, is controversial. The goal of shielding is to limit unnecessary irradiation to nontarget, radiosensitive
organs, and bismuth shields, which have been shown to reduce anterior surface dose, are available.
However, shielding has several disadvantages, not the least of which is unpredictable results when combined
with automated exposure control features. Alternative methods, such as a global reduction in dose together
with iterative reconstruction to reduce image noise, as mentioned above in Section IV.A, can achieve the
same goal. For further information, see the AAPM Position Statement on the Use of Bismuth Shielding for
the Purpose of Dose Reduction in CT Scanning [105].

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-

In addition to CT radiation safety and quality control, appropriateness studies, and utilization review, and outcomes
studies facilitating best practices for CT brain imaging should also be considered and encouraged as part of a
comprehensive continuous quality improvement program [46,106-114]. [146,150,151]
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OLD REFERENCES


*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.*

Development Chronology for this Practice Parameter

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Amended 2014 (Resolution 39)

Revised 2015 (Resolution 20)
BE IT RESOLVED,

that the American College of Radiology adopt the ACR–SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI)

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 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.

Revised 2015 (Resolution 11) *

ACR–SPR PRACTICE PARAMETER FOR THE SAFE AND OPTIMAL PERFORMANCE OF FETAL MAGNETIC RESONANCE IMAGING (MRI)

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

1 Iowa 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Magnetic resonance imaging (MRI) is a proven, established imaging modality for evaluating fetal anomalies that are not well adequately or completely assessed by sonography [1-8]. MRI is used for problem solving and only in select circumstances for screening. Properly performed and interpreted, MRI not only contributes to diagnosis but also serves as an important guide to treatment, delivery planning, and counseling. However, sonography is the most appropriate first-line imaging screening modality of choice in the fetus. Fetal MRI should be performed only for a valid medical reason and only after careful consideration of sonographic findings or family history of an abnormality for which screening with MRI might be beneficial.

This practice parameter addresses the use of MRI in fetal diagnosis.

Although MRI is an effective noninvasive diagnostic test for characterizing many fetal abnormalities, its findings may be misinterpreted misleading if not closely correlated with the clinical history and sonographic findings. Adherence to the following practice parameters will enhance the probability of appropriately diagnosing such abnormalities.

II. INDICATIONS

When an anomaly is visualized suspected on by ultrasound (US), but the etiology remains uncertain due to the nature of the abnormality, or due to sonographic limitations from fetal lie, descent of the fetal head into the maternal pelvis, maternal body habitus, oligohydramnios, overlying bone/gas, and/or small field of view (FOV) may limit adequate assessment of the fetus and fetal anomalies. MRI can add additional information that may impact parental counseling, perinatal management, and delivery planning, and postnatal care [9-17]. Primary indications for MRI include, but are not limited to, the following:

A. Brain and Spine

1. Congenital anomalies of the brain or skull suspected or not adequately assessed by sonography [3,18-41] include, but are not limited to, the following:
   a. Ventriculomegaly
   b. Agenesis of the corpus callosum
   c. Abnormalities of the cavum of the septum pellucidum
   d. Holoprosencephaly
   e. Posterior fossa anomalies
   f. Cerebral cortical malformations or migrational anomalies
   g. Solid or cystic masses
   h. Cephalocele
In addition, MRI can be helpful in screening fetuses with a family risk for brain abnormalities, such as tuberous sclerosis, corpus callosal dysgenesis, or lissencephaly.

2. Vascular abnormalities of the brain suspected or not adequately assessed by sonography [42,43] include, but are not limited to, the following:
   a. Vascular anomalies
   b. Hydranencephaly
   c. Infarction
   d. Hemorrhage
   e. Monochorionic twin pregnancy complications

3. Congenital anomalies of the spine suspected or not adequately assessed by sonography [9,13,14,29,44-48] include, but are not limited to, the following:
   a. Neural tube defects
   b. Sacrococcygeal teratomas
   c. Caudal regression/sacral agenesis
   d. Sirenomelia
   e. Vertebral anomalies

B. Skull, Face, and Neck

1. Masses of the face and neck suspected or not adequately assessed by sonography [11,33,49-52] include, but are not limited to, the following:
   a. Vascular or lymphatic anomalies
   b. Goiter
   c. Teratomas
   d. Facial clefts
   e. Congenital cysts and cystic masses

2. MRI can be helpful in assessing airway obstruction that may impact parental counseling, prenatal management, delivery planning, and postnatal therapy [11,49-52].

C. Thorax

1. Thoracic pathology suspected or not adequately assessed by sonography [53-55] include, but is not limited to, the following:
   a. Congenital airway and lung malformations (including congenital high airway obstruction, pulmonary airway malformations, bronchogenic cyst, sequestration, and congenital lobar over inflation)
   b. Congenital diaphragmatic hernia
   c. Effusions
   d. Mediastinal masses
   e. Assessment for Suspected esophageal atresia
   f. Lymphangiectasia (primary or secondary from congenital heart disease)

2. MRI can be used for volumetric assessment of fetal lung parenchyma [56-60], particularly in those fetuses at risk for pulmonary hypoplasia secondary to diaphragmatic hernia, oligohydramnios, omphalocele, chest mass, or skeletal dysplasias.
D. Abdominal, Retroperitoneal, and Pelvic

1. Abdominal and pelvic pathology suspected or not adequately assessed by sonography include, but is not limited to, the following:
   a) Assessing the size and location of tumors, such as hemangiomas, neuroblastomas, sacrococcygeal teratomas, and suprarenal or renal masses
   b) Determining the etiology of an abdominal-pelvic cyst
   c) Assessing complex genitourinary anomalies, such as bladder exstrophy, cloacal malformation or exstrophy, and anorectal malformations, or complex lower urinary tract obstruction, such as encountered in the setting of Prune Belly Syndrome
   d) Assessing renal anomalies in cases of severe oligohydramnios
   e) Diagnosing complex bowel anomalies, such as cloaca, anorectal malformations, or complex bowel obstructions such as with megacystis microcolon hypoperistalsis syndrome
   f) Assessment of complex abdominal wall defects

E. Musculoskeletal

1. Assessment of extremity masses, such as lymphatic malformations and Klippel-Trenaunay-Weber
2. Skeletal dysplasias, for assessment of associated anomalies
3. Confirmation of suspected limb anomalies

F. Complications of Multiple Gestation Pregnancies

1. Monochorionic twins: delineation of vascular anatomy prior to laser treatment of twins, assessment of morbidity after death of a monochorionic co-twin area in which MRI may be useful [62-64] because of its high spatial resolution, contrast resolution, large FOV, and multiplanar imaging capabilities.
2. Conjoined twins: further delineation of anatomy can impact parental counseling, delivery planning, and postnatal management

G. Complications of Monochorionic Twins

Delineation of vascular anatomy prior to laser treatment of twins, assessment of morbidity after death of a monochorionic co-twin, and improved delineation of anatomy in conjoined twins are areas where MRI may be useful [62-64] due to its high spatial resolution, contrast resolution, large field of view, and multiplanar imaging capabilities. This additional information may impact parental counseling, delivery planning, and postnatal management.

G. Fetal Interventions Surgery Assessment

When an abnormality is identified that may benefit from fetal interventions surgery, MRI is a useful adjunct in confirming the diagnosis and planning potential interventional surgical options [13,65-69]. It can also be utilized in assessing the fetal brain both before and after surgical interventions [70].

The high risk to mother and fetus of potential in utero interventions surgery requires accurate assessment of all anomalies. This includes, but is not limited to, the following:

1. Open neural tube defects Meningomyelocele
2. Sacrococcygeal teratomas
3. Processes obstructing the airway, such as a neck mass or congenital high airway obstruction
4. Complications of monochorionic twins needing surgery
5. Chest masses [71]
6. Congenital diaphragmatic hernia
7. Lower urinary tract obstruction
H. Placental Assessment

1. Although US remains the reference standard, MRI may be particularly useful for the assessment of placental disorders, such as gestational trophoblastic disorders and abnormalities of implantation [72].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [73].

Individuals interpreting fetal MRI should be familiar with both fetal and neonatal diagnoses because these knowledge bases overlap but can differ, both from each other and from those of the older pediatric and adult populations.

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [73], the ACR Guidance Document on MR Safe Practices [74], and the ACR Manual on Contrast Media [75].

A. Imaging pregnant patients, see the ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [76].

Present data have not conclusively documented any deleterious effects of MRI at 1.5T and 3T on the developing fetus [77-88]. Therefore, no special consideration is recommended for any trimester in pregnancy. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel-designated attending radiologist [74], the risk-benefit ratio to the patient warrants that the study be performed. The radiologist should review the indications and document them in the radiology report or the patient’s medical record.

There are theoretical radiofrequency (RF) power considerations that are greater at long exposure times and at a higher specific absorption rate [89,90]. Radiologists should be cognizant of the increased power deposition typically accompanying some higher field studies and ensure that they do not exceed established guidelines [91,92].

B. MRI contrast agents should not be routinely administered in fetal MRIs to pregnant patients. Gadolinium is a pregnancy class C drug, meaning that the safety in humans has not been proven. This document describes fetal MRI, but for completeness we will discuss use of gadolinium contrast agents in pregnancy.

There are no documented fetal indications for the use of MRI contrast, but there may be rare instances where contrast is considered potentially helpful in assessing maternal anatomy or pathology. Please refer to the ACR Manual on Contrast Media for further discussion of contrast administration in pregnancy [75].

The decision to administer contrast must be made on a case-by-case basis by the covering level 2 MR personnel-designated attending radiologist who will assess the risk-benefit ratio for that particular patient. The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk-benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus, outweighing the theoretic but potentially real risks of long-term exposure of the developing fetus to free gadolinium ions.
Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation [93]. From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location, the gadolinium-chelate molecules are in a relatively protected space and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects. The risk to the fetus with administration of gadolinium-based MR contrast agents remains unknown and may be harmful.

C. It is suggested that pregnant patients undergoing an MRI examination have a discussion with the referring or supervising physician concerning potential risks versus benefits of performing a fetal MRI. At this stage, the preponderance of research studies have failed to discover any reproducible harmful effects of exposure of the mother or developing fetus to the 3T or weaker magnetic fields used in the routine clinical MRI process. However, far less is known about the potential effects, if any, of the time-varying gradient and/or radiofrequency magnetic fields used during actual scanning to potentiate image generation. Furthermore, the considerable majority of our data to date comes from research involving magnetic fields of 1.5T or less. Thus, we have less information regarding the potential safety issues that may exist at higher field strength systems. These theoretical risks should be carefully balanced against the potential benefits to the patient undergoing an MR examination. A decision as to whether or not to proceed with the requested MRI study will need to be based on a thorough and thoughtful evaluation of the potential and at times unknown risks of the MR examination versus the potential benefits to the patient as well as the risks associated with declining to do so.

V. SPECIFICATIONS OF THE EXAMINATION

The supervising physician must have an understanding of the indications, risks, and benefits of the examination as well as alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The written or electronic request for fetal MRI should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

Documentation that satisfies medical necessity includes 1) fetal gestational age and 2) relevant history (including sonographic findings and family history of pertinent abnormalities). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.
A. Patient Selection

The physician responsible for the examination should supervise appropriateness of patient selection and preparation and be available in person or by phone for consultation. Patients must be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment.

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate or “conscious” sedation may be needed to achieve a successful examination. If moderate sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [94].

Knowledge of the gestational age of the pregnancy is important for optimal planning timing of the examination and positioning of the surface coil.

Prior to 18 weeks gestational age, the fetal MRI study can give limited diagnostic information due to the small size of the fetus and fetal movement. If the examination is limited by early gestational age, then it may need to be repeated later. The need for early diagnosis should be balanced against the advantages of improved resolution later in pregnancy, with the choice dependent on the anomalies to be assessed. Fetal motion typically occurs constantly during the examination. However, using single-shot or other rapid acquisition techniques, slices are obtained in less than 1 second; therefore, images are only degraded if motion occurs during image acquisition. Sequences may need to be repeated if motion degrades the image of the region of interest.

B. Facility Requirements

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis.

The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. Examination Technique

Depending on the size of the uterus and fetal area of interest, either a torso or cardiac phased array surface coil is placed over the gravid uterus. If the patient will not fit into the magnet with a surface coil, then a body coil can be used. The mother lies supine or in the left lateral decubitus position. The maternal foot-first position helps minimize claustrophobia. Maternal sedation is not necessary in the vast majority of cases. Scout images orthogonal to the gravid uterus can be performed.

Fetal MRI single-shot acquisition sequences or other rapid acquisition sequences are employed to limit the effects of fetal motion. A T2-weighted spin-echo single-shot sequence reveals excellent anatomy. Fast acquisition T1-weighted images with gradient-echo sequences are less anatomically discriminating but help to define certain fetal tissue or fluid characteristics, such as fat, hemorrhage, liver, and meconium in bowel. It is preferable to have T1-weighted fast gradient-echo sequences performed during a breath hold or using the respiratory trigger technique.

Short tau inversion recovery (STIR) images may provide improved resolution of tissue characteristics when the water contents of structures are similar. Additional sequences such as fluid attenuated inversion recovery (FLAIR), Steady-state free precession (SSFP) sequences, Fast Imaging Employing Steady-state Acquisition (FIESTA, TrueFISP (fast imaging with steady state precession), balance fast field echo (bFFE), hydrography, BOLD imaging, diffusion-weighted imaging (DWI) or diffusion-tensor imaging (DTI), and echo planar (EPI) and cine [95] imaging can also be useful sequences, may be performed as needed.
FOV (and corresponding choice of matrix and any phase-encoding oversampling) should be tailored to fetal (and maternal) size. Overlap of maternal onto maternal anatomy (“wrap-around” or spatial misregistration artifact) is acceptable if fetal structures are well visualized. A spatial resolution in the range of 1.5-mm pixel size (or better) is highly desirable to provide accurate depiction of most anatomic structures (eg, 35 FOV with 256 × 192 matrix). On DWI sequences, resolution of 2.0-mm pixel size is usually adequate.

1. Fetal brain
Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal brain. Optimal slice thickness is 2 to 3 mm, but, in some patients, a 4- to 5-mm slice thickness may be needed because of signal-to-noise consideration. A high echo time TE value (160-240) can help optimize evaluation of the brain parenchyma. The fast T1 gradient-echo sequence should be performed in the coronal or axial plane if there is suspicion of fat or hemorrhage. Additional FLAIR sequences may be done to suppress the bright signal of the cerebral spinal fluid in certain cases. The use of DWI to evaluate metabolic or ischemic processes and EPI to evaluate for hemorrhage may be performed as needed [96-98].

2. Fetal spine
Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal spine. Optimal slice thickness is 2 to 3 mm, but, in some patients, a 4- to 5-mm slice thickness may be needed because of signal-to-noise consideration. Additional sequences are rarely indicated in the spine evaluation but may include EPI a FLAIR or spoiled fast gradient-echo sequence as noted above regarding brain evaluation. A fast T1 gradient-echo sequence may be performed if there is suspicion of a fat-containing lesion.

3. Fetal face and neck
Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal face and neck. A slice thickness of up to 5 mm should be used with knowledge of signal-to-noise considerations, with earlier gestational age fetuses having thinner slices. A fast T1 gradient-echo sequence should be performed in the appropriate plane if there is suspicion of fat or hemorrhage. STIR images may provide improved resolution of tissue characteristics in masses such as teratoma or in lymphatic anomalies. Repetitive sagittal images, including real-time cine, can be useful may be needed to visualize fluid in the oropharynx if a lesion of the palate or proximal esophagus is suspected.

4. Fetal thorax
Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal thorax. The slice thickness should be up to 5 mm. A fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver and meconium in cases of congenital diaphragmatic hernia. STIR images may provide improved resolution of tissue characteristics in lesions such congenital pulmonary airway malformations in some instances [54]. SSFP sequences (FIESTA, TrueFISP) and cine images [99] can be used to refine assessment of the heart and vascular masses.

5. Fetal abdomen
Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal abdomen. The slice thickness should be up to 5 mm. The fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver, meconium, fat, or hemorrhage [100]. STIR images may provide improved resolution of tissue characteristics in lesions of the solid organs, such as kidneys, liver, or adrenal glands. The use of DWI to identify renal tissue may be used as needed. BOLD T2*gradient recalled echo GRE imaging can be used to screen for hemochromatosis [11,101].
6. Fetal volumetry

Various studies have established MRI-derived volumes and equations for weight [14,102-107]. The most commonly used are lung volumes to predict hypoplasia. Fetal weight has also been estimated. The technique involves adding together measured areas obtained by drawing free-form regions of interest on sequences that allow complete imaging of the volume without motion-induced artifact and multiplying by slice thickness. Volume assessments should be reserved for specific indications.

7. Dynamic imaging

Studies have demonstrated the utility of multisection balanced steady state–free precession cine sequences to assess fetal limb motion, swallowing, breathing, and cardiac motion [108-111].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [112].

VII. EQUIPMENT SPECIFICATIONS

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [113].

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic strength, maximum rate of change of the magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

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).

Specific policies and procedures related to MRI safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines should be provided that deal with potential hazards associated with the MRI examination of the patient as well as to others in the immediate area. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination.

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2010 (Resolution 13)
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BE IT RESOLVED, 
that the American College of Radiology adopt the ACR–SPR Practice Parameter for the 
Performance of Contrast Esophagrams and Upper Gastrointestinal Examinations in Infants and 
Children 

Sponsored By: ACR Council Steering Committee 

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Revised 2015 (Resolution 36) *

ACR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF 
CONTRAST ESOPHAGRAMS AND UPPER GASTROINTESTINAL 
EXAMINATIONS IN INFANTS AND CHILDREN

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication.

1 Iowa 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.
of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Radiographic examination of the esophagus and the upper gastrointestinal (GI) tract by single-contrast or double-contrast technique are proven and useful procedures for evaluation of the esophagus, stomach, and duodenum. The goal of radiologic examination is a proven method to establish the presence or absence, nature, and extent of disease and to define the nature and extent of disease with a diagnostic-quality study using the minimum radiation dose necessary. The following standards are for outline indicates key elements in the performance of single-contrast and double-contrast (biphasic) esophagrams and single-contrast and double-contrast (biphasic) upper GI examinations in infants and children. Typically, single-contrast studies technique is studies are used in infants and children; but occasionally, double-contrast technique is studies are indicated.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications for Esophagram

1. Pertinent history, signs, and symptoms serving as indications for an esophagram including, but are not limited to, the following:
   a. Dysphagia
   b. Odynophagia
   c. Noncardiac chest pain
   d. Recurrent pneumonia or chronic tracheobronchial inflammation

2. The esophagram is helpful in the diagnosis and Evaluation of suspected or known many conditions, including, but not limited to, the following:
   a. Great-vessel anomalies
   b. H-type tracheoesophageal fistula
   c. Extrinsic compression
   d. Postsurgical Evaluation following repair of esophageal atresia and/or tracheoesophageal fistula
   e. Esophageal strictures obstruction
   f. Suspected or known Motility disorders
   g. Esophagitis
   h. Foreign bodies
   i. Unexplained Pneumomediastinum or with clinical/imaging findings of esophageal injury [1]
   j. Suspected esophageal perforation
   k. Neoplasm
   l. Varices
B. Indications for Upper GI Examinations

1. Pertinent history, signs, and symptoms including, but not limited to, serving as indications for an upper GI examination include, but are not limited to, the following:
   a. Vomiting
   b. Abdominal pain
e. Epigastric distress or discomfort
c. Weight loss or failure to thrive
d. Congenital syndromes or anomalies associated with intestinal malrotation
e. Chronic or recurrent respiratory disease, including cough
g. Acute life-threatening event. The term “ALTE” infers a respiratory arrest or near arrest that has a differential diagnosis (apnea, child abuse, aspiration, etc).
f. Preoperative evaluation prior to gastrostomy tube placement
g. Postoperative evaluation such as to exclude leak or obstruction
   i. Abdominal masses
   j. Vomiting
   l. Signs and/or symptoms of upper GI bleeding

2. The upper GI examination is helpful in diagnosing and evaluating many conditions including, but not limited to, the following:
   a. Intestinal malrotation anomalies
   b. Hiatal hernia
c. Suspected or known Gastritis or duodenitis
d. Pyloric stenosis when ultrasound is not available
e. Gastric outlet or upper intestinal obstruction
f. Peptic ulcer disease
g. Duodenal laceration or intramural hematoma
h. Additional hernias (diaphragmatic, paraesophageal), including recurrent diaphragmatic hernia
i. Neoplasms

In reviewing indications for a contrast study of the stomach and duodenum, alternative imaging and nonimaging methods of examining these structures should be considered as might be relevant to the individual case.

For the pregnant or potentially pregnant patient, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [2] and the ACR Manual on Contrast Media [3].

III. QUALIFICATIONS OF PERSONNEL

For qualifications of physicians, medical physicists, radiologist assistants, and radiologic technologists, see the ACR–SPR Practice Parameter for General Radiography [4].

Additionally, Physicians performing this procedure should have documented formal training in the performance and interpretation of GI fluoroscopy as part of an accredited residency training program.
Qualifications of technologists performing GI radiography should be in accordance with the current ACR policy statement on fluoroscopy\(^2\) and with operating procedures or manuals at the imaging facility. Fluoroscopy technologists assisting in esophagrams or upper GI examinations should be thoroughly trained in GI radiography.

### IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for pediatric contrast esophagram or upper gastrointestinal examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

#### A. Patient Selection

For a routine esophagram, the patient should not have ingested anything by mouth for a minimum of 2 to 3 hours. For upper GI examinations, oral feeding should be withheld for a time period appropriate for the patient’s age: approximately 2 to 3 hours for neonates and young infants and 4 hours for older infants and children. Adolescents should fast for at least 6 to 8 hours prior to the examination. Emergency examinations may be performed with shorter fasting times as determined by the radiologist in concert with the referring physician.

#### B. Examination Preliminaries

An appropriate medical history should be available, including results of laboratory tests and imaging, endoscopic, and surgical procedures as applicable.

Use of a child life specialist and/or parent may be helpful in enabling young patients to cooperate for the examination. Immobilization devices may be helpful in patient positioning. These devices may help limit repeat radiographic exposures and unnecessary radiation dose to patients, parents, technologists, and other personnel.

A preliminary radiographic or fluoroscopic “scout” image of the chest and/or abdomen may be useful, depending on the specific clinical concern. Image hold or image-grab images should NOT be used as scout images since they are of much lower resolution, and subtle findings such as calcifications, small amounts of free air or pneumatosis, or bony abnormalities, etc., may be missed. Routine scout imaging prior to upper GI series in the outpatient setting, unless specifically requested by the ordering physician, can be replaced by a brief, initial fluoroscopic assessment, as the risk of radiation outweighs the benefit because the addition of a clinically significant finding that would change management is unlikely in outpatients \(^5\). A scout image should be obtained for inpatients if there

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\(^2\)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 12-m)

\(^5\)*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.
has been no recent radiograph as well as in postoperative patients and in those with an acute abdomen [5]. Preliminary images should be assessed for calcifications, skeletal abnormalities, anomalies of situs, bowel gas pattern, pneumoperitoneum, residual intraluminal contrast, evidence of prior surgery, catheters, and monitoring devices. A scout image of the chest should be assessed for pneumomediastinum and pleural effusion, especially in cases where an esophagram is performed [5]. A horizontal beam dependent image (upright or decubitus views) should be performed if the patient has an underlying condition that might predispose to GI tract perforation. In the absence of preceding abdominal imaging, scout images are especially helpful in the workup of neonatal bowel obstruction because they may influence the choice of initial fluoroscopic study and GI contrast (eg, upper GI for proximal bowel obstruction and contrast enema for distal small bowel or colonic obstruction).

C. Examination Technique

The examination procedure should be tailored by the radiologist to the individual patient to produce a diagnostic-quality examination as warranted by clinical circumstances and the condition of the patient, to produce a diagnostic-quality examination. Preliminary findings during the examination may indicate a need to alter technique in subsequent portions of the examination.

The contrast medium should be delivered in a manner that is appropriate for the patient’s age. Flavoring agents may be added in older patients. Neonates and infants may be fed contrast from a baby bottle with a nipple. Alternatively, a device consisting of a feeding tube or an orogastric tube passed through a nipple may be sometimes used to deliver the contrast into the mouth [6] or an enteral tube may be placed directly into the stomach; this tube placement should be performed done under careful fluoroscopic control to ensure correct positioning prevent aspiration. Older infants able to bottlefeed themselves may be allowed to do so. In the older child, the contrast may be given by straw, or taken directly from a cup, or administered by syringe; by an older child flavoring agents may be added. A nasogastric tube gastrostomy tube or jejunostomy tube may be used as appropriate.

In neonates or young infants with a history of bilious emesis, a nasogastric tube can be placed with the tip in the distal stomach to empty the stomach so that a controlled upper GI with a small amount of contrast and air can effectively evaluate for malrotation and/or volvulus using the least amount of contrast and fluoroscopic time.

The amount and type of contrast material given are determined by the child’s age and the indications for the study. Barium is the preferred contrast medium for most studies [7]. Nonionic, isomotic, or iodinated contrast media may be used given to assess the integrity of an esophageal anastomosis, diagnose duodenal obstruction or perforation, or diagnose intestinal malrotation/volvulus in selected critically ill patients. Iso-osmolar solutions are important in cases in which there is risk of aspiration [8]. Iso-osmolar contrast media are particularly important in critically ill premature neonates and infants to avoid serum electrolyte shifts. Diatrizoic acid, a very highly osmotically active water-soluble contrast agent, should not be administered orally in neonates and young infants because this patient population has a higher risk of gastroesophageal reflux and aspiration, and aspirated hyperosmolar contrast Diatrizoic acid may result in pulmonary edema and a severe chemical pneumonitis.

Sufficient still images and/or fluoroscopic image clips should be recorded to adequately evaluate normal anatomy and characterize any abnormalities. In general, this includes at least Anteroposterior and lateral projections of all anatomic structures should be obtained and often complemented by oblique images when indicated for adequate assessment. The use of fluoroscopic image store/last image-hold can markedly reduce patient dose compared to spot images. Although fluoroscopic stored store/last image-hold images do not have the same resolution as spot images, they may be adequate for documentation, depending upon the study circumstances, and can markedly reduce patient dose compared with spot images.

1. Single-contrast esophagram
a. The anatomic structure and motility of the entire esophagus should be evaluated fluoroscopically. Appropriate images should be obtained to document normal and abnormal findings. The examination is optimally performed in the lateral and anteroposterior projections, with visualization of the nasopharynx to the gastric fundus [9].

b. Esophagrams performed in infants with a suspected H-type tracheoesophageal fistula are optimally performed with the infant in a left or right lateral position in a controlled manner, with full distension of the esophagus, which can be achieved with normal drinking in patients who drink contrast readily. In patients who do not drink sufficient contrast to distend the esophagus, the contrast can be administered in small amounts at various points in the esophagus from the level of the carina to the level of the thoracic inlet initially through a small feeding tube placed prior to the examination in the upper esophagus near the thoracic inlet, with the infant in a right anterior oblique or lateral position. This requires careful fluoroscopic monitoring of the contrast as it exits the tube to prevent aspiration. If no fistula is identified on the early images, the study may be completed with standard oral administration of contrast. Fluoroscopic observation from hypopharynx to carina in the lateral view throughout contrast instillation usually will allow differentiation of contrast in the trachea due to aspiration versus a fistula.

c. Imaging of the esophagus should include an assessment of swallowing in the lateral view, especially if the patient has symptoms suggesting swallowing dysfunction, such as coughing and choking and/or gagging during feeding. This should include imaging from the base of the tongue through the lower esophageal sphincter. Modified barium swallow is a more detailed evaluation of the oral, pharyngeal, and upper esophageal phases of swallowing with variable consistency materials, usually performed in conjunction with a speech pathologist or occupational therapist. Please refer to the ACR-SPR Practice Parameter for the Performance of the Modified Barium Swallow [10] for additional information.

2. Double-contrast (biphasic) esophagram

Double-contrast esophagrams are seldom performed in pediatric patients, but they may help to evaluate mucosal integrity in adolescents. (See the ACR Practice Parameter for the Performance of Esophagrams and Upper Gastrointestinal Examinations in Adults [11], section IV.C.)

3. Single-contrast upper GI examination

a. Fluoroscopic assessment of swallowing and the anatomic structure and motility of the entire esophagus, stomach, and duodenum should be performed, and appropriate images should be obtained to document normal and abnormal findings. Suggested images include frontal and lateral views of the barium-distended esophagus, stomach, and duodenum and images of the partially filled esophagus. Initial passage of contrast through the duodenum should be observed directly with fluoroscopy to confirm the position of the duodenojejunal junction (DJJ) [12]. This can be documented with serial multiple fluorocapture images or fluoroscopy video capture where available [13]. On the first upper GI examination in an infant or child, the position of the DJJ should be documented on both frontal and lateral positions to diagnose or exclude malrotation [12,14]. The lateral view is important to ensure the retroperitoneal position of the normally rotated duodenum and the normal height of the DJJ at the level of the duodenal bulb; additionally, the straight anteroposterior (AP), nonobliqued frontal view ensures the normal position of the DJJ at or to the left of the left pedicle of the vertebral bodies and at a height approximately at the level of the duodenal bulb [15-17].

b. Images of gastroesophageal reflux should be recorded by last image-hold if reflux occurs during the examination. However, because reflux is a physiologic phenomenon and more sensitive tests exist, neither provocation of reflux nor prolonged fluoroscopic monitoring for detection is recommended [18].

c. A final image documenting gastric emptying and the progress of contrast through small-bowel loops may be obtained at the conclusion of the examination.
4. Double-contrast (biphasic) upper GI examination

Double-contrast upper GI examinations are seldom performed in pediatric patients, but they may help to evaluate mucosal integrity in adolescents and to detect subtle strictures because of the better esophageal distention that can often be achieved with the gas produced by swallowing Sodium Bicarbonate, Citric Acid, and Simethicone Effervescent Granule Pkt (eg, EZ gas crystals). (See the ACR Practice Parameter for the Performance of Esophagrams and Upper Gastrointestinal Examinations in Adults [11], section IV.C.)

5. Quality control indicators

The following quality control indicators should be applied to all esophagram and upper GI examinations:

a. When examinations are completed, patients should be held in the fluoroscopic area until the physician has reviewed the images.

b. An attempt should be made to resolve questionable radiologic findings before the patient leaves. Repeat fluoroscopy should be performed as necessary.

c. Correlation of radiologic, endoscopic, surgical, and pathologic findings is valuable for quality improvement whenever feasible.

V. DOCUMENTATION

An official interpretation (final report) of the examination should be included in the patient’s medical record.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [19].

VI. EQUIPMENT SPECIFICATIONS

Examinations must be performed with fluoroscopic and radiographic equipment meeting all applicable federal, state, and local radiation standards. Fluoroscopy units with settings for pediatric technique are recommended. If possible, a pulsed fluoroscopic technique and equipment should be used to reduce the radiation exposure. The equipment should provide diagnostic fluoroscopic image quality and recording capability (radiographs, video, or digital). The equipment should be capable of producing kilovoltage greater than 100 kVp. Equipment necessary to compress and isolate accessible regions of the small bowel should be readily available. Digital equipment with fluorohold and/or fluorocapture capability is desirable.

Facilities should have the ability to deliver supplemental oxygen, to suction the oral cavity and the upper respiratory tract, and to respond to life-threatening emergencies that may accompany aspiration, allergic reaction to contrast agents, or reflux.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf].

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used. Radiation doses should be determined periodically based on a reasonable sample of pediatric examinations. Technical factors should be appropriate for the size and the age of the child and should be determined with consideration of parameters such as characteristics of the imaging system, organs in the radiation field, lead shielding, etc. Guidelines concerning effective pediatric technical factors are published in the radiologic literature and at websites such as www.imagegently.org.

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 Position Statement on QC & 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).
ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Pediatric Radiology of the Commission on Pediatric Radiology, in collaboration with the SPR.

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REFERENCES


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.

Development Chronology for this Practice Parameter

- 1997 (Resolution 25)
- Revised 2001 (Resolution 29)
- Revised 2006 (Resolution 43, 17, 34, 35)
- Amended 2007 (Resolution 12m)
- Revised 2010 (Resolution 42)
- Amended 2014 (Resolution 39)
- Revised 2015 (Resolution 36)
RESOLUTION NO. 47

Multispecialty/General Radiologist

WHEREAS, the ACR Task Force on General Radiology and Subspecialization found in its 2012 report that “radiology and the medical community at large would be best served by maintaining a strong and well-trained cadre of general multispecialty radiologists who also develop additional focused expertise in a number of subspecialty areas.” [1]; and

WHEREAS, this Task Force also stated that “the future of radiology depends on radiologists’ maintaining a multidisciplinary team approach, for which the multispecialty radiologist can become a powerful and key facilitator”; and

WHEREAS, the ACR Workforce Survey has defined the General Radiologist as one who interprets more than 50% of their total work RVUs outside any single subspecialty; and

WHEREAS, recent analysis of Medicare claims has shown that 55% of practicing radiologists in the United States meet this definition of a General Radiologist [2]; and

WHEREAS, only 15% of radiologists in the 2019 ACR Workforce Survey self-identified as General Radiologists, possibly due to confusion with an older definition of a General Radiologist as one who has not completed any subspecialty training post-residency; and

WHEREAS, 58% of radiologists performing invasive procedures in the United States are General Radiologists [3]; and

WHEREAS, Multispecialty/General Radiologists provide essential diagnostic and interventional services to radiology groups, multispecialty groups, hospitals, and health systems throughout the country, particularly in underserved and rural areas with limited access to care; and

WHEREAS, many of these groups and hospitals report difficulty in replacing retiring radiologists or filling new positions as recent trainees report discomfort or even inability to interpret examinations or perform minor procedures outside their subspecialty; and
WHEREAS,

there is concern that non-radiologist providers are filling this unmet need in many health systems, particularly for minor interventional and fluoroscopic procedures; therefore,

BE IT RESOLVED

that the ACR will appoint a Task Force on the Multispecialty/General Radiologist to pick up on the work of the 2012 Task Force on General Radiology and Subspecialization and further study the contributions of this skillset to the current and future practice of radiology in the United States; and

BE IT FURTHER RESOLVED,

that the Task Force will consider promoting the use of the term “Multispecialty Radiologist” in addition to “General Radiologist” for those radiologists who practice more than 50% outside any area of subspecialty training to reduce confusion regarding this practice pattern; and

BE IT FURTHER RESOLVED,

that the Task Force will consider outreach to private practice radiology groups to discuss their workforce needs and novel ways in which these groups, the ACR, or other outside organizations might provide the necessary training to new graduates or other radiologists seeking to bolster skills in Multispecialty/General Radiology.

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Virginia Chapter of the American College of Radiology
West Virginia Radiological Society
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Fiscal Note

Multispecialty/General Radiologists

To support the resolution for Multispecialty/General Radiologists, the ACR would incur the following estimated costs:

Costs:
De minimis (< $10,000)

REFERENCES