# REFERENCE COMMITTEE I

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RESOLUTION NO. 1

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) C. COMMISSIONS AND COMMITTEES

1. APPOINTMENTS TO COMMISSIONS AND COMMITTEES

The Board of Chancellors shall regularly canvas all members to solicit the names of individuals who deserve consideration for and who would be interested in working on ACR Commissions and/or Committees.

Non-Members shall be used on College commissions and committees only when the talent needed is not available from the ACR membership; 1980, 1990, 2000, amended 2010 (Res. 39-a).

(b) C. COMMISSIONS AND COMMITTEES

2. REPRESENTATION OF RELATED ORGANIZATIONS

The ACR encourages inclusion of representatives of other radiological organizations as members on ACR commissions and committees; adopted 1980, 1990, 2000, amended 2010 (Res. 39-b).

(c) D. ANNUAL COUNCIL MEETING

5. EDUCATIONAL TOPICS FOR ACR MEETINGS

The Commission on Education and the Council Steering Committee, when planning educational sessions at the Annual Meeting, shall consider inclusion of topics deemed relevant to practice leadership and management, professional workforce development and diversity, along with quality and safety issues; adopted 2000, amended 2010 (Res. 39-c).

(d) A. EDUCATION

2. RESIDENT AND FELLOWSHIP TRAINING PROGRAMS

a. Medical Physics Residency Training Program
The American College of Radiology endorses the concept of a clinically oriented medical physics residency program which meets the requirements of the Commission on Accreditation of Medical Physics Education Programs (CAMPEP); adopted 1990, 2000, 2010 (Res. 1-a).

(e) A. EDUCATION

2. RESIDENT AND FELLOWSHIP TRAINING PROGRAMS

e. Residency Programs in Socioeconomics

The members of the American College of Radiology Council and all chapters reaffirm commitment to the socioeconomic education of residents and fellows. Directors of radiologic and radiation oncology residency programs shall strive to provide regular programs on socioeconomics and practice management. The program directors shall also encourage residents to attend ACR-sponsored educational meetings; 1990, 2000, amended 2010 (Res. 39-d).

(f) A. EDUCATION

4. MISCELLANEOUS EDUCATION POLICIES

b. Qualifications of Non-Physician Personnel Who Provide Radiologic and Radiation Oncologic Services

The American College of Radiology supports state licensure, certification or appropriate methods designed to assure the qualifications of all personnel who provide the technical aspects of medical imaging and/or radiation therapy procedures.

Non-physician personnel, may provide those aspects of radiological or therapeutic procedures for which they have appropriate education, training and experience as defined in the appropriate current American College of Radiology Practice Guideline(s) Parameters and Technical Standards, and then only under the supervision of a licensed physician(s) who has the qualifications described in those Practice Guideline Parameters and Technical Standards; 2000, amended 2010 (Res. 1-b).

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)
RESOLUTION NO. 2

BE IT RESOLVED,
that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Preoperative Image-Guided Localization in the Breast

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.

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF PREOPERATIVE IMAGE-GUIDED LOCALIZATION IN THE BREAST

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.

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...

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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.
I. INTRODUCTION

Preoperative image-guided localization of breast pathology before surgical resection is currently the standard of care for breast cancer and high-risk lesions. Localization devices guide appropriate excision and provide a surgeon with the best means to ensure complete removal of the target tissue. Preoperative localization with image-guided wire placement has been a standard of breast imaging diagnosis and treatment since its development in the 1970s [1]. Several recent advancements in nonwire localization (NWL) techniques minimize limitations of wire localization and have improved patient care and clinical workflow.

II. INDICATIONS

Presurgical localization in the breast may be performed for patients with selected indications including:

1. Biopsy-proven cancer
2. Biopsy-proven metastatic lymphadenopathy
3. High-risk lesions diagnosed at percutaneous biopsy
4. Imaging pathological discordance at core needle biopsy
5. Cases in which core needle biopsy is not an option or fails to provide a definitive histological diagnosis

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in breast imaging must meet the requirements that are appropriate to the scope of their practice as outlined in the following documents or practice parameters:

2. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures [3]
4. ACR Practice Parameter for the Performance of a Breast Ultrasound Examination [5]
7. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [8]

IV. SPECIFICATIONS OF THE PROCEDURE

Prior to localization, the radiologist should review all pertinent imaging examinations to determine the extent of disease. Review should determine whether biopsy markers deployed at the time of biopsy were placed in the appropriate position or whether they have migrated. In patients who have undergone neoadjuvant therapy, the original extent of disease and the visible residual are both important to consider. The localization may target a biopsy marker and/or the spectrum of breast imaging abnormalities: mass, calcifications, asymmetry, architectural distortion. If there is known malignancy, it is necessary to understand the extent of malignancy and its location with
respect to previously placed biopsy markers(s). More than one guidance device may be used to bracket the extent of disease [9,10]. The use of multiple localizing devices can decrease the number of procedures required to obtain clear lumpectomy margins and increase the rate of breast conservation versus mastectomy [9].

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented. 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 time-out. The breast, imaging equipment, field in which the procedure is to be performed, and physician performing the procedure should be prepared in conformity with the principles of infection control.

A. Localization Techniques

1. Wire localizations

Preoperative wire localization using mammographic, sonographic, or Magnetic Resonance Imaging (MRI) guidance is optimally performed the day of surgery. The wire may be placed at the breast lesion, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a biopsy marker is not present. If ultrasound guidance is used to place the wire, marking the location of the lesion on the overlying skin with the patient in the supine operative position and measuring the depth of the lesion can assist the surgeon during excision. Tomosynthesis-guided localization is an emerging alternative that may be used by some vendors and practices and differs slightly in technique from standard orthogonal mammographic practice. Limitations of wire localizations include need for same day placement as surgery, imprecision that results from variability in positioning by the radiologist, and inadvertent wire displacement (during patient transfer, postprocedure mammography, or surgical positioning) [11].

2. NWLs

Alternative forms of preoperative localization that do not use wire and mitigate wire localization limitations are now available and include radioactive seed, radiofrequency reflector, and magnetic seed. These localization devices offer increased patient comfort and decreased risk of movement of the localizing device compared to wires. In addition, the devices can be placed before the day of surgery. This uncoupling of localization from the day of surgery provides flexibility to both the radiologist and surgeon in the localization and surgical procedures and less waiting time for patients [12-14]. All forms of NWL typically have two components: a single-use sterilized device preloaded into a needle introducer and a reusable console with dedicated handheld probe for detection of deployment by radiologist and surgical guidance by surgeon. The localizing device may be placed at the breast lesion, adjacent to the biopsy marker (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a biopsy marker is not present. In addition to some type-specific limitations (outlined below), nonwire devices may be subject to imprecise positioning during placement or deployment.

a. Radioactive seed localization (RSL)

The radioactive seed placed for localization is composed of titanium and contains iodine-125. The radioactive seed is inserted through a needle with sonographic or mammographic guidance. Because the iodine-125–labeled seed half-life is 59.4 days, preoperative RSL using mammographic or sonographic guidance can be performed up to several days prior to surgery.

RSL programs require adherence to regulations for nuclear materials under the Nuclear Regulatory
Commission (NRC). A lost radioactive seed is a reportable medical event, and an established protocol is needed to manage the event. In addition, a migrated radioactive seed in the breast must be recovered [1,11,14-18].

b. Radar reflector

Radar localization technology was introduced in 2014 and utilizes radar device as an alternative to wire or radioactive seed. The device is delivered to the desired target in the breast via a needle. The reflector is passive until activated with infrared light from the dedicated handheld probe. Once activated, the device reflects the radar signal, which is detected by the probe and recorded by the console. The console provides audible and visual indicators that increase in cadence and decrease in number as the probe is closer to the reflector. The reflector can be placed with guidance from mammography or ultrasound any time prior to surgery. There is no limitation on length of time the reflector can stay in the breast, providing the opportunity for placement prior to initiation of neoadjuvant therapy. Reflectors placed at significant depth or within a postbiopsy hematoma may not produce a detectable signal to the skin [1,18-20].

c. Magnetic seed

Magnetic seed localization technology was introduced in 2016. The localization device is made from stainless steel. The seed is not magnetic, but it is induced to become a magnet under the influence of the handheld probe that produces an alternating magnetic field that transiently magnetizes the seed. The seed is delivered into the breast via a needle. Once the needle tip is in the desired position, a stylet is advanced within the needle to deploy the seed. Similar to radar reflector, the console provides increasing audible and numeric feedback as the probe is in closer proximity to the seed. The seed can be placed with guidance from mammography or ultrasound any time prior to surgery. There is no restriction on length of time the reflector can remain in the breast, providing the opportunity for placement prior to initiation of neoadjuvant therapy. The device is not compatible for deployment under MRI guidance; however, the patient can have an MRI following deployment, albeit with significant artifact. Nonmagnetic surgical tools need to be used while the probe is in use, and certain stainless steel instruments may not be compatible with the system. Compared with wires and other NWL devices, the magnetic seed is more resistant to damage on deployment, following implantation, or with electrocautery during surgery. There is no limitation on depth placement of magnetic seeds for detectable signal [1,18,21-23].

In each of the NWL methods, more than one localizing device may be placed to bracket the full extent of disease in patients with large masses, masses with satellite nodules or accompanying microcalcifications extending from the mass, or segmental or linearly distributed microcalcifications alone. When two or more localizing devices are used, each manufacturer recommends a specific minimum distance between the devices in order to discriminate between them.

In general, postlocalization preoperative orthogonal mammograms should be obtained to depict the localization and to guide the surgeon in the operative procedure. However, in the rare occasion of young women undergoing ultrasound-guided localizations, some practices will only use ultrasound to document placement of localizing device. Radiologists may elect to annotate the target and specify the final relation of the localization device to the target for the surgeon on the postlocalization mammogram. In all forms of preoperative wire localization, communication with the surgeon may avoid misunderstanding and may take the form of a telephone call, written comments, or annotation of the images.

B. Specimen Imaging

Specimen radiography is essential to document removal of the target and localization device and provide guidance to the surgeon as to the adequacy of excision [24,25]. This should occur while the patient is still in the operating room.
so the surgeon can remove more tissue if warranted.

If the lesion is a single mass, particularly if it was mammographically occult, ultrasound of the specimen can be used to document mass removal [26]. If the lesion contains microcalcifications, either extending from a mass or alone, specimen radiography is better to evaluate the adequacy of excision. When tumor can be seen extending to the specimen margins on the specimen radiograph, there is a high positive predictive value for residual tumor in the breast. Conversely, the negative predictive value of clear margins on specimen radiography is low. Therefore, even though the tumor may not appear to extend to the margins of the resected specimen on the specimen radiograph, the residual tumor may still be present in the breast. This may be particularly true for noncalcified Ductal carcinoma in situ DCIS and infiltrating lobular carcinoma [27,28].

C. Targeted axillary dissection

In an effort to minimize morbidity from complete axillary dissection, targeted axillary dissection with removal of sentinel lymph node and the index biopsy-proven metastatic node has been reported in patients who have undergone neoadjuvant therapy [29]. If a patient converts to node-negative status after therapy, the patient can potentially be spared complete nodal dissection. In this procedure, a pathology-proven metastatic lymph node with biopsy marker may be localized following neoadjuvant therapy. Routine intraoperative lymphatic mapping is performed along with removal of the localized metastatic lymph node. This combined sentinel lymph node dissection with localized removal of metastatic lymph node has a false-negative rate for axillary staging below 5% and provides a potentially safe way to limit axillary surgery [30].

V. DOCUMENTATION

Permanent records of image-guided breast localizations should be documented in a retrievable image storage format.

A. Image labeling should include permanent identification containing the following:

1. Patient’s first and last names
2. Identifying number and/or date of birth
3. Examination date
4. Facility name and location
5. Designation of left or right breast
6. Annotation of mammographic view (eg, craniocaudal, mediolateral oblique (MLO), 90° mediolateral [ML])
7. Technologist’s identification number or initials

B. The physician’s report of image-guided localizations should include the following:

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Safety time-out having been performed
5. Approach used
6. Type and amount of local anesthesia
7. Skin incision, if made
8. Type of localization device
9. Confirmation of postprocedure mammogram documenting accurate localizing device placement and location with respect to the targeted lesion
10. Complications and treatment, if any
11. Confirmation of specimen imaging (if not detailed in a separate report)
C. Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [31].

D. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility’s policies for retention of mammograms and in compliance with federal and state regulations.

VI. 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).

VII. EQUIPMENT

Equipment requirements are outlined in the following practice parameters:

1. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures [3]

ACKNOWLEDGEMENTS

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 – Breast Imaging of the ACR Commission on Breast Imaging.

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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.

Development Chronology for this Practice Parameter
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 3

BE IT RESOLVED,
that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures

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 2016 (Resolution 36)*

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF STEREOTACTIC/TOMOSYNTHESIS-GUIDED BREAST INTERVENTIONAL PROCEDURES

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.

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 Stereo/Tomosynthesis- Breast Guided 2020 Resolution No. 3
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

Image-guided core-needle biopsy (CNB) has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, less lower cost, and similar accuracy [1-9].

Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from breast imaging programs and have decreased the number of surgical procedures needed to treat breast cancer [3,5-7]. Therefore, minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions and is associated with low complication rates [10]. High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions as well as to accurately target these lesions for image-guided biopsy. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, including stereotactic guidance, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on lesion visualization and accessibility, availability of the imaging modality, efficiency, safety, patient comfort, and the practitioner’s experience [1].

Stereotactic guidance enables percutaneous placement of a needle within the breast to sample mammographically detected suspicious breast lesions. Successful use of stereotactic-guided breast interventional procedures relies on high-quality imaging, expertise in breast imaging feature analysis, experience in stereotactic-guided techniques for accurate lesion targeting/localization, and sampling, and effective methods of obtaining tissue for analysis [11-14].

Digital breast tomosynthesis (DBT) may be used with or without stereotactic guidance as another biopsy technique, either for findings visible only on DBT, or if preferred in certain cases over stereotactic guidance for mammographically visible findings, including calcifications, asymmetries, and especially architectural distortion. This technique, along with the other methods of image-guided biopsy, has changed the management of breast disease. Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from breast imaging programs and have decreased the number of surgical procedures needed to treat breast cancer [3,5,7]. Therefore, minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions. The imaging features and the histopathologic interpretations should be assessed for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations [1].

II. INDICATIONS/CONTRAINDICATIONS

A. Indications

Stereotactic and/or DBT-guided breast intervention is suitable for most mammographically depicted lesions, including microcalcifications, masses, asymmetries, and architectural distortions. DBT guidance may be used for findings that are amenable to mammographic stereotactic technique. For lesions seen only or better on DBT than on 2-D mammography, DBT-guided percutaneous biopsy is preferred if available [15-21]. In some cases,
a combination of tomosynthesis and stereotactic guidance may be optimal. Please refer to ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis (DBT) [22].

Indications for stereotactic and DBT-guided breast intervention include, but are not limited to, the following:

1. Biopsy for primary diagnosis (see Appendix) of:

   a. Lesions that are assessed as highly suggestive of malignancy in the Breast Imaging Reporting and Data System, Breast Imaging Atlas (BI-RADS®) Category 5 [23]
   b. Lesions that are assessed as suspicious abnormalities (BI-RADS® Category 4)
   c. Lesions that are assessed as probably benign (BI-RADS® Category 3) when there are valid clinical indications for biopsy or when short-interval imaging follow-up would be difficult or unreasonable (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, or plans to become pregnant in immediate future, etc) [24-27]
   d. Multiple suspicious lesions, particularly in a multifocal or multicentric distribution, to facilitate treatment planning
   e. Lesions seen on mammography that correlate with suspicious areas of enhancement present on contrast-enhanced breast MRI

2. Repeat biopsy

Repeat stereotactic or DBT-guided percutaneous sampling is an alternative to surgical biopsy in cases when the in which initial core biopsy results are nondiagnostic or are discordant with the imaging findings [1,28,29].

3. Presurgical localization

Stereotactic-guided localization or DBT-guided localization may be used as an alternative to standard mammographic localization for mammographically identifiable lesions prior to surgical procedures [30]. Devices that may be placed using these guidance methods include wires and other localizing devices. Localization may be performed with wire, needle-wire combination, or radioactive seeds.

B. Contraindications

Inability to visualize the target or breast lesion stereotactically at the time of the biopsy is a contraindication to stereotactic-guided breast intervention. Prior to the procedure, the patient should be asked about allergies, including metal allergies for clip placement. Patients may be asked whether they use of medications, such as aspirin or other platelet inhibitors, anticoagulants, or other agents known to impact bleeding times, and whether there is they have a history of a bleeding diathesis. However, a recent report suggested a report suggests that it is safe to proceed with biopsy when patients are anticoagulated [31]. Decisions regarding postponement or cancellation of a procedure or temporary cessation of anticoagulants can be made on a case-by-case basis at a programmatic level. The patient’s weight (for prone table), compressed breast thickness, and ability to remain in the position required for the procedure also should also be assessed in determining the appropriateness of the procedure for that patient. For lesions that are equally well seen on mammography and ultrasound, ultrasound guidance is usually preferred.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician
Stereotactic-guided breast biopsy procedures should be performed by physicians who meet the “Physician Qualifications for Stereotactic Breast Biopsy” [32,33]. Stereotactic breast biopsies may be performed in either collaborative or independent settings. Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactic- or DBT-guided breast procedures. DBT-guided breast procedures should be performed only by physicians who have completed the FDA mandated 8 hours of DBT training. Please refer to ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis (DBT) [22].

Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactic- or DBT-guided breast procedures prior to the stereotactic procedure, the physician should be able to identify the significant lesion(s) on mammography so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is used.

1. Initial qualifications

Training in mammographic image interpretation, medical physics, and specific hands-on training in the performance of stereotactic biopsy are imperative for successful performance of this procedure.

The initial qualifications as outlined for Stereotactic Breast Biopsy Accreditation Program Requirements provide this foundation [33].

2. Maintenance of competence

The physician should perform a sufficient number of procedures to maintain their skills. Continued competence should depend on participation in a quality control program as laid out under Section VIII in this practice parameter.

3. Continuing medical education (CME)

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [34].

4. Responsibilities for assessment of concordance

The physician who performs the procedure (either the radiologist or, in the collaborative setting, the surgeon) is responsible for determining sample adequacy of sampling. The performing physician or, if unavailable, his/her qualified designated physician, is responsible for obtaining histopathologic results and determining concordance [1,28-30,35]. These results should be communicated to the referring physician and/or to the patient, as appropriate.

B. Qualified Medical Physicist


1. Initial qualifications

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2 The following definitions are taken from the ACR Stereotactic Breast Biopsy Accreditation Program Requirements: A collaborative setting is one in which both radiologists and surgeons (or other physicians) conduct stereotactic breast biopsy procedures. An independent setting is one in which either radiologists or other physicians (typically surgeons) conduct stereotactic breast biopsies.
Medical physicists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [36]. In addition, medical physicists should have performed at least 1 hands-on stereotactic breast biopsy unit survey under the guidance of a medical physicist qualified to perform such surveys [33].

2. Maintenance of competence

Medical physicists should at least 2 stereotactic breast biopsy unit surveys every 2 years [33].

3. Continuing medical education

Medical physicists should obtain 3 hours of CME in stereotactic breast biopsy unit physics every 3 years [33].

C. Radiologic Technologist

1. Initial qualifications

Radiologic technologists should meet the qualifications specified in the ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography [36]. Radiologic technologists should also have documented 3 hours of Category A continuing education units in stereotactic-guided breast intervention and must have participated in at least 5 hands-on procedures under the guidance of a qualified physician or radiologic technologist [33]. For DBT-guided interventions, technologists also should have documented DBT training.

2. Maintenance of competence

Radiologic technologists should participate in at least 24 stereotactic-guided breast interventions every 2 years [33].

3. Continuing medical education (CME)

Radiologic technologists should be in compliance with the continuing education requirements of their certifying organization for the imaging modality for which they perform services [33].

IV. SPECIFICATIONS OF THE PROCEDURE

The written or electronic request for stereotactic/tomosynthesis-guided breast 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. Prior to the Procedure

The decision to perform a stereotactic- or DBT-guided breast interventional procedure should be made by an MQSA-certified physician who is qualified under Mammography Quality Standards Act (MQSA) and only after adequate imaging evaluation, including orthogonal views, of the breast is performed. In some cases, it may be preferred to employ a combination of stereotactic and DBT guidance for tissue sampling. Appropriate documentation stating the use of stereotactic guidance, DBT guidance, or both, should be made.

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented [1].

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 (see http://www.jointcommission.org/standards_information/up.aspx for more information).

The organization should have processes and systems in place for reconciling differences in staff responses during the time-out.

B. Procedure Technique

The breast is compressed between the image receptor and the compression plate. Scout imaging is performed to confirm that the targeted lesion lies within the accessible area. The physician performing the procedure may decide on the best approach utilizing either stereotactic guidance, DBT guidance, or a combination of the two techniques, based on the ability to see the lesion and the needle during the biopsy. Prior to the procedure, the physician should be able to identify the significant lesion(s) on mammography (or DBT) so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is used. Lesion targeting should be performed by the physician performing and/or supervising the procedure. The computer-generated coordinates are then transferred to the stereotactic targeting device, and the skin entry site is prepared.

The breast, the field in which the procedure is to be performed, and the physician performing the procedure should be prepared in conformity with the principles of infection control.

Documentation of appropriate needle positioning for sampling or localization should be obtained as part of the medical record, usually consisting of paired prefire stereotactic images or DBT image showing the device in the breast approaching the target. Postfire imaging usually is obtained at the discretion of the proceduralist. (If the device is placed in nonfire or not in fire mode, paired stereotactic images or DBT image with the needle in its final prebiopsy position should be obtained.)

When the biopsy is performed for microcalcifications, a magnification image of the core biopsy specimens specimen radiograph with magnification should be obtained to verify that the microcalcifications have been adequately sampled [1,35,37] prior to needle removal.

Placement of a tissue marker after biopsy is recommended, especially if a lesion may be difficult to see after the biopsy (eg, due to complete target removal or obscuration by postbiopsy change), of the target or a subtle target, when needing for confirmation that the proper lesion has been sampled or if neoadjuvant chemotherapy is contemplated. When multiple lesions are present and biopsy of >1 suspicious lesion is performed, placement of markers with different characteristics should be considered. Following performance of stereotactic-guided breast biopsy, a tissue marker should be placed at the biopsy site whenever...
To minimize hematoma formation, the skin entry site and the region of needle sampling should be adequately compressed until hemostasis is achieved.

Postprocedure mammography should be performed in 2 orthogonal views to document tissue marker position, and the report should state the position in relation relative to the biopsy site. If the procedure is performed for a DBT-only visible finding, then postprocedure images should include DBT images.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [38].

Permanent records of stereotactic- and DBT-guided breast interventions should be documented in retrievable image storage format.

A. Image labeling should include permanent identification containing the following:

1. Patient’s first and last names
2. Identifying number and/or date of birth
3. Examination date
4. Facility name and location
5. Designation of left or right breast
6. Annotation of mammographic view (e.g., craniocaudal, mediolateral oblique (MLO), 90° mediolateral [ML])
7. Technologist’s identification number or initials

Physician identification may be included on the permanent image record.

B. The physician’s report of stereotactic-guided breast intervention procedures should include document the following:

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Informed consent is obtained
5. Safety time-out having been performed
6. Approach used
7. Type and amount of local anesthesia
8. Skin incision, if made
9. Gauge of Needle gauge and device type of device (spring-loaded, vacuum-assisted, etc)
10. Number of specimen cores or samples acquired, if applicable
11. Specimen images, if performed, and findings their results

12. Use of stereotactic guidance, DBT guidance, or both
13. Tissue marker placement type/shape, if placed performed
14. Complications and treatment, if any
15. Postprocedure mammography, if obtained, documenting tissue marker placement and describing location of the tissue marker with respect to the biopsied lesion
16. Other information may include presence or absence of residual target calcifications or mammographically evident residual mass mammographic abnormality for future localization and follow-up purposes.
C. Postprocedure patient follow-up should consist of the following:

1. Documentation of any delayed complications and treatment administered
2. A Determination of concordance of pathology results with imaging findings by the physician who performed the procedure or the designated physician. (designee When discordant, biopsy should be repeated by imaging-guided image-guided percutaneous method or surgical excision [1,28,29].
3. Recommendations based on tissue sampling results, imaging information, and concordance analysis.
   Surgical consultation is usually recommended for high-risk lesions known to be subject to upgrade to malignancy at excision. These lesions include including atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, complex sclerosing lesion, phyllodes tumor, and, to a lesser degree, papilloma [39-51]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate [52,53]. For malignant results, patients are usually referred for consultation to a surgeon or oncologist for consultation.
4. Record of communications with the patient and/or referring physician
5. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility’s policies for retention of mammograms and in compliance with federal and state regulations.

VI. EQUIPMENT SPECIFICATIONS

Radiographic equipment used for stereotactic- and DBT-guided breast intervention procedures includes prone and add-on systems. The equipment should be calibrated by the manufacturer, and the medical physicist should complete verification of calibration and acceptance testing upon installation [54].

Several needle biopsy devices are available for stereotactic-guided procedures, including automated core needles, vacuum-assisted devices, and other tissue biopsy systems. The choice of biopsy device depends on the type of lesion as well as the operator’s experience. However, vacuum-assisted devices of 11 gauge and larger have been shown to be most effective in the performance of stereotactic biopsy for microcalcifications [55].

VII. EQUIPMENT QUALITY CONTROL

Refer to ACR stereotactic breast biopsy quality control manual [54].

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).

A documented quality control program with procedure manuals and records should be maintained for stereotactic-guided breast interventions. Imaging findings and pathologic interpretations should be correlated. Results of stereotactic-guided breast interventions should be monitored.

The following records should be maintained for the facility, practice, and individual physicians:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
Total number of stereotactic biopsies needing repeat biopsy, categorized by reason and biopsy type:

<table>
<thead>
<tr>
<th>Reason for Repeat Biopsy</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient sample</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
<tr>
<td>Discordance</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
<tr>
<td>High-risk lesions</td>
<td>• Total number of cases&lt;br&gt;• Number with repeat biopsy&lt;br&gt;• Final pathology results</td>
</tr>
</tbody>
</table>

Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy or the qualified physician designee. Postbiopsy patient follow-up should be performed per radiologist discretion (in some cases at 6 or 12 months, for example) to detect and record any false-negative and false-positive results.

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 Committee on Practice Parameters – Breast Imaging of the ACR Commission on Breast Imaging.

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REFERENCES


OLD REFERENCES


APPENDIX

ACR BI-RADS® ATLAS 5th Edition (BREAST IMAGING REPORTING AND DATA SYSTEM 2013 [23] (BI-RADS® Category 5)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Management</th>
<th>Likelihood of Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 0: Incomplete – need additional imaging evaluation</td>
<td>Recall for additional imaging</td>
<td>N/A</td>
</tr>
<tr>
<td>Category 1: Negative</td>
<td>Routine screening</td>
<td>Essentially 0% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 2: Benign</td>
<td>Routine screening</td>
<td>Essentially 0% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 3: Probably benign</td>
<td>Short-interval (6 month) follow-up or continued surveillance</td>
<td>&gt;0% but ≤2% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4: Suspicious</td>
<td>Tissue diagnosis</td>
<td>&gt;2% but &lt;95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4A: Low suspicion for malignancy</td>
<td></td>
<td>&gt;2% to ≤10% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4B: Moderate suspicion for malignancy</td>
<td></td>
<td>&gt;10% to ≤50% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 4C: High suspicion for malignancy</td>
<td></td>
<td>&gt;50% to &lt;95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 5: Highly suggestive of malignancy</td>
<td>Tissue diagnosis</td>
<td>≥95% likelihood of malignancy</td>
</tr>
<tr>
<td>Category 6: Known biopsy-proven malignancy</td>
<td>Surgical excision when clinically appropriate</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*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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Revised 2000 (Resolution 41)
Revised 2005 (Resolution 45)
Amended 2006 (Resolution 34,35)
Revised 2009 (Resolution 28)
Revised 2014 (Resolution 6)
Revised 2016 (Resolution 36)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 4

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACOG–AIUM–SRU Practice Parameter for the Performance of Sonohysterography and Hysterosalpingo-Contrast-Sonography (HyCoSy)

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 37) *

ACR–ACOG–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF SONOHYSTEROGRAPHY AND HYSTERO­SALPINGO-­CON­TRAST-­SONOGRAPHY (HyCoSy)

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

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications and Contraindications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician qualifications, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control and Patient Education vary among the 4 organizations and are addressed by each separately.

This practice parameter has been developed to assist qualified physicians performing saline infusion sonohysterography (SIS) and hysterosalpingo contrast sonography (HyCoSy); each procedure is addressed separately. Properly performed SIS sonohysterography and HyCoSy can provide information about the uterus, endometrium, and fallopian tubes. Additional studies may be necessary for complete diagnosis. Adherence to the following practice parameter will maximize the diagnostic benefit of each procedure: sonohysterography.

Sonohysterography SIS is the evaluation of the endometrial cavity using the transcervical injection of sterile fluid. Various terms, such as saline infusion sonohysterography or hysterosonography, have been used to describe this technique. The primary goal of sonohysterography is to visualize the endometrial cavity in more detail than is possible with standard routine transvaginal endovaginal ultrasound (US) [1]. Sonohysterography may also be used to assess tubal patency [2]. The accuracy of SIS approaches hysteroscopy in detecting endometrial abnormalities [2,3]. An increase in the amount of free pelvic fluid at the end of the procedure indicates that at least one tube is patent.

HyCoSy, also known as sonosalpingography, is the US evaluation of tubal patency. Tubal patency is demonstrated by instilling contrast into the fallopian tubes via the endometrial cavity, with either direct visualization of fluid flowing through the various tubal segments and out of the tube or the accumulation of fluid in the cul-de-sac. An increase in the amount of free pelvic fluid at the end of the procedure indicates that at least one tube is patent. HyCoSy has been demonstrated to have an accuracy essentially equivalent to hysterosalpingogram (HSG) and chromoperturbation at laparoscopy [2,3].

II. INDICATIONS AND CONTRAINDICATIONS

A. Sonohysterography (SIS):

1. Indications [1,4-13]

Indications include, but are not limited to, evaluation of the following:

a) Abnormal uterine bleeding
b) Uterine cavity evaluation, especially with regard to relating to uterine leiomyomas, polyps, and synechiae, and cesarean scar niches [14]

c) Abnormalities detected on endovaginal transvaginal sonography, including focal or diffuse endometrial or intracavitary abnormalities

d) Congenital or acquired abnormalities of the uterus

e) Infertility [15-17]

f) Recurrent pregnancy loss

g) Suboptimal visualization of the endometrium by standard sonography endovaginal ultrasound

2. Contraindications

Sonohysterography should not be performed in a woman who is pregnant or who could be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has essentially completely or almost completely ceased and but before the patient has ovulated. In a patient with regular cycles, sonohysterography should ideally not in most cases be performed prior to later than the 10th day of the menstrual cycle. Sonohysterography should not be performed in patients with a pelvic infection or unexplained pelvic tenderness which that could be due to pelvic inflammatory disease. Active vaginal bleeding is not a contraindication to the procedure but may make the interpretation more challenging [18].

B. HyCoSy

1. Indications [15,16]

Indications include, but are not limited to, evaluation of the following:

a) Determination of tubal patency in patients desiring fertility [19]

b) Confirmation of tubal occlusion after sterilization procedures [20]

2. Contraindications

HyCoSy should not be performed in a woman who is pregnant or who could be pregnant. In patients with regular cycles, this is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has completely or almost completely ceased and before the patient has ovulated. HyCoSy should not be performed in patients with a pelvic infection or unexplained pelvic tenderness which that could be due to pelvic inflammatory disease. The presence of a hydrosalpinx is not an absolute contraindication to HyCoSy [21]. HyCoSy should not be performed in the presence of active vaginal bleeding.

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:

See the ACR–SPR–SRU Practice Parameter for the Performing and Interpreting Diagnostic Ultrasound Examinations [22].

In addition, it is strongly recommended that the physician performing the study has must have spent a minimum of 3 months in documented formal training in the performance, interpretation, and reporting of US examinations of the female pelvis, reproductive system. Additionally, the physician should supervise and interpret US examinations of the female pelvis reproductive system on a regular basis and be familiar with techniques of cervical cannulation.
IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for SIS and HyCoSy Sonohysterography 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)

V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A. Patient Preparation

Pelvic organ tenderness should be assessed during the preliminary transvaginal sonogram. If the patient’s history or physical examination is concerning for active pelvic inflammatory disease, the SIS/HyCoSy examination should be deferred until an appropriate course of treatment has been completed. In the presence of nontender hydrosalpinges, consideration may be given to administering antibiotics at the time of the examination; in this case it is prudent to discuss the antibiotic regimen with the referring physician. A pregnancy test is advised when clinically indicated. Patients should be questioned about a latex allergy or a reaction to povidone-iodine betadine or other topical antiseptic (2% -4% chlorhexidine gluconate is a safe alternative [23,24]) prior to use of these products. In patients with regular cycles, a sonohysterogram or HyCoSy should be performed in the early follicular phase, as close to the end of the menstrual bleeding period as possible.

B. Procedure

1. SIS

A previous transvaginal sonogram should be performed prior to performing an SIS. is useful for measurement of the endometrium and evaluation of the uterus, ovaries, and pelvic free fluid. A speculum is used to allow visualization of the cervix. The presence of unusual pain, lesions, or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. The pre-SIS US allows identification of pertinent pelvic anatomy, may visualize other adnexal or ovarian abnormalities, and allows the unenhanced (with no fluid) assessment of the myometrium and endometrium. This study allows visualization of the orientation and flexion of the uterus, which may assist in placement of the catheters. Prior to insertion, the catheter should be flushed with sterile fluid to avoid introducing air during the study. After cleansing the external os, the cervical canal and/or uterine cavity should be catheterized using an aseptic technique and appropriate normal saline or other contrast fluid sterile fluid should be instilled slowly by means of manual injection under real-time sonographic imaging. Imaging should include real-time scanning of the endometrium and cervical canal [25,26]. Imaging may include evaluation of fallopian tube patency if indicated.
2. **HyCoSy**

A transvaginal sonogram should be performed prior to performing HyCoSy. The presence of unusual pain or purulent vaginal or cervical discharge may require rescheduling the procedure pending further evaluation or treatment. The preliminary US allows identification of pertinent pelvic anatomy and may visualize other adnexal or ovarian abnormalities. The preliminary study visualizes the orientation and flexion of the uterus, which may assist in placement of the catheters. A sonohysterogram (SIS) can be performed, as described above, immediately prior to HyCoSy. If performing an SIS, the catheter should be flushed with sterile fluid prior to insertion. After cleansing the external os, the cervical canal or uterine cavity should be catheterized using an aseptic technique, typically using a balloon catheter to avoid backflow of fluid during HyCoSy. Appropriate sterile fluid, with air, contrast, or foam, is instilled slowly by means of manual injection under real-time sonographic imaging [19,25-27]. Commercial devices that mix air and saline together to form the air-infused saline for HyCoSy are available. One can produce similar results by filling a 30-cc syringe with 15 cc of saline and 15 cc of air. Pushing the plunger while rocking the syringe up and down effectively infuses air with saline, which is easily seen on US.

C. **Contrast Agent**

1. **SIS**

Appropriate sterile fluid, such as Sterile normal saline should be used for sonohystrography. If the requesting physician is interested in tubal patency, then a sonosalpingogram can be offered using agitated saline [28,29].

2. **HyCoSy**

Appropriate sterile fluid, such as normal saline infused with air or appropriate contrast medium, should be used for HyCoSy.

D. **Analgesics**

1. **SIS**

Nonsteroidal anti-inflammatory drugs (NSAIDS) may benefit some patients during SIS.

2. **HyCoSy**

Some authors advocate the use of nonsteroidal anti-inflammatories to reduce pain and potentially reduce tubal spasm, similar with HSG [30-32].

E. **Images** [33]

1. **SIS**

Precatheterization images should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis [34], in at least two planes, to demonstrate normal and abnormal findings. These images should include the thickest bilayer endometrial measurement, which includes the anterior and posterior endometrial thicknesses, obtained in a sagittal view.

It is recommended to instill fluid into the endometrial cavity with real-time US, ensuring adequate visualization. Once the uterine cavity is filled with fluid, a complete survey of the uterine cavity should be performed, and representative with images obtained to document normal and abnormal findings. **Images should**
include sagittal and transverse images of the endometrium, with measurement of each layer of the endometrium in the sagittal plane. One should also evaluate the endometrium for any asymmetry, irregularity, or presence of focal lesions. 3-D imaging may be helpful in the evaluation. If an intrauterine balloon catheter filled with saline is used for the examination, additional images should be obtained at the end of the procedure with the balloon deflated to fully evaluate the endometrial cavity, particularly the cervical canal and lower portion of the endometrial cavity, including a cesarean scar niche, if present.

The location of any focal lesions should be demonstrated in sagittal and transverse planes, or with 3-D imaging. The size, sonographic characteristics, and depth of penetration into the myometrium, in the case of submucous myomas, should be documented. The use of color Doppler or power Doppler sonography may be helpful in evaluating the vascularity of an intrauterine abnormality, and tubal patency.

3-D imaging, specifically reconstructed coronal plane imaging, is also useful in the assessment of Müllerian duct anomalies and for preoperative mapping of myomas [35,36].

2. HyCoSy

Precatheterization images of the pelvis should be obtained and recorded in accordance with the ACR-ACOG-AIUM-SPR-SRU Practice Parameter for the Performance of Ultrasound of the Female Pelvis [34].

It is recommended to instill fluid into the endometrial cavity with real-time US, ensuring adequate visualization. If SIS is performed prior to HyCoSy, images are obtained as described above. Prior to instilling contrast for HyCoSy, the uterus is imaged in a transverse plane, visualizing both cornua simultaneously. Contrast is then instilled under direct US visualization, assessing the passage of contrast through the courses of the fallopian tubes, including the interstitial and isthmic portions, the ampulla, and passage of contrast from the fimbria. Accumulation of contrast in the pelvis is consistent with at least one patent tube. Rotating the patient on each hip may assist in demonstrating tubal patency. Various authors have found power Doppler and 3-D imaging helpful in evaluating tubal patency [37,38]. The lack of tubal patency should be considered with swirling of contrast in the cornual regions of the endometrium. Tubal spasm may result in a similar appearance [39].

F. Postprocedure Care

The imaging or referring physician should discuss the SIS sonohysterogram and/or HyCoSy findings with the patient. The patient should be told to expect may experience leaking of fluid after the procedure that could may be blood-tinted or may have a similar color as the cleaning solution. The patient should be instructed to contact their physician if the symptoms such as fever, persistent pain, or unusual bleeding develop following the procedure. The patient should be told to expect leaking of fluid after the procedure that may be blood-tinted or may have a similar color as the cleaning solution.

VI. DOCUMENTATION

Adequate documentation is essential for high quality in patient care. There should be a permanent record of the US examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. The initials of the operator should be accessible on the images or electronically on the PACS. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the US examination should be included in the patient’s
Retention of the US examination images should be based on clinical need and relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [40].

1. SIS

Measurement of the endometrium should be done in the sagittal plane by measuring each layer of the endometrium separately and then adding the results together to obtain the endometrium thickness. One should document whether the layers are uniform and symmetric or if there is asymmetry or irregularities present. Measurement of endometrial polyps and fibroids should be made in three orthogonal planes. When addressing fibroids, a comment about the subjective depth of projection into the endometrial cavity, as a percentage of the overall size of the fibroid, is helpful in determining treatment options.

2. HyCoSy

Images should be obtained in the transverse plane, ideally visualizing both uterine cornua simultaneously. Documentation should include flow of contrast through the interstitial portion of the tube, the ampullary portion of the tube, and out the fimbriated end of the tube. Documentation should include any change in the amount of cul-de-sac fluid during the HyCoSy. Flow of contrast may not be seen in all tubal segments because of overlying bowel loops or acoustic shadows from bowel contents. If brisk flow is seen through at least one tubal segment, without associated tubal dilatation, the tube is considered patent. The lack of flow into and through the tube should be documented.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [32].

Sonohysterography HyCoSy is usually conducted with a high-frequency transvaginal transducer. In cases of an enlarged uterus, additional transabdominal images during infusion may be required to fully evaluate the endometrium. The transducer should be adjusted to operate at the highest clinically appropriate frequency under the ALARA (“as low as reasonably achievable”) principle.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

Vaginal transducers should be covered by a protective sheath prior to insertion. Coupling gel should be used. Following the examination, the sheath should be disposed of and the transducer cleaned with a high-level disinfectant. The type of solution and amount of time for cleaning should follow manufacturer and infectious disease control recommendations.

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 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 – Ultrasound of the ACR Commission on Ultrasound in collaboration with the AIUM, the ACOG, and the SRU.

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Members represent their societies in the initial and final revision of this practice parameter.

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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.

Development Chronology for this Practice Parameter

2002 (Resolution 28)
Amended 2006 (Resolution 35)
Revised 2007 (Resolution 26)
Revised 2011 (Resolution 6)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 37)
RESOLUTION NO. 5

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of Scrotal Ultrasound Examinations

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 35) *

ACR–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF SCROTAL ULTRASOUND EXAMINATIONS

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.

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 Scrotal Ultrasound
2020 Resolution No. 5
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

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the Society of Radiologists in Ultrasound (SRU), and the Society for Pediatric Radiology (SPR). Recommendations for Qualifications and Responsibilities of Personnel, physician requirements Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the four organizations and are addressed by each separately.

These practice parameters are intended to assist practitioners performing ultrasound studies of the scrotum. In some cases, additional and/or specialized examinations may be necessary. Although it is not possible to detect every abnormality, adherence to the following practice parameters will maximize the probability of detecting most of the abnormalities that occur in the scrotum.

II. INDICATIONS

Indications for scrotal ultrasound include, but are not limited to [1,2], the following:
1. Evaluation of scrotal pain, including, but not limited to, testicular trauma, ischemia/torsion, postsurgical and infectious or inflammatory scrotal disease [3-10]
2. Evaluation of a palpable inguinal, intrascrotal, or testicular mass [1,2,11-13]
3. Evaluation of scrotal asymmetry, swelling, or enlargement [1,2,14-16]
4. Evaluation of potential intrascrotal hernia [17]
5. Detection/evaluation of varicoceles [18]
7. Follow-up of prior indeterminate scrotal ultrasound findings [19]
8. Localization of nonpalpable testes [20,21]
9. Evaluation of inguinal testes [22]
10. Detection of an occult primary tumor in patients with metastatic germ cell tumor [23] or unexplained retroperitoneal adenopathy
11. Follow-up of patients with prior primary testicular neoplasms, leukemia, or lymphoma [24]
12. Evaluation of an abnormality noted on other imaging studies (including, but not limited to, computed tomography [CT], magnetic resonance imaging [MRI] and positron emission tomography [PET])

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:
See the ACR-SPR-SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [26].

IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for scrotal ultrasound 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)

V. SPECIFICATIONS OF THE EXAMINATION

The presence of two testes should be documented either on a single transverse, coronal, or coronal oblique image. Also, a cine loop survey scan, taken in both longitudinal and transverse projections, can be obtained and stored with the rest of the study. The testes should be evaluated in at least two planes, longitudinal and transverse. Transverse images should be obtained in the superior, mid, and inferior portions of the testes. Longitudinal views should be obtained centrally as well as medially and laterally. In cases of acute swelling or pain, some authors suggest that the asymptomatic side should be evaluated first and the symptomatic side afterward with the same/similar grayscale and Doppler settings [8]. Each testis should be evaluated in its entirety. The size, echogenicity, and blood flow of each testis and the epididymis should be compared with the contralateral side. Comparison of the testes is best accomplished with a side-by-side transverse image. If a palpable abnormality is the indication for the sonogram, this area should be directly imaged [1,2]. In the event that a testis is not identified within the scrotum, the ipsilateral inguinal canal and inguinal rings should be scanned. The pelvis and the retroperitoneum may also be scanned to look for testicular ectopia [21].

Relevant extratesticular structures should be evaluated. The head, body, and tail of the epididymis should be evaluated when technically feasible. The spermatic cord and the suprastesticular area should be evaluated if there is suspicion for testicular torsion [9,10,27]. The scrotal wall, including the overlying skin, should be evaluated. Additional techniques, such as the Valsalva maneuver or upright positioning, can be used as needed. Any abnormality should be documented. In pediatric patients, Testicular volumes could be provided using the Lambert formula length (L) × width (W) × height (H) × 0.71) or ellipsoid formula (L × W × H × 0.52) [28].

Doppler sonography (spectral and color/power Doppler imaging) should be used as necessary in examinations of the scrotum and is required in the setting of acute scrotal pain and evaluation of varicocele. If used, color and/or power Doppler sonography should include at least one side-by-side image comparing both testes. Identical Doppler settings should be used to evaluate symmetry of flow between the testes. Low-flow detection settings should be used, if necessary, to document testicular blood flow.

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VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [29].

VII. EQUIPMENT SPECIFICATIONS

Scrotal studies should be conducted with a real-time scanner, preferably using a 7–12 MHz or higher linear array transducer. A curvilinear or vector transducer or linear transducer with lower frequencies may be needed if the scrotum is enlarged, recognizing that there is a trade-off between spatial resolution and beam penetration. The highest possible Doppler frequencies (typically in the 5.0-10 MHz range) providing optimal resolution and flow detection should be utilized. The Doppler frequency may differ from imaging frequency. Stand-off pads can be used, if necessary, to improve imaging.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

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).

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [30].

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 – Ultrasound of the ACR Commission on Ultrasound and by the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the AIUM, the SPR, and the SRU.
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REFERENCES


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 Guideline
1993 (Resolution 5)
Revised 1997 (Resolution 30)
Revised 2001 (Resolution 38)
Revised 2006 (Resolution 42, 35)
Revised 2010 (Resolution 33)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 35)
RESOLUTION NO. 6

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SRU Practice Parameter for the Performance of Ultrasound Evaluation of the Prostate (and Surrounding Structures)

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 34) *

ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND EVALUATION OF THE PROSTATE (AND SURROUNDING STRUCTURES)

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

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician qualifications, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the three organizations and are addressed by each separately.

Ultrasound examination of the prostate and surrounding structures is used in the diagnosis of prostate cancer, benign prostatic enlargement, prostatitis, prostatic abscess, congenital anomalies, ejaculatory dysfunction, and male infertility as well as for the treatment of prostate cancer, abscess, and benign prostatic enlargement [1]. Ultrasound-guided biopsy of the prostate is useful for evaluating those patients who have abnormal digital rectal examinations or an abnormal serum prostate-specific antigen (PSA) level, azoospermia, a low ejaculatory volume, and those in whom tissue diagnosis is needed for further management.

Ultrasound findings may be used to guide targeted or systematic biopsy of the prostate or guide a targeted biopsy approach, which is performed to supplement the standard systematic biopsy protocol in order to improve the positive cancer yield of prostate biopsy [2,3]. However, current Conventional ultrasound techniques using grayscale Doppler, color Doppler, and power Doppler imaging elastography, and contrast-enhanced ultrasound are not sufficient to confirm or exclude the presence of prostate cancer and they should not be used to preclude the performance of prostate biopsy [4-6]. Although newer techniques using elastography and contrast-enhanced ultrasound may provide superior detection of prostate cancer, these techniques are not sufficiently established to be included as standard of care at this time.

These practice parameters are intended to assist practitioners performing an ultrasound examination of the prostate. Ultrasound of the prostate and surrounding structures should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure should be used to gain the necessary diagnostic information. In some cases, an additional and/or specialized examination may be necessary. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of abnormalities of the prostate.

II. INDICATIONS

Indications for prostate ultrasound include, but are not limited to, the following:

1. Guidance for biopsy in the presence of an abnormal digital rectal examination or elevated PSA [7] or a suspicious prostatic lesion detected on MR. This includes use of transrectal ultrasound (TRUS) biopsy as part of the TRUS/MRI fusion technique [6]
2. Assessment of prostate volume prior to medical, surgical, or radiation therapy [8,9] and to calculate PSA density [10]
5. Assessment of congenital anomalies [13]
6. Infertility including azoospermia and a low ejaculatory volume
7. Hematospermia
8. Evaluation for suspected recurrence in the prostatectomy bed in patients who have undergone prostatectomy
9. Ejaculatory dysfunction or painful ejaculation

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document. ACR language is as follows:

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [14].

IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document. ACR language is as follows:

The written or electronic request for ultrasound evaluation of the prostate 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)

V. SPECIFICATIONS OF THE EXAMINATION

The following practice parameters describe the examination of the prostate and surrounding structures.

A. Prostate

The transrectal approach to ultrasound of the prostate is the method of choice because the resulting image quality is superior to transabdominal or transperineal examinations. In patients for whom the transrectal approach is not possible, a transperineal ultrasound examination may be used to direct a biopsy procedure [15]. A transabdominal approach can be useful to obtain an estimate of prostate size in some settings.

The prostate should be imaged in its entirety in at least two orthogonal planes, sagittal and axial or longitudinal and coronal, from the apex to the base of the gland. An estimated volume is determined from measurements in three orthogonal planes (volume = length x height x width x 0.52) [16,17]. The volume of the prostate may be correlated with the PSA level. Alternatively, prostate volume can be calculated using prostate planimetry, which allows greater accuracy by accommodating individual variations in prostate shape [18].
The gland should be evaluated for focal mass, echogenicity, symmetry, and continuity of margins. Color and power Doppler sonography may be helpful in detecting areas of increased vascularity that can be used to select potential sites for biopsy [19]. A cine loop survey scan, taken in both longitudinal and transverse projections, can be obtained and stored with the rest of the study. The periprostatic fat and neurovascular bundle should be evaluated for symmetry and echogenicity. Demonstration of any interruption in the normal fat plane along the anterior perirectal space may be particularly important to aid characterization of malignant lesions in the prostate and for evaluation of periprostatic spread of cancer. The course of the prostatic urethra should be documented when possible, and asymmetry between left and right periurethral tissues as well as any effect on the base of the bladder should be noted.

B. Seminal Vesicles, Vasa Deferentia, and Perirectal Space

The seminal vesicles should be evaluated for size, shape, position, symmetry, and echogenicity from their insertion into the prostate via the ejaculatory ducts to their cranial and lateral extents. Particular attention should be given to the normal tapering of the seminal vesicle as it joins the prostate. In patients being evaluated for infertility, the vasa deferentia must be evaluated. The presence and size of seminal vesicle, ejaculatory, Müllerian, or utricle cysts or evidence of seminal vesicle or ejaculatory duct obstruction should be noted. Inclusion of the anterior perirectal space, in particular the region that abuts the prostate and perirectal tissues, is important.

VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [20].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. The prostate should be measured in three planes. Any focal abnormality should also be measured. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [21].

A. Equipment

Endorectal ultrasound of the prostate should be conducted with a transrectal (also termed endorectal) transducer using the highest clinically appropriate frequency (usually 6 MHz or higher), realizing that there is a trade-off between resolution and beam penetration. Both side-fire and end-fire transducers may be used. A lower-frequency transducer may be necessary for transabdominal and transperineal examinations, which may be performed with curvilinear or sector transducers.
Ultrasound-guided prostate biopsy can be performed with side-fire probe, or end-fire probe, or biplanar or triplanar transducer configuration, acknowledging that transducer selection may vary with specific anatomic considerations [22].

B. Care of the Equipment

The transrectal probe, after ultrasound gel application, must be covered by a disposable sheath prior to its insertion. Additional gel should be applied after covering the probe with a disposable sheath to aid in comfort with probe insertion and optimizing transducer to target interface. Following the examination and disposal of the sheath, the probe must be disinfected. The method of disinfection may vary by manufacturer recommendations and institutional practices. It is optimal to use a high-level disinfection protocol. Disposable accessory items used during the study must be discarded after each examination. Reusable accessory items should be processed or sterilized according to appropriate guidelines and procedures.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:

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

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 – Ultrasound of the ACR Commission on Ultrasound, in collaboration with the AIUM and the SRU.

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REFERENCES


5. Kundra V, Silverman PM, Matin SF, Choi H. Imaging in oncology from the University of Texas M. D. Anderson Cancer Center: diagnosis, staging, and surveillance of prostate cancer. AJR. American journal of roentgenology 2007;189:830-44.


*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

1992 (Resolution 10)
Revised 1996 (Resolution 21)
Revised 2000 (Resolution 39)
Revised 2005 (Resolution 31)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 32)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 34)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SRU Practice Parameter for the Performance of Diagnostic and Screening Ultrasound of the Abdominal Aorta 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 32)*

ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF DIAGNOSTIC AND SCREENING ULTRASOUND OF THE ABDOMINAL AORTA IN ADULTS

PREAMBLE

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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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I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician requirements, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the three organizations and are addressed by each separately.

These practice parameters are intended to assist in the performance and interpretation of the dedicated sonographic examination of the abdominal aorta. The examination may be performed as a diagnostic or screening study [1-3]. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of abnormalities of the abdominal aorta.

II. INDICATIONS/CONTRAINdications

Indications for ultrasound of the abdominal aorta include, but are not limited to, the following:

A. Diagnostic Evaluation for Abdominal Aortic Aneurysm (AAA).

1. Palpable or pulsatile abdominal mass or abdominal bruit
2. Unexplained lower back pain, flank pain, or abdominal pain
3. Follow-up of a previously demonstrated AAA

Recommendations for rescanning patients are as follows [4]:
   a. For AAA size 3.0-3.9 cm: follow-up ultrasound every three years
   b. For AAA size 4.0-4.9 cm: follow-up annually
   c. For AAA size 5.0-5.4 cm: follow-up every 6 months
4. Follow-up of patients with an abdominal aortic and/or post-AAA repair, particularly post-endovascular aortic aneurysm repair (EVAR) iliac endoluminal stent graft

B. Screening Evaluation for Abdominal Aortic Aneurysm

1. Men age 65 or older who have ever smoked
2. Women age 65 or older with cardiovascular risk factors
3. Patients Individuals age 50 or older with a family history of aortic and/or peripheral vascular aneurysmal disease
4. Patients Individuals with a personal history of peripheral vascular aneurysmal disease
5. **Individuals with other risk factors for AAA** 

Groups with additional risk include patients with a history of smoking, hypertension, or certain connective tissue diseases (e.g., Marfan syndrome).

There are no absolute contraindications to ultrasound of the aorta. If aortic rupture or dissection is clinically suspected, ultrasound is usually not the examination of choice.

III. **QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

Each organization will address this section in its document. ACR language is as follows:

See the [ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations](https://www.acr.org) [5].

IV. **WRITTEN REQUEST FOR THE EXAMINATION**

Each organization addresses this requirement individually. ACR language is as follows:

The written or electronic request for ultrasound of the abdominal aorta 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)

V. **SPECIFICATIONS OF THE EXAMINATION**

A. **Diagnostic Examination**

The examination includes the following, when feasible:

1. **Abdominal aorta**
   
   a. Longitudinal images (along the long axis of the vessel)
      
      i. Proximal (below diaphragm, near the celiac artery)
      
      ii. Mid (near the level of the renal arteries)
      
      iii. Distal *(above through)* the iliac bifurcation
      
      iv. The aorta should be imaged in the plane that is parallel to the long axis of the lumen (for measurement of the anteroposterior (AP) dimension) and perpendicular to the long axis of the lumen (for measurement of the transverse dimension). The transverse measurement may also be obtained in the coronal plane [6].
   
   b. Transverse images (perpendicular to the long axis of the vessel)
      
      i. Proximal (below diaphragm, near the celiac artery)
      
      ii. Mid (near the level of the renal arteries)
      
      iii. Distal *(above through)* the iliac bifurcation
c. Measurements
  i. Measurements of the proximal, mid, and distal aorta should be obtained using predominantly the
     long axis view to measure the AP dimension. Transverse or coronal views should also be obtained
     to measure the width. Measurements are taken at the greatest diameter of the aorta, from outer edge
     to outer edge. The aorta should be imaged in the plane that is parallel to the long axis of the
     lumen (for measurement of the anteroposterior [AP] dimension) and perpendicular to the
     long axis of the lumen (for measurement of the transverse dimension). The aorta may also be
     scanned using a lateral or coronal approach if it cannot be visualized from an anterior
     transducer approach. The measurements obtained via these scan planes are equivalent to
     transverse measurements.
  ii. If an AAA is present, the maximal size and location of the aneurysm should be documented and
     recorded. The relationship of the dilated segment to the renal arteries and to the aortic bifurcation
     should be determined if possible.
  iii. At a minimum, the largest measurement should be recorded and reported. A measurement of the
     length of the aneurysm is optional.
  iv. If an AAA is present, the shape of the aneurysm should be documented either as fusiform,
     eccentric, or saccular. Documentation should include representative images, which enable the
     radiologist to characterize the shape of the aneurysm.

2. Common iliac arteries
   a. Longitudinal images of the proximal right and left common iliac arteries (along the long axis of the
      vessel)
   b. Transverse images (perpendicular to the long axis of the vessel) of the proximal common iliac arteries,
      just below the bifurcation
   c. Measurement of the widest visualized portion of each common iliac artery, from outer edge to outer
      edge

Color Doppler imaging and/or spectral Doppler with waveform analysis of the aorta and iliac arteries may be helpful

to demonstrate patency and the presence of intraluminal thrombus.

After EVAR endoluminal graft placement, color (or power) and spectral Doppler are required to document the

presence or absence of endoleaks. Contrast-enhanced ultrasound (CEUS) may be helpful for identification of

donleaks. Note: This would be an off-label use of CEUS based upon current FDA approval status [6].

Interobserver measurements of an aortic aneurysm can vary by as much as 5 mm. Visual comparison with prior

studies is recommended to ensure measurements are obtained at similar locations and to assess for interval change

in aneurysm size. Consistent measurements of aneurysm diameter are recommended following endograft repair to

check for interval enlargement in sac size [7]. Excessive transducer pressure should be avoided when measuring

aortic size.

B. Screening Examination for Abdominal Aortic Aneurysm AAA

1. Abdominal aorta
   a. Longitudinal images (along the long axis of the vessel)
      i. Proximal (below diaphragm, near the celiac artery)
      ii. Mid (near the level of the renal arteries)
      iii. Distal (above the iliac bifurcation)
   b. Transverse images (perpendicular to the long axis of the vessel)
      i. Proximal (below diaphragm, near the celiac artery)
      ii. Mid (near the level of the renal arteries)
iii. Distal (above the iliac bifurcation)

C. Interpretation of the Screening Examination Should Include at Least 3 Categories

1. Positive: Infrarenal abdominal aortic aneurysm AAA greater than or equal to 3 cm in diameter or greater than or equal to 1.5 times the diameter of the more proximal infrarenal aorta [8]. The latter definition is particularly important in women and small adults [9].

2. Negative: No infrarenal AAA

3. Indeterminate: Aneurysmal status not defined because of nonvisualization or partial visualization of the infrarenal abdominal aorta and/or iliac bifurcation.

4. The report should also state whether or not the suprarenal aorta was seen and, if seen, should reflect whether or not it is normal. The report should also state whether dilation of the aorta above the celiac artery is noted. For the area above the celiac artery, an aneurysm may be reported if the diameter is greater than 3.9 cm for males or 3.1 cm for females.

VI. DOCUMENTATION

Each organization will address this section in its document. ACR language is as follows:

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [10].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.


VII. EQUIPMENT SPECIFICATIONS

Abdominal aortic ultrasound should be performed with real-time scanners with transducers that allow for appropriate penetration and resolution, depending on the patient’s body habitus. Diagnostic information should be optimized while keeping total ultrasound exposure as low as reasonably achievable.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Each organization will address this section in its document. ACR language is as follows:
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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OLD REFERENCES


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Development Chronology for this Practice parameter

- 2005 (Resolution 32)
- Amended 2006 (Resolution 35)
- Revised 2010 (Resolution 34)
- Amended 2014 (Resolution 39)
- Revised 2015 (Resolution 32)
RESOLUTION NO. 8

Non-Physician Radiology Providers (NPRP) – Definitions

WHEREAS, the 2018 ACR Task Force on Non-physician Providers (NPPs) in Radiology (“the Task Force”) cited inconsistencies and ambiguity in ACR policies and practice parameters regarding the use of the various terms for NPPs and called for clarity in existing and future ACR policies and practice parameters; and

WHEREAS, ACR existing policies and practice parameters, including “Section II Professional and Public Policy Statements” of the ACR’s Digest of Council Actions, refer to various types of NPPs who work in radiology departments and with radiologists, using many different terms, including Nurse Practitioners (NP), Physician Assistants (PA), Registered Radiologist Assistants (RRA), Radiologist Assistants (RA), Radiology Practitioner Assistants (RPA), allied health professionals, ancillary personnel, and radiologist extenders; and

WHEREAS, the education and training requirements, licensing, credentialing, and roles and responsibilities differ among various types of NPPs (e.g. NPs, PAs, RRAs, …) on radiologist-led teams; and

WHEREAS, Radiology physicians (e.g. diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians) possess the knowledge and leadership skills that are needed to provide the highest level of care to patients; and

WHEREAS, the concept of physician-led team-based care is supported by the American Medical Association and patients and considered an important component of achieving the quadruple aim of providing better patient experience, better population health, lower overall costs and improved professional satisfaction; and

WHEREAS, the Task Force concluded that current ACR policies and practice parameters concerning scope of practice and roles of NPs and PAs do not necessarily distinguish NPs and PAs from RRAs; and

WHEREAS, some current ACR policies and practice parameters regarding scope of practice and roles of NPPs are written to apply broadly to all NPPs, rather than
specific/individual types of NPPs (e.g. NPs vs. PAs vs. RRAs) and that this approach can be confusing, result in unintended consequences, and disenfranchise one or more type of NPP relative to another; and

WHEREAS,

the ACR NPP Task Force called for all existing and future ACR policies and practice parameters concerning scope of practice and roles of NPPs to be modified and written, whenever possible and appropriate, such that each policy or practice parameter explicitly address individual type(s) of NPP (e.g. NP, PA, and RRA), rather than addressing all NPPs similarly or generically; therefore,

BE IT RESOLVED,

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

BE IT FURTHER RESOLVED,

that the term 'Radiologist-led team' is defined as a team supervised by a radiologist (i.e. diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients; and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters will be reviewed, modified and written to incorporate the term “Non-Physician Radiology Provider” (NPRP); and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters concerning NPRPs or NPRP-issues will be reviewed, modified, and written as necessary to address the intention of the policy and practice parameter by referring separately and specifically to each particular NPRP (e.g. NP, PA, RRA, and any other specific NPRP impacted by the policy or practice parameter); and
BE IT FURTHER RESOLVED,

that any existing and future ACR policies and practice parameters concerning NPRP or NPRP-issues that are intended to apply broadly and generically to all NPRPs should explicitly state this intention; and

BE IT FURTHER RESOLVED,

that these ACR policy and practice parameter reviews and language modifications would ideally be accomplished prior to the 2021 ACR annual meeting and will be completed no later than the 2022 ACR annual meeting.

Sponsored by: Council Steering Committee
Fiscal Note

Non-Physician Radiology Providers (NPRP) – Definitions

To support the resolution for Non-Physician Radiology Providers (NPRP) – Definitions, the ACR would incur the following estimated costs:

Costs:
De minimis (< $10,000)
RESOLUTION NO. 9

Roles of Non-Physician Radiology Providers (NPRP) – Policies, Parameters and Legislation/Regulations

WHEREAS,

the 2018 ACR Task Force on Non-physician Providers (NPPs) in Radiology (“the NPP Task Force”) reported that “there is little if any guidance in ACR policy related to scope of practice of Nurse Practitioners (NPs) and Physician Assistants (PAs) within radiology practices;”; and

WHEREAS,

the NPP Task Force reported that ACR’s policies regarding NPPs do not clearly state that performance of diagnostic interpretations is outside of the scope of practice of many NPPs (e.g. NPs, PAs); and

WHEREAS,

the 2018 ACR Human Resources Task Force report stated that greater than 50% of radiology practices in the United States employ or will hire NPPs to enhance services; and

WHEREAS,

some NPPs are generally expected to pursue scopes of practice to the level of independent practitioners; and

WHEREAS,

NPPs, other than RRAs, can be supervised by any physician and perform and interpret imaging procedures as determined by individual state regulation; and

WHEREAS,

no training program curricula of NPPs (except RRAs) specifically include imaging procedures, vocabulary, radiation safety, protocols, appropriateness; and

WHEREAS,

the American Medical Association (AMA) has specific policy [H-160.949] to actively oppose legislation allowing non-physician groups to engage in the practice of medicine without physician (MD, DO, MBBS) training or appropriate physician supervision; the AMA encourages state medical societies to oppose legislation allowing non-physician groups to practice medicine without physician oversight; the AMA, through legislative and regulatory efforts, vigorously supports and advocates for the requirement of appropriate physician supervision of non-physician clinical staff in all areas of medicine; and
WHEREAS,

the ACR strongly supports the statement that Radiologists (e.g. diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians) are the best trained and most expert in the use of imaging and image-guided, diagnostic and therapeutic, non-invasive and minimally-invasive exams, and the therapeutic use of radiation; and

WHEREAS,

all NPPs have significantly less training than Radiologists in the comprehensive understanding of anatomy, physiology, pathophysiology, physics of various forms of medical imaging (e.g. x-ray, ultrasound, MRI, etc.), imaging artifacts, visualization of additional significant findings not associated with the original indication, and the knowledge to discern when and when not to perform a procedure for a patient; and

WHEREAS,

independent, non-supervised performance and interpretation of diagnostic and therapeutic non-invasive and invasive medical imaging procedures could put the patient population at significant additional risk; and

WHEREAS,

for the purposes of this resolution, the term “Non-Physician Radiology Provider (NPRP)” is used in accordance with the definition established by an accompanying 2020 Resolution (see Resolution 8):

“all Non-Physician Providers (e.g. RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a Radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians)”; therefore,

BE IT RESOLVED,

that the ACR continue to oppose any legislation or regulation permitting NPPs (e.g. NPs, PAs, RRAs, ...) to provide interpretations (preliminary, final, or otherwise) of diagnostic imaging examinations; and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters concerning NPRPs will be reviewed, modified, and written such that the intention of the policy and practice parameter reflects that NPRPs (including but not limited to NPs, PAs, and RRAs) will not perform interpretations (preliminary, final, or otherwise) of any radiological examination. NPRPs may identify imaging findings or observations and communicate those only to the supervising radiologist. Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond the scope of practice and is not
the intended role of an NPRP. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses and/or differential diagnoses; and

BE IT FURTHER RESOLVED,

that existing and future ACR policies and practice parameters concerning NPRPs will be reviewed, modified, and written such that the intention of the policy and practice parameter reflects that NPRPs working in a radiology setting (e.g. diagnostic, interventional, or neurointerventional radiology; nuclear medicine; or radiation oncology setting) assisting with or participating in minimally-invasive procedures must operate under the supervision of a Radiologist and as part of a Radiologist-led team; and

BE IT FURTHER RESOLVED,

that the ACR continue to oppose any legislation or regulation permitting the independent practice of NPRPs (e.g. NPs, PAs, RRAs, ...) in radiology; and

BE IT FURTHER RESOLVED,

that the ACR will:

1. assist medical and radiology societies and specialty organizations that seek to enact legislation that would define the valued role of mid-level and other health care professionals within a physician- and radiologist-led team-based model structured to efficiently deliver optimal quality patient care and to assure patient safety; and

2. actively support the concept of radiologist-led radiology teams and oppose radiology teams that are not radiologist-led;

BE IT FURTHER RESOLVED,

that these ACR policy and practice parameter reviews and language modifications would ideally be accomplished prior to the 2021 ACR annual meeting and will be completed no later than the 2022 ACR annual meeting.

Sponsored by: Council Steering Committee
To support the resolution for *Roles of Non-Physician Radiology Providers (NPRP) – Policies, Parameters and Legislation/Regulations*, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
RESOLUTION NO. 10

Interim Support Position for RRA Legislation and Regulation

WHEREAS,

the American College of Radiology (ACR) Council adopted its original RRA policy (ACR RRA policy) in 2003 and renewed it in 2013; and

WHEREAS,

the ACR RRA policy was amended in 2008 to require Board of Chancellors (BOC) and Council Steering Committee (CSC) review and approval of Intersocietal Commission of the Radiologist Assistant (ICRA) recommended changes to the roles and responsibilities of the RRA; and

WHEREAS,

the ACR has worked with and supported non-radiologist societies [eg. American Registry of Radiologic Technologists’ (ARRT), American Society of Radiologic Technologists (ASRT)] to co-promote the Medicare Access to Radiology Care Act (MARCA) legislation as well as federal- and state-level regulations to support the role of registered radiologist assistants (RRAs) in clinical care, the development of the RRA as a profession, and appropriate payment for work rendered by RRAs; and

WHEREAS,

the ARRT’s current Entry-Level Clinical Activities (ELCA) document (which describes entry-level clinical activities potentially performed by RRAs under radiologist oversight ) explicitly includes clinical activities that substantially broaden the scope of practice of RRAs beyond those cited and approved in current ACR RRA policies; and

WHEREAS,

the current ELCA was not submitted to the BOC and CSC for formal review. Thus, the modifications to the ARRT ECLA documents that broaden the scope of practice of RRAs have not been approved (as required per 2008 ACR RRA Policy); and

WHEREAS,

the next scheduled update of the ARRT ELCA is not until 2023 and communication from the ARRT leadership suggests that the earliest that the current ECLA could potentially be significantly revised is 2022; therefore

BE IT RESOLVED,

that the ACR supports its RRA policies as approved by Council in 2003 (and renewed in 2013), 2006, and 2008; and
BE IT FURTHER RESOLVED,

that ACR will study updating the 2003 RRA policy to contemporary practice (2020) at or before its scheduled 10-year renewal in 2023; and

BE IT FURTHER RESOLVED,

that any current, past, or future RRA ELCA document that has not followed the approval process outlined in 2003, 2008, and other ACR RRA policies is not ACR policy; and

BE IT FURTHER RESOLVED,

that the ACR will work with the ARRT, ASRT, and other RRA stakeholders to align both the ELCA document and the processes for modification and approval of future RRA scope of practice changes with ACR policy; and

BE IT FURTHER RESOLVED,

that until the BOC and CSC review and approve ELCA and RRA scope of practice documents consistent with existing ACR policy, the ACR shall suspend all activities to promote, sponsor, or otherwise support MARCA and other legislation and regulations on the national, state, and local levels that would in any way expand or modify RRA clinical activities beyond those explicitly cited in ACR policy.

Sponsored by: Council Steering Committee
Fiscal Note

Interim Support Position for RRA Legislation and Regulation

To support the resolution Interim Support Position for RRA Legislation and Regulation, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
RESOLUTION NO. 11

Update to Existing ACR Policies on Radiologist Assistants

WHEREAS,
the ACR has existing Registered Radiologist Assistant (RRA) policies originally approved in 2003, 2006, 2008; and

WHEREAS,
the ACR’s RRA policies were written by different authors, for different ACR Councils, spanning a period of many years; and

WHEREAS,
in 2018 a late resolution named “Updating ACR Policy on Non-MD or Non-DO Healthcare Personnel in Radiology” was submitted as a late resolution and subsequently withdrawn in response to the Council Speaker calling for review of existing ACR policies regarding non-physicians working in radiology; and

WHEREAS,
in 2018 ACR leadership formed a Task Force to report to the CSC and Council about non-physician providers (NPP) working in radiology and related ACR NPP policies; and

WHEREAS,
the ACR Council Speaker, in 2018, formed an NPP Work Group to consider and implement the NPP Task Force’s recommendations; and

WHEREAS,
the NPP Work Group recommended to CSC that existing 2003, 2006, and 2008 ACR RRA policies should be updated to reflect contemporary (2020) radiology practice and use consistent language among all ACR RRA policies; therefore,

BE IT RESOLVED,
that the Council of the American College of Radiology adopt the revised ACR Statement on Radiologist Assistant Roles and Responsibilities in lieu of the ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities, currently Appendix H, adopted in 2003 as Resolution 2; and

BE IT FURTHER RESOLVED,
that the ACR will work with ASRT to get approval for the revised statement so that it may be accepted as a new ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities; and
BE IT FURTHER RESOLVED,

that the ACR Council of the American College of Radiology adopt the revised policy *Registered Radiologist Assistant Inclusion in Practice Parameters* in lieu of the policy originally adopted in 2006 and renewed in 2016 as Resolution 1-c; and

BE IT FURTHER RESOLVED,

that the Council of the American College of Radiology adopt the revised policy *Developing a Process for Updating the Roles and Responsibilities of the Radiologist Assistant* in lieu of the policy originally adopted in 2008 as Resolution 39.

Sponsored by: Council Steering Committee
Update to Existing ACR Policies on Radiologist Assistants

To support the resolution, Update to Existing ACR Policies on Radiologist Assistants, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities

The American College of Radiology adopted a statement on Radiologist Assistant – Roles and Responsibilities; 2003 (Res. 2).

A Registered Radiologist Assistant (RRA) is an advanced-level radiologic technologist who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the diagnostic imaging environment. The RRA is an ARRT-certified radiographer who has successfully completed an advanced academic program encompassing a nationally recognized RRA curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and assist the radiologist with selected exams, as described below and subject to state law:

- Obtaining consent for and injecting agents that facilitate and/or enable contrast agents administered as part of radiology procedures diagnostic imaging
- Obtaining clinical history from patients or the medical record
- Performing pre-procedure and post-procedure evaluation of patients undergoing invasive procedures
- Assisting radiologists with invasive procedures
- Performing fluoroscopy for non-invasive procedures with the under radiologist providing direct supervision of the service
- Monitoring and tailoring selected exams under radiologist direct supervision [e.g. IVU, CT Urogram, GI studies, VCUG, and retrograde urethograms, and preparation and colonic insufflation for CT Colonography.]
- Communicating the reports of radiologist’s findings to the referring physician or an appropriate representative with appropriate documentation
- Providing naso-enteric and oro-enteric feeding tube placement in uncomplicated patients. Attempt placement of fluoro-guided naso- or oro-enteric feeding tubes in patients whom the supervising radiologist has determined are appropriate for RRA involvement and under radiologist supervision as part of a radiologist-led team.
- Performing selected peripheral venous diagnostic procedures

The RRA will not perform interpretations (preliminary, final or otherwise) of any radiological examination, nor will he or she transmit his or her observations other than to the supervising radiologist. The RRA may make initial observations of diagnostic images and forward communicate them to the supervising radiologist. The RRA may identify imaging findings or observations and communicate those only to the supervising radiologist (i.e. make ‘observations’). Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond scope of practice and is not the intended role of an RRA. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses, differential diagnoses, and/or medical decision-making.

At the supervising radiologist’s direction, the RRA may communicate the radiologist’s findings and interpretation to the referring physician or an appropriate representative, consistent with the ACR policies on Communication of Diagnostic Imaging Findings

Documentation of any RRA’s observations/findings on a diagnostic imaging examination as required by the institution, statute, or regulatory body, should describe the RRA’s role and clearly state that the RRA
did not interpret the imaging examination (preliminary, final, or otherwise). Documentation of any
RRA’s participation in a procedure should (1) describe the RRA’s role in the procedure, (2) clearly state
that the RRA did not perform the procedure independently, and (3) include the name of the supervising
radiologist.

The education of the RRA should be granted through nationally recognized accredited academic
programs that lead to certification through the ARRT. Advisory committees to such programs should
include representation of radiologists.

The RRA should actively participate in a facility quality assurance program.

Any formal national, state, or facility certification and/or credentialing of RRA competency should
include representation of radiologists. Any facility RRA credentialing process should involve
radiologists.

The ACR believes that the advent of the RRA working under the supervision of a radiologist and part of a
radiologist-led team, with defined responsibilities as described herein, will enhance the performance of
radiological procedures and patient care and also provide a professionally satisfying career pathway for
radiologic technologists.

The Centers for Medicare and Medicaid Services (CMS) direct supervision requirement states that the
“physician is required on site and immediately available.”
2. ACR POLICY ON DEVELOPMENT OF PRACTICE PARAMETERS AND TECHNICAL STANDARDS

e. Registered Radiologist Assistant (RRA) Inclusion in Practice Parameters

The American College of Radiology will insert the following language describing the role of the RRA into the appropriate Practice Parameters of the various radiologic examinations in which an RRA might participate:

Registered Radiologist Assistant (RRA)

An RRA is an advanced level radiographer who is certified and registered as a “Registered Radiologist Assistant” by the American Registry of Radiologic Technologists (ARRT) after successful completion of an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) RRA curriculum and a radiologist-directed clinical preceptorship.

Under radiologist supervision, the RRA 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” subject to state law. The RRA transmits to the supervising radiologist those observations that have a bearing on diagnosis. Performance of diagnostic interpretations (preliminary, final, or otherwise) remains outside the scope of practice of the RRA. 

adopted 2006, 2016 (Res. 1-c).

RRAs performing invasive or non-invasive procedures should function under radiologist supervision and as part of radiologist-led teams.
12. DEVELOPING A PROCESS FOR UPDATING THE ROLES AND RESPONSIBILITIES OF THE RADIOLOGIST ASSISTANT (RRA)

The American College of Radiology will continue to require that the tasks performed by the RRA are under radiologist supervision and that they should be well-defined and documented; within the criteria and standards defined in the “ACR ASRT Joint Statement on Radiologist Assistant Roles and Responsibilities;” and that the RRA will not independently interpret imaging studies (preliminary, final, or otherwise). The RRA may identify imaging findings or observations and communicate those only to the supervising radiologist. Rendering interpretations of medical imaging studies (preliminary, final, or otherwise) is beyond scope of practice and is not the intended role of an RRA. Interpretations are distinguished from observations in that interpretations involve synthesizing imaging findings in the context of clinical histories, physical examination findings, laboratory testing, and/or comparison with prior or other imaging studies in a manner that leads to clinical impressions or conclusions, specific diagnoses, differential diagnoses, and/or medical decision-making.

The ACR will have and follow a process to participate in enabling the expeditious ongoing review of the roles and responsibilities of the RRA and ensure communication of recommendations to the ACR Board of Chancellors and Council Steering Committee. This process will incorporate an expert panel, including a member(s) of the from an ACR Commission such as Quality and Safety, Human Resources, or equivalent to review and make initial recommendations for any changes in the roles and responsibilities of the RRA over time.

The ACR representatives to the Intersocietal Commission on the Radiologist Assistant (ICRA) will present for review and recommendation to the ACR Council Steering Committee and ACR Board of Chancellors only any those changes recommended by the expert panel and agreed to by all members of ICRA.

Only approval of the ICRA recommendations by the CSC and BOC will be sufficient to permit implementation of changes in the roles and responsibilities of the RRA; adopted 2008 (Res. 39).
### RESOLUTIONS

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RESOLUTION NO. 12

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) B. DRUGS AND EQUIPMENT

5. PORTABLE IMAGE MEDIA (CDS AND DVDS)

The ACR strongly encourage the nation’s PACS vendors to adopt the IHE standards-based profiles; adopted 2010 (Res. 36).

(b) B. DRUGS AND EQUIPMENT

7. RADIOGRAPHICALLY IDENTIFIABLE MARKERS ON MEDICAL DEVICES

The American College of Radiology recommends that manufacturers include radiographic markers that are identifiable in vivo on all devices designed for use in the body; 1990, 2000, amended 2010 (Res. 1-c).

(c) D. PROFESSIONAL LIABILITY

3. TORT MEDICAL LIABILITY REFORM

The American College of Radiology supports federal and state legislative initiatives for medical liability reforms to reduce the burden of unwarranted claims and unjustified damage awards on the nation’s physicians. Such reforms might include:

• limitations on recovery of non-economic damages;
• the mandatory offset of collateral sources of plaintiff compensation;
• decreasing sliding scale regulation of attorney contingency fees;
• periodic payment for future awards of damages;
• limiting the period of suspension of statutes of limitations for minors to no more than six years;
• a certificate of merit requirement as a condition to filing medical liability suits; and
• the imposition of regulation of expert witness qualifications; 1990, 2000, amended 2010 (Res. 39e).
E. WORKFORCE

1. FEDERAL/STATE RESTRICTIONS

The ACR believes it to be contrary to the public interest for federal and/or state authorities to:

• arbitrarily or artificially manipulate or restrict postgraduate training in various medical specialties; or
• dictate or restrict freedom of choice of medical practice opportunities by arbitrary or artificial means; 1980, 1990, 2000, amended 2010 (Res. 39-f).

I. RADIOLOGICAL PRACTICE AND ETHICS

1. ACCREDITATION

b. Accreditation Programs: Council Approval

The Council recognizes the success of the existing ACR accreditation programs. Future accreditation programs in radiology shall be approved by the ACR Council prior to their development. Each completed accreditation program shall be presented to the Council Steering Committee for comment prior to presentation to the Board of Chancellors for final approval prior to implementation; 1994, amended 2004, 2014 (Res. 21-a).

Once a completed accreditation program has been reviewed by the Council Steering Committee and approved by the Board of Chancellors, that program may only be modified by the accreditation committee which developed it, either acting on its own volition to improve the program based on annual or more frequent review, or by a majority vote of the accreditation committee members in response to an appropriately filed, written appeal (Appendix C) by any active or eligible participant. Any modification to a program, which includes the Certificate of Accreditation that is or will be issued, must be submitted for review to the Speaker and Vice Speaker, and if they deem material, shall be presented to the Council Steering Committee and approved by the Board of Chancellors, but in any event, the Board of Chancellors may require that any modification, material or immaterial, be submitted for such review and approval; Any modification to a program, which includes the Certificate of Accreditation that is or will be issued, must be submitted for review to the Speaker and Vice Speaker, and if they deem material, shall be presented to the Council Steering Committee and approved by the Board of Chancellors, but in any event, the Board of Chancellors may require that any modification, material or immaterial, be submitted for such review and approval; 2000, amended 2010 (Res. 10-b).

Sponsored by: ACR Council Steering Committee
To support the resolution for **Ten Year Extension of Policy**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
BE IT RESOLVED, that the American College of Radiology adopt the ACR–AAPM–ACNM–SNMMI Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging

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.

ACR–AAPM–ACNM–SNMMI PRACTICE PARAMETER FOR REFERENCE LEVELS AND ACHIEVABLE ADMINISTERED ACTIVITY FOR NUCLEAR MEDICINE AND MOLECULAR IMAGING

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 has been developed revised collaboratively by the American College of Radiology (ACR), and the American Association ofPhysicists in Medicine (AAPM), the American College of Nuclear Medicine (ACNM), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) to guide appropriately trained and licensed physicians and Qualified Medical Physicists involved in nuclear medicine and molecular imaging procedures.

The establishment of reference levels (RLs) in nuclear medicine and molecular imaging requires close cooperation and communication between the physicians responsible for the clinical management of the patient and the Qualified Medical Physicist responsible for monitoring equipment, image quality, and estimating patient dose. Adherence to this practice parameter should help to maximize the efficacious use of these procedures, minimize radiation dose to patients, minimize radiation dose to and staff, maintain safe conditions, and ensure compliance with applicable standards. This is particularly important for children, who are more vulnerable than adults to the potential risks adverse effects of ionizing radiation.

The goal of this practice parameter is to provide benchmark national nuclear medicine and molecular imaging achievable administered activities (AAA) and RLs for the United States in order to help practices optimize radiopharmaceutical administered activity while meeting the diagnostic needs of the medical imaging procedure.

RLs are used to help manage the radiation dose to the patient. The medical radiation exposure must be optimized, avoiding unnecessary radiation that does not contribute to the clinical objective of the procedure. By the same token, an administered activity that is significantly lower than the AAA may also be a cause for concern because it may indicate that adequate image quality is not being achieved. The specific purpose of the RL is to provide a benchmark for comparison, not to establish regulatory limits. The goal in medical imaging is to obtain image quality consistent with the medical imaging task provide guidance to physicians and Qualified Medical Physicists on the establishment and implementation of RLs in the practice of nuclear medicine and molecular imaging.

RLs for nuclear medicine and molecular imaging should be based on administered activity or (dosage²). There are published surveys and guidelines of administered activity from various professional organizations that can be used to establish RLs are usually based on published surveys from professional organizations or of representative groups performing nuclear medicine and molecular imaging procedures [1-4]. [1-15]

An RL in nuclear medicine is an investigational (action) level that, when it is exceeded, indicates the use of a higher than typical administered activity activities for a routine nuclear medicine and molecular imaging procedure [5-8]. A procedure RL is set at approximately around the 75th percentile of the range of the available administered activity data. The International Commission on Radiological Protection (ICRP) Publication 135

2 Dosage is the term used by the U.S. Nuclear Commission and other agencies that regulate radioactive materials to describe the patient administered activity and differentiate it from absorbed dose.
on Diagnostic Reference Levels (DRL) in Medical Imaging provides the current guidance on how to develop RLs [8]. RLs are derived thresholds from radiation metric data that are obtained locally and collected nationally or regionally. If a facility or practice consistently exceeds an RL, it should review its procedures and equipment to determine if acceptable image quality can be achieved with a lower administered activity.

AAA is a concept that can be used with RLs to assist in optimization of image quality and dose to the patient. Although no formal system exists for determining AAA, the concept The AAA is based on the median value (the 50th percentile) of the distribution of a DRL quantity, which, for nuclear medicine and molecular imaging, is the administered activity [3]. The AAA provides a goal that facilities should strive to achieve through the optimization of image quality and patient absorbed doses. In that 50% of facilities are producing images below that administered activity, AAAs for nuclear medicine and molecular imaging are set at approximately the 50th percentile of the range of administered activities.

Further information on RLs and AAAs in nuclear medicine and molecular imaging is available in ICRP Publication 135 [8] and the National Council on Radiation Protection and Measurements (NCRP) Report 172 [3].

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [9].

B. Qualified Medical Physicist

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

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [10]. (ACR Resolution 17, adopted in 1996 – revised in 2012, Resolution 42)

The appropriate subfields of medical physics for this practice parameter is Nuclear Medical Physics (including medical physics certification categories of Radiological Physics, Medical Nuclear Physics, and Nuclear Medicine Physics).

Certification by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation is also acceptable.

The Qualified Medical Physicist must be familiar with the principles of imaging physics and radiation protection; the guidelines guidance of the NCRP; the laws and regulations pertaining to nuclear medicine; the function, clinical uses, and performance specifications of nuclear medicine imaging equipment; and the calibration processes and limitations of the equipment. The Qualified Medical Physicist must also be familiar with the relevant clinical procedures.
III. NUCLEAR MEDICINE RLS FOR IMAGING WITH IONIZING RADIATION

The concept of the RL can be a practical tool in nuclear medicine. Achieving acceptable diagnostic information, consistent with the medical imaging task, is the overriding clinical objective. The quantity that is recommended for RLs and AAAs is the administered activity (dosage) or dosage \[8\]. Administered activity RLs (in MBq or MBq/kg of body mass) are then used to help manage the radiation dose to patients so that the organ doses are appropriate for the clinical purpose.

Determining RLs for nuclear medicine procedures in the United States has previously been difficult because of the limited amount of available survey data, the large number of radiopharmaceuticals that are used, and variability in procedures among practitioners. In the absence of survey data for adults, other guidance has been used. For adults, manufacturers recommend a standard administered activity based on a standard 70-kg person in their package insert as required by the US Food and Drug Administration (FDA). Guidance for minimum and maximum administered activities for adults and children is available from various sources \[3,11-21\].

The individual(s) listed as an authorized user(s) on the regulatory license or permit is ultimately responsible for the supervision and appropriate use of all radiopharmaceuticals received, prepared, or administered under the user’s direction \[22\]. The physician listed on the regulatory license or certificate (often called the authorized user) is ultimately responsible for the supervision and appropriate utilization of all radiopharmaceuticals received, prepared, or administered under his or her direction.

It is strongly recommended that each administered dosage be assayed onsite at the medical facility prior to administration to verify the prescribed activity \[9\].

Determining RLs for nuclear medicine procedures is difficult due to the limited available survey data, number of radiopharmaceuticals used, and variability in procedures. Due to the limited availability of survey data, local assessment may be necessary. For pediatric procedures, the standard is based on recommended activity per unit body mass. For adults, manufacturers recommend a standard administered activity based on a standard 70-kg person in their package insert as required by the US Food and Drug Administration. Guidelines for minimum and maximum administered activities for adults and children are available from various publications \[4,8,11-20,23,24\]. This is the initial practice parameter on nuclear medicine RLs. Although the recommendations are based on limited survey data, they are the best available data we have for the modality.

RLs and AAAs are part of the optimization process. It is essential to assure that image quality appropriate for the diagnostic purpose is maintained when modifying administered activity. Optimization must balance image quality and patient absorbed dose, i.e., image quality must be maintained at an appropriate level as administered activity is decreased. If diagnostic quality images are not achievable using the RLs or AAAs presented in Tables 1 and 2 due to requirements of particular imaging devices or patient weight, the recommended RLs may need to be exceeded.

A. Adult Examinations

Table 1 summarizes the RLs and AAAs for common some radiopharmaceuticals that are commonly administered to adults. Administered activity information that was recently provided by thousands of U.S. nuclear medicine facilities to accreditation programs during the accreditation process \[1,2,4\] has been updated or added to the limited survey data of nine academic facilities that were available for NCRP 172 \[3\]. The RLs and AAAs for the specific radiopharmaceutical in Table 1 were determined using the 75th percentile and 50th percentile, respectively of the ACR accreditation data or the NCRP 172 survey data. NCRP 172 values for RLs are based on the 75th percentile of the maximum administered activities, and AAAs are based on the median value of routine administered activities from the survey. It uses data obtained from NCRP 172 and Collaborative Practice Parameters and Procedural Guidelines from the ACR, Society of Nuclear Medicine and Molecular Imaging, and American Society of Nuclear Cardiology \[1,11,20\]. It is important to note that the NCRP 172 data tables are the results of multiple surveys of clinical facilities and the Collaborative Practice Parameters and Procedural Guidelines are recommended administered activity ranges. The RLs and AAAs in Table 1 were
determined using the 75th percentile and 50th percentile of the NCRP data, respectively, and 75% and 50% of the range of recommended administered activities for the Collaborative Practice Parameters and Procedural Guidelines, respectively.

**TABLE 1**
Radiopharmaceutical Achievable Administered Activities and Reference Levels for Adults

<table>
<thead>
<tr>
<th>Radiopharmaceutical - Examination</th>
<th>Achievable Administered Activity</th>
<th>Reference Level Administered Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{99m}$Tc-Hydroxymethylene Diphosphonate (HDP)/Methylene Diphosphonate (MDP) – whole body bone [1,4]</td>
<td>929 MBq (25.1 mCi)</td>
<td>988 MBq (26.7 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Iminodiacetic Acid (IDA) analog – hepatobiliary imaging [4]</td>
<td>204 MBq (5.5 mCi)</td>
<td>241 MBq (6.5 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Macroaggregated Albumin (MAA) – perfusion lung [4]</td>
<td>185 MBq (5.0 mCi)</td>
<td>215 MBq (5.8 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Sulfur Colloid – liver/spleen [4]</td>
<td>222 MBq (6.0 mCi)</td>
<td>255 MBq (6.9 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Dimercaptosuccinic Acid (DMSA) [3]</td>
<td>185 MBq (5.0 mCi)</td>
<td>289 MBq (7.8 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Mercaptoacetyltriglycine (MAG3) [3]</td>
<td>278 MBq (7.5mCi)</td>
<td>379 MBq (10.0 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-RBC – tagged RBC [4]</td>
<td>840 MBq (22.7 mCi)</td>
<td>925 MBq (25 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Pertechnetate – thyroid imaging [4]</td>
<td>370 MBq (10.0 mCi)</td>
<td>407 MBq (11.0 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-labeled solids – GI Emptying [3]</td>
<td>37 MBq (1.0 mCi)</td>
<td>50 MBq (1.3 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Exametazime (HMPAO) [3]</td>
<td>740 MBq (20.0 mCi)</td>
<td>1,193 MBq (32.0 mCi)</td>
</tr>
<tr>
<td>$^{123}$I-Sodium Iodide (NaI) – thyroid imaging [4]</td>
<td>9.0 MBq (0.255 mCi)</td>
<td>11.0 MBq (0.300 mCi)</td>
</tr>
<tr>
<td>$^{123}$I-Metaiodobenzylguanidine (MIBG) [3]</td>
<td>370 MBq (10.0 mCi)</td>
<td>391 MBq (11.0 mCi)</td>
</tr>
<tr>
<td>$^{131}$I-Sodium Iodide (NaI) – whole body imaging thyroid cancer [4]$^3$</td>
<td>148 MBq (4.0 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
</tr>
<tr>
<td>$^{111}$In-Pentetreotide – octreotide SPECT imaging [4]</td>
<td>226 MBq (6.1 mCi)</td>
<td>237 MBq (6.4 mCi)</td>
</tr>
<tr>
<td>$^{111}$In-Oxine Leukocytes [16,23]$^4$</td>
<td>24 MBq (0.7 mCi)</td>
<td>30 MBq (0.8 mCi)</td>
</tr>
<tr>
<td>$^{67}$Ga citrate-inflammatory disease [3]</td>
<td>185 MBq (5.0 mCi)</td>
<td>371 MBq (10.0 mCi)</td>
</tr>
<tr>
<td>$^{18}$F-Fluorodeoxyglucose (FDG) – oncology PET [1,4]</td>
<td>485 MBq (13.1 mCi)</td>
<td>555 MBq (15.0 mCi)</td>
</tr>
<tr>
<td>$^{18}$F-Fluorodeoxyglucose (FDG) – brain PET [4]</td>
<td>370 MBq (10 mCi)</td>
<td>414 MBq (11.2 mCi)</td>
</tr>
<tr>
<td>$^{18}$F-Florbetaben – brain PET [4]</td>
<td>363 MBq (9.8 mCi)</td>
<td>377 MBq (10.2 mCi)</td>
</tr>
</tbody>
</table>
### B. Pediatric Examinations

ICRP 135 [8] specifies that the data quantities collected to develop RLs for pediatric nuclear medicine studies should be based on administered activity with adjustments for the size or weight of the child.

Because of limited accreditation or survey data for pediatric nuclear medicine, development of AAAs or RLs that are linked to pediatric size or weight is not practical at this time. However, applicable guidance is available from the 2016 Update: North American Consensus Guidelines for Pediatric Administered Radiopharmaceutical Activities [21]. These guidelines were developed as a result of surveys and consensus workshops by nuclear medicine experts in North America and Europe. Conforming to the North American Consensus Guidelines is the recommendation of NCRP 172. Availability of the North American Consensus Guidelines has been shown to reduce the variability of pediatric radiopharmaceutical administration in the United States [25-27].

### C. Adult and Pediatric RL Summary

RLs and AAAs are part of the optimization process for both adult and pediatric examinations. It is essential to ensure that image quality appropriate for the diagnostic purpose is maintained when modifying administered activity. Optimization must balance image quality and patient absorbed dose (ie, image quality must be maintained at an appropriate level as administered activity is decreased). If diagnostic-quality images are not achievable using the RLs and AAAs presented in Table 1 or the recommendations provided

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<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Adult Administration</th>
<th>Pediatric Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>18F-Florbetapir</strong></td>
<td>brain PET/CT [4]</td>
<td>- 374 MBq (10.1 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sestamibi</strong></td>
<td>one-day protocol (cardiac rest/stress) [2]</td>
<td>- 388/1,169 MBq (10.5/31.6 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Tetrofosmin</strong></td>
<td>one-day protocol (cardiac rest/stress) [2]</td>
<td>- 388/1,147 MBq (10.5/31.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sestamibi</strong></td>
<td>two-day protocol (cardiac rest/stress) [2]</td>
<td>- 1089/1,110 MBq (29.4/30.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Tetrofosmin</strong></td>
<td>two-day protocol (cardiac rest/stress) [2]</td>
<td>- 1084/1,110 MBq (29.3/30.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sestamibi</strong></td>
<td>(cardiac stress only) [3]</td>
<td>- 925 MBq (25.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Tetrofosmin</strong></td>
<td>(cardiac stress only) [3]</td>
<td>- 833 MBq (23.0 mCi)</td>
</tr>
<tr>
<td><strong>201Tl-Chloride/99mTc-Sestamibi</strong></td>
<td>one-day protocol (cardiac rest/stress) [2]</td>
<td>- 148/1,110 MBq (4.0/30 mCi)</td>
</tr>
<tr>
<td><strong>201Tl-Chloride/99mTc-Tetrofosmin</strong></td>
<td>one-day protocol (cardiac rest/stress) [2]</td>
<td>- 141/1,110 MBq (3.8/30.0 mCi)</td>
</tr>
<tr>
<td><strong>201Tl-Chloride</strong></td>
<td>(cardiac rest/stress) [3]</td>
<td>- 111 MBq (3.0 mCi)</td>
</tr>
</tbody>
</table>

1. 50th percentile of median values obtained in a survey of representative centers
2. 75th percentile of median values obtained in a survey of representative centers
3. Stunning of the thyroid gland occurs when 131I administered for imaging causes a decrease in uptake of radiiodine subsequently given for ablation. Because of concerns about the possible effects of stunning on 131I therapy, administered activities of 74 MBq (2 mCi) or less for diagnostic imaging may be preferable because these dosages do not cause stunning [24].
4. AAA and DRL for 111In-Oxine Leukocytes are based on recommended dose ranges [16,23]
in the North American Consensus Guidelines for Pediatric Radiopharmaceuticals Activities because of the requirements of particular imaging devices or patient weight, the guidance may need to be exceeded.

Table 2 summarizes the RLs and AAAs for radiopharmaceuticals commonly used for pediatric procedures. It uses data obtained from NCRP 172 and North American Consensus guidelines. It is important to note that the NCRP 172 data tables are based on multiple surveys of clinical facilities, and the North American Consensus Guidelines are recommended administered activity ranges. The RLs and AAAs for Table 2 were determined using the 75th percentile and 50th percentile of the NCRP data, respectively, and 75% and 50% of the range of recommended administered activities for the North American Consensus guidelines, respectively. Table 2 data are primarily taken from the North American Consensus Guidelines. The NCRP 172 survey data were used for those procedures that were not included in the North American Consensus Guidelines. Where no maximum administered activity was provided, the maximum administered activity was determined using the higher end of the range for the recommended administered activity per kg, multiplied by the weight for a 70 kg patient. Thus, if the child’s weight exceeds 70 kg, the maximum should not be that for a standard adult. If diagnostic quality images are not achievable for the RLs and AAAs presented in Table 2, then the recommended RLs may need to be exceeded.

### TABLE 1

**Radiopharmaceutical Administered Activity in Adults**

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Minimum Administered Activity</th>
<th>Achievable Administered Activity</th>
<th>Reference Level Administered Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>18F-Fluorodeoxyglucose (FDG)</td>
<td>370 MBq (8.0 mCi)</td>
<td>555 MBq (15 mCi)</td>
<td>650 MBq (18.5 mCi)</td>
</tr>
<tr>
<td>67Ga-Citrate</td>
<td>185 MBq (5.0 mCi)</td>
<td>280 MBq (7.5 mCi)</td>
<td>325 MBq (8.8 mCi)</td>
</tr>
<tr>
<td>123I-Metaiodobenzylguanidine (MIBG)</td>
<td>185 MBq (5.0 mCi)</td>
<td>280 MBq (7.5 mCi)</td>
<td>325 MBq (8.8 mCi)</td>
</tr>
<tr>
<td>123I-Sodium Iodide (NaI)</td>
<td>2.4 MBq (0.2 mCi)</td>
<td>11 MBq (0.3 mCi)</td>
<td>13.0 MBq (0.35 mCi)</td>
</tr>
<tr>
<td>99mTc-Dimercaptosuccinic Acid (DMSA)</td>
<td>130 MBq (3.5 mCi)</td>
<td>160 MBq (4.25 mCi)</td>
<td>170 MBq (4.6 mCi)</td>
</tr>
<tr>
<td>99mTc-Disofenin or Methrofenin (hepatobiliary)</td>
<td>111 MBq (3.0 mCi)</td>
<td>150 MBq (4.0 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td>99mTc-Exematabizime (HMPAO) Leukocytes</td>
<td>185 MBq (5.0 mCi)</td>
<td>460 MBq (12.5 mCi)</td>
<td>600 MBq (16.2 mCi)</td>
</tr>
<tr>
<td>99mTc-Labeled Solids (GI emptying)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>41 MBq (1.1 mCi)</td>
<td>50 MBq (1.3 mCi)</td>
</tr>
<tr>
<td>99mTc-Macroaggregated Albumin</td>
<td>111 MBq (3.0 mCi)</td>
<td>150 MBq (4.0 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td>99mTc-Mertiatide (MAG3)</td>
<td>130 MBq (3.5 mCi)</td>
<td>250 MBq (6.8 mCi)</td>
<td>310 MBq (8.4 mCi)</td>
</tr>
<tr>
<td>99mTc-Medronate (MDP)</td>
<td>555 MBq (15 mCi)</td>
<td>835 MBq (23 mCi)</td>
<td>970 MBq (26 mCi)</td>
</tr>
<tr>
<td>99mTc-Sestamibi or Tetrofosmin One-day Protocol (cardiac rest/stress)</td>
<td>296/888 MBq (8/24 mCi)</td>
<td>370/1110 MBq (10/30 mCi)</td>
<td>407/1221 MBq (11/33 mCi)</td>
</tr>
<tr>
<td>99mTc-Sestamibi or Tetrofosmin Two-day Protocol (cardiac rest/stress)</td>
<td>925 MBq per day (25 mCi per day)</td>
<td>1018 MBq per day (27.5 mCi per day)</td>
<td>1073 MBq per day (29 mCi per day)</td>
</tr>
<tr>
<td>Radiopharmaceutical</td>
<td>Recommended Administered Activity</td>
<td>Minimum Administered Activity</td>
<td>Achievable Administered Activity</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>------------------------------------</td>
<td>-------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>99mTc-Sestamibi or Tetrofosmin, (cardiac stress only protocol)</td>
<td>518 MBq (14 mCi)</td>
<td>888 MBq (24 mCi)</td>
<td>1073 MBq (29 mCi)</td>
</tr>
<tr>
<td>99mTc-Chloride, (cardiac rest/stress)</td>
<td>37 MBq (1.0 mCi)</td>
<td>165 MBq (4.4 mCi)</td>
<td>172 MBq (4.6 mCi)</td>
</tr>
<tr>
<td>99mTc-Galium, (for inflammatory disease)</td>
<td>1.48 – 2.59 MBq/kg (0.04 – 0.07 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td>111mIn-Gallium, (for tumor imaging)</td>
<td>2.96 – 5.25 MBq/kg (0.08 – 0.14 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>333 MBq (9.0 mCi)</td>
</tr>
<tr>
<td>123I-Metaiodobenzylguanidine (MIBG)</td>
<td>5.2 MBq/kg (0.14 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>204 MBq (5.5 mCi)</td>
</tr>
<tr>
<td>123I-Sodium-Iodide (NaI) for Thyroid</td>
<td>0.06 – 0.2 MBq/kg (0.002 – 0.006 mCi/kg)</td>
<td>0.56 MBq (0.015 mCi)</td>
<td>8.14 MBq (0.2 mCi)</td>
</tr>
<tr>
<td>99mTc-Dimercaptosuccinic Acid (DMSA)</td>
<td>1.85 MBq/kg (0.05 mCi/kg)</td>
<td>18.5 MBq (0.5 mCi)</td>
<td>50.3 MBq (1.6 mCi)</td>
</tr>
<tr>
<td>99mTc-Disofenin (IDA) (hepatobiliary)</td>
<td>1.85 MBq/kg (0.05 mCi/kg)</td>
<td>18.5 MBq (0.5 mCi)</td>
<td>74.3 MBq (2.0 mCi)</td>
</tr>
<tr>
<td>99mTc-Macroaggregated Albumin— if 99mTc used for Ventilation</td>
<td>2.59 – 4.88 MBq/kg (0.07 – 0.13 mCi/kg)</td>
<td>34.5 MBq (0.9 mCi)</td>
<td>188 MBq (5.0 mCi)</td>
</tr>
<tr>
<td>99mTc-Macroaggregated Albumin— No 99mTc Ventilation</td>
<td>1.11 MBq/kg (0.03 mCi/kg)</td>
<td>14.8 MBq (0.4 mCi)</td>
<td>46.3 MBq (1.3 mCi)</td>
</tr>
<tr>
<td>99mTc-Mertiatide (MAG3) without Flow Study</td>
<td>3.7 MBq/kg (0.10 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>92.5 MBq (2.5 mCi)</td>
</tr>
<tr>
<td>99mTc-Mertiatide (MAG3) with Flow Study</td>
<td>5.55 MBq/kg (0.15 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>213 MBq (5.8 mCi)</td>
</tr>
<tr>
<td>99mTc-Medronate (MDP)</td>
<td>9.3 MBq/kg (0.25 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>740 MBq (20.2 mCi)</td>
</tr>
<tr>
<td>99mTc-Pertechnetate (meckel diverticulum imaging)</td>
<td>1.85 MBq/kg (0.05 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>70 MBq (1.9 mCi)</td>
</tr>
<tr>
<td>99mTc-Sulfur Colloid (for oral liquid gastric emptying)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>23.1 MBq (0.6 mCi)</td>
</tr>
<tr>
<td>99mTc-Sulfur Colloid (for solid gastric emptying)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>13.9 MBq (0.4 mCi)</td>
</tr>
<tr>
<td>99mTc-Ultrasound (for GI bleeding)</td>
<td>3.7 – 11.0 MBq/kg (0.10 – 0.30 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>74.0 MBq (20.0 mCi)</td>
</tr>
<tr>
<td>99mTc-Sestamibi</td>
<td>5.7 – 19.0 MBq/kg (0.154 – 0.50 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>777 MBq (21.0 mCi)</td>
</tr>
<tr>
<td>99mTc-(different forms) for Cystography</td>
<td>Not weight based</td>
<td>Not weight based</td>
<td>18.5 MBq (0.5 mCi)</td>
</tr>
</tbody>
</table>

**TABLE 2**

Radiopharmaceutical-Administered Activity for Children

---

1. 50% of range recommended
2. 75% of range recommended
3. Not weight based

Reference Levels
2020 Resolution No. 13
IV. PATIENT-SPECIFIC DOSIMETRY

Internal absorbed dose can be estimated from anthropomorphic computer models and used for comparison of radiation doses among procedures. Although dose estimates are available for children of various ages, adult individuals males and females, as well as pregnant patients females at different gestational stages, they are based on specific generic body-size estimates and tracer kinetics, which may be very different from those of any individual patient [26,28-30, 22].

On occasion, the need may arise it may be necessary to estimate the dose delivered to an individual patient because of a specific situation (eg, pregnancy or the request of a referring physician request). In these situations, it is recommended that the physician have a written medical physics consider executing a formal written medical physics consultation consult with the a Qualified Medical Physicist. Using the information about the patient’s weight, administered activity, and the radiopharmaceutical, the Qualified Medical Physicist can render an estimate of the specific dose to tissue and organs in the patient. The consultation request and the Qualified Medical Physicist’s report should be duly signed by the requesting physician and the Qualified Medical Physicist and should be incorporated into the patient’s medical record.

V. 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).
For the purpose of this practice parameter, the radiation dose index that is used is the administered activity of the radiopharmaceutical.

VI. 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).

Performance evaluation, quality control, acceptance testing, written survey reports, and follow-up procedures of all nuclear medicine and PET imaging systems and support equipment should be in accordance with the appropriate ACR Medical Physics Technical Standards (http://www.acr.org/Quality-Safety/Standards-Guidelines/Technical-Standards-by-Modality/Medical-Physics).

The Qualified Medical Physicist should report on an annual basis a review of the most common nuclear medicine and PET protocols for adults and pediatric patients performed at the facility and report the results of that review. The report should include estimates of radiation dose based on administered activity and a comparison of these estimates with the current RLs. It should provide recommendations of means of improvement if the dose estimates or administered activity exceeds the RLs.

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 and Technical Standards – Medical Physics of the ACR Commission on Medical Physics and the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging in collaboration with the AAPM, the ACNM, and the SNMMI.

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REFERENCES


OLD REFERENCES

APPENDIX-A

This addendum table is taken from the NCRP Report 172 to illustrate survey results for adult administered activities. The survey data was reflective of the responses from “selected nuclear medicine departments at academic centers.” The minimum and maximum values are reflective of the practice of nuclear medicine in 2010 without necessarily assessing if the administered activity was optimized by the respective facility or recommended from another source. Accordingly, the range from the survey is wide for some radiopharmaceutical studies.

Recommended Radiopharmaceutical Administered Activity for Adults From NCRP Report 172, Table 6.16

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Minimum Administered Activity</th>
<th>Maximum Administered Activity</th>
<th>Recommended Achievable-Administered Activity</th>
<th>Recommended Reference Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>18F-Fluorodeoxyglucose (FDG)</td>
<td>269 MBq (8.0 mCi)</td>
<td>814 MBq (22.0 mCi)</td>
<td>666 MBq (18.0 mCi)</td>
<td>710 MBq (19.0 mCi)</td>
</tr>
<tr>
<td>radionuclide and agent</td>
<td>median maximum value used</td>
<td>75th percentile maximum value used</td>
<td>reference level</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------</td>
<td>----------------------------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Metaiodobenzylguanidine (MIBG)</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>407 MBq (11.0 mCi)</td>
<td>370 MBq (10.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Sodium Iodide (NaI)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>22 MBq (0.6 mCi)</td>
<td>12 MBq (0.3 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Dimercaptosuccinic Acid (DMSA)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>407 MBq (11.0 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Diisofenin or Mibefenum (hepatobiliary)</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>370 MBq (10.0 mCi)</td>
<td>222 MBq (6.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Labeled Solids (GI emptying)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>74 MBq (2.0 mCi)</td>
<td>41 MBq (1.1 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Macrogaggregated Albumin</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>244 MBq (6.6 mCi)</td>
<td>122 MBq (6.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Mertiatide (MAG3)</td>
<td>11.1 MBq (0.3 mCi)</td>
<td>407 MBq (11.0 mCi)</td>
<td>370 MBq (10.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Medronate (MDP)</td>
<td>37.0 MBq (10.0 mCi)</td>
<td>4480 MBq (120 mCi)</td>
<td>1064 MBq (29.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Sestamibi (cardiac rest)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td>907 MBq (25.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Sestamibi (cardiac stress)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td>1277 MBq (35.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Tetrofosmin (cardiac rest)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td>907 MBq (25.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{123}$I-Te-Tetrofosmin (cardiac stress)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1726 MBq (48.0 mCi)</td>
<td>1295 MBq (35.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>$^{201}$Tl-Chloride (cardiac rest/stress)</td>
<td>37 MBq (2.0 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
<td>165 MBq (4.1 mCi)</td>
<td></td>
</tr>
</tbody>
</table>

*Median maximum value used

75th percentile maximum value used

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 53)
BE IT RESOLVED,
    that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Neuroendocrine Tumor Scintigraphy (with Gamma Cameras)

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 48) *

ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF NEUROENDOCRINE TUMOR SCINTIGRAPHY (WITH GAMMA CAMERAS)

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.

---

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 Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to guide interpreting physicians performing neuroendocrine tumor scintigraphy in adult and pediatric patients. Properly performed imaging with gamma-emitting radiopharmaceuticals that localize in neuroendocrine tumors is a sensitive method for assessing certain tumors. See the ACR–SPR Practice Parameter for the Performance of Parathyroid Scintigraphy, ACR–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy, ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy, ACR–SPR Practice Parameter for the Performance of Skeletal Scintigraphy (Bone Scan), and ACR–SNMMI–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease for specific tumors [1-5]. This practice parameter will center on gamma-emitting radiopharmaceuticals rather than organ systems.

Tumor scintigraphy is a rapidly evolving field. Discussion will be confined primarily to gamma-emitting radiopharmaceuticals that the US Food and Drug Administration (FDA) has approved for use as of January 2014 but will also consider some gamma-emitting radiopharmaceuticals used for tumor imaging under specific physician direction.

As with all scintigraphic examinations, correlation of findings with results of other imaging and nonimaging modalities, as well as with clinical information such as serum tumor biomarkers, is necessary for maximum diagnostic yield.

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

Neuroendocrine tumor scintigraphy involves the intravenous or oral administration of a gamma-emitting radiopharmaceutical that localizes in certain tumor tissues, allowing subsequent imaging. This practice parameter is limited to scintigraphic agents used for gamma camera imaging. Positron emission tomography (PET) imaging of neuroendocrine tumors is covered in the ACR–SPR Practice Parameter for Performing FDG-PET/CT in Oncology and the ACR Practice Parameter for the Performance of Gallium-68 DOTATATE PET/CT for Neuroendocrine Tumors [2,3]. Information concerning the imaging of tumors not discussed in this practice parameter may be found in organ specific parameters, such as those for thyroid, parathyroid, musculoskeletal and gastrointestinal procedures.

(For pediatric considerations see section VI.)
II. GOAL

The goal of tumor scintigraphy is to enable the interpreting physician to detect and evaluate local (primary), regional nodal, distant metastatic, and residual or recurrent tumor tissue by producing images of diagnostic quality.

II. INDICATIONS

Indications for neuroendocrine tumor scintigraphy include, but are not limited to, the following:

1. Detection of certain primary and metastatic neuroendocrine tumors
2. Neuroendocrine tumor staging
3. Assessment of tumor response to therapy
4. Detection and restaging of residual disease after completion of therapy
5. Detection and restaging of recurrent disease in patients who had been clinically and radiologically free of disease after prior therapy
6. Evaluation of abnormal imaging and nonimaging findings in patients with a history of certain neuroendocrine tumors
7. Planning of treatment with unsealed radiopharmaceuticals using either empirical or dosimetric dosage calculations

Specific clinical applications depend on the specific radiopharmaceutical.

For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [4].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for neuroendocrine tumor scintigraphy 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. Radiopharmaceuticals

1. Radioiodinated Metaiodobenzylguanidine (MIBG)

MIBG is a chemical analog of norepinephrine. Iodine-123 (I-123-iodide)-labeled MIBG is used specifically for evaluating neuroendocrine tumors such as pheochromocytoma, paraganglioma, neuroblastoma,
ganglioneuroma, ganglioneuroblastoma, carcinoid tumors, medullary thyroid carcinoma, Merkel cell tumor, and multiple endocrine neoplasia (MEN) type 2 syndromes [5-11].

In adults, the administered activity is 5.0 to 10 mCi (185 to 370 MBq) of I-123-iodide MIBG injected intravenously [5-7,11-13]. For children, the administered activity should be as low as reasonably achievable for diagnostic image quality [9,14,15]. For children, the minimum administered activity is 1.0 mCi (37 MBq), and the maximum administered activity is 8.8 mCi (326 MBq). See table 4 below (the table is a picture file and cannot be struck so we have inserted the ‘x’).

2. Indium-111 Pentetreotide (In111-pentetreotide)

In111-pentetreotide is an octapeptide similar to the active component of somatostatin [16-20]. It interacts with somatostatin receptors in both normal tissue and certain tumors, especially those of neuroendocrine origin that have high expression of somatostatin receptors (eg, sympathoadrenal system tumors [pheochromocytoma, neuroblastoma, ganglioneuroma, and paraganglioma]), gastroenteropancreatic tumors (GEP) [eg, carcinoid, gastrinoma, insulinoma, glucagonoma, vasoactive intestinal peptide (VIP) VIPoma, etc], medullary thyroid carcinoma, pituitary adenoma, Merkel cell carcinoma, and small-cell lung carcinoma [19]. However, certain nonneuroendocrine tumors and nonneoplastic conditions can express somatostatin receptors, resulting in In111-pentetreotide avidity [19].

The usual adult administered activity is 4 to 6 mCi (148 to 222 MBq). Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality.

B. Patient Preparation and Imaging

1. Radioiodinated Metaiodobenzylguanidine (MIBG)

Patient Preparation: Many classes of drugs (eg, tricyclic antidepressants and sympathomimetic amines) may interfere with the uptake or vesicular storage of MIBG [5]. Patients should be screened for interfering medications, which should be discontinued whenever possible in coordination with the referring physician. For a majority of medications, a withdrawal time of 24 to 48 hours is sufficient; however, for some medications, a withdrawal period of up to several weeks is optimal [5,13]. Over-the-counter decongestants and “cold” remedies also should be discontinued. Thyroid blockade can be achieved by administering oral potassium iodide (130-300 mg/day) or potassium perchlorate (400-600 mg/day) [5-7,9,11]. Thyroid blockade may be administered 1 day prior to or at the time of planned radiopharmaceutical injection and should be continued for 1 to 2 additional days for I-123-iodide MIBG. Oral potassium iodide preparation includes tablets (65, 130, and 170 mg), supersaturated potassium iodide solution (SSKI; 1,000 mg/mL), or
Lugol solution (1% solution contains 25.3 mg/mL). For solutions dispensed as drops, 1 drop is 0.05 mL (20 drops per milliliter). Suggested pediatric dosing of potassium iodide is 32 mg/day for children from 1 month to 3 years; 65 mg/day for children 3 to 13 years; and 130 mg/day for children over 13 years [9]. Newborns may receive 16 mg potassium iodide only on the day before tracer injection [9]. For I-123-iodide MIBG, breastfeeding should be discontinued for 12 hours (4 mCi dosage) or 24 hours (10 mCi dosage).

Imaging Technique: For I-123-iodide MIBG, imaging typically is performed at 24 hours (18-48 hours) after administration using low-energy or medium-energy collimators [5,6,21]. Total-body imaging (5-10 cm/min) or 500,000 counts static images are obtained. Single-photon emission CT (SPECT) or SPECT/CT imaging of areas of abnormality or clinical concern (128 × 128 × 16 matrix, 3° stops, 30 seconds per stop) can should be performed and may be of additional diagnostic benefit [22-24].

2. In111-pentetreotide

Patient Preparation: For In111-pentetreotide imaging, interruption of breastfeeding is usually unnecessary because a radiation dose to the child is unlikely to exceed 100 mrem. No dietary restrictions are necessary; however, patients should be encouraged to drink fluids. A mild laxative taken the evening before the injection may facilitate detection of abdominal and pelvic lesions. The examination should be carefully considered in patients who have severely impaired renal function because this is the primary route of excretion for the radiopharmaceutical. Hemodialysis might improve image quality [19]. Temporary withdrawal of somatostatin analogue therapy prior to In111-pentetreotide imaging (eg, 1 day for short-acting and 3-4 weeks for long-acting somatostatin analogues) is controversial and should be performed (if feasible) in coordination with the referring physician [19]. In111-pentetreotide should not be administered through a total parenteral nutrition (TPN) line or injected into TPN solution. In patients with insulinoma or in patients with diabetes receiving high dosages of insulin, administration of pentetreotide can cause severe hypoglycemia; in these patients, blood glucose should be checked prior to pentetreotide administration, and an intravenous line with 5% dextrose in 0.9% NaCl (D5 NS) should be continuously infused prior to and during radiopharmaceutical administration.

Imaging Technique: Imaging with In111-pentetreotide is usually performed 4 to 24 hours, or 24 and 48 hours, after injection using medium-energy collimators (172 and 245 keV photopeaks [19]). Additional imaging at 48 to 72 hours after injection may sometimes be helpful. Between 24 and 48 hours, laxative therapy can be administered to achieve clear physiologic bowel activity [19]. Planar imaging, SPECT, and SPECT/CT practice parameters are similar to those described in section VII.A.

A. Gallium-67 Citrate

(See the ACR–SPR Practice Parameter for the Performance of Scintigraphy for Inflammation and Infection [25].) Injected intravenously, gallium-67 is bound by plasma transferrin and lactoferrin. Although the exact mechanism is not known with certainty, its localization within a tumor is believed to relate to intracellular ferritin and/or lactoferrin [26]. Though many different tumors are reported to have a variable affinity for gallium-67, this radiopharmaceutical has been used most commonly in assessing Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, lung cancer, and hepatocellular carcinoma [27-35]. Note that FDG-PET/CT has replaced gallium-67 citrate for Hodgkin and non-Hodgkin lymphoma, melanoma, and lung cancer [36]. Although CT and MRI are mainstay modalities for the evaluation of hepatocellular carcinoma, gallium-67 might be useful in differentiating hepatocellular carcinoma from regenerating nodule [37].

The usual adult administered activity is 5.0 to 10.0 millicuries (185 to 370 MBq) injected intravenously. Due to the high radiation exposure, gallium-67 should not be used in children younger than 14 years of age, unless there is a clear evidence of malignancy and imaging with gallium-67 is absolutely necessary to address the clinical question [29]. Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality [14].
C. Indium-111 Capromab Pendetide

Capromab pendetide is an indium-111-labeled immunoconjugate of the murine monoclonal antibody that reacts with a prostate-specific membrane antigen expressed by prostate epithelial cells [38]. The examination can be performed to either stage newly diagnosed prostate cancer prior to definitive treatment [39-43] or more commonly to detect prostate cancer recurrence after definitive treatment in the setting of rising prostate-specific antigen (PSA) [38,42,44]. The examination is considered more effective for detecting local and nodal regional or metastatic disease than for detecting osseous metastatic disease [43,45,46].

The usual adult administered activity of indium-111 capromab pendetide is 4 to 7 millicuries (150 to 260 MBq).

E. Thallium-201 (Thallous Chloride)

(See the ACR-SPR Practice Parameter for the Performance of Parathyroid Scintigraphy [1] ) Thallium-201 is a potassium analog that enters cells in proportion to local blood flow. For reasons that are not well understood, it appears to have an affinity for certain tumors (eg, glioblastoma, osteosarcoma, soft-tissue tumors, and lymphoma) [47-51]. Currently, thallium-201 is rarely used as a tumor-imaging radiopharmaceutical, but it might be helpful as a problem-solving tool, for example in differentiating toxoplasmosis from lymphoma in the brain and for differentiating radiation necrosis from glioma recurrence [50,51].

The usual adult administered activity is 3 to 5 millicuries (111 to 185 MBq). Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality.

F. Technetium-99m Sestamibi

(See the ACR-SPR Practice Parameter for the Performance of Parathyroid Scintigraphy [1] ) Technetium-99m sestamibi is a nonpolar lipophilic radiopharmaceutical that crosses the cell membrane, undergoes deamination, and becomes trapped within the cell. Localization is dependent on local blood flow and mitochondrial uptake. In addition to imaging of parathyroid lesions, this radiopharmaceutical is useful for evaluating breast lesions [52-61].

The usual adult administered activity is 20 to 30 millicuries (740 to 1110 MBq) for single detector breast specific gamma imaging devices. Molecular breast imaging with a dual-headed configuration with solid-state (nonscintillating) detectors allows for a lower administered activity (eg, 8 millicuries or less) [62-64]. Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic imaging quality [13].

Although technetium 99m sestamibi has an affinity for many other tumors (eg, bone and soft tissue, lung, head and neck, and thyroid tumors [65-72]), it is rarely used for tumor imaging other than parathyroid and breast due to widespread availability of 18F-FDG PET/CT. At the present time, technetium-99m sestamibi retains a prominent role in tumor imaging only when 18F-FDG PET/CT is not available.

A. Gallium-67 Citrate

(See the ACR-SPR Practice Parameter for the Performance of Scintigraphy for Inflammation and Infection [25] )

Patient Preparation: In the pregnant patient, risks versus benefits need to be considered prior to performing any procedure. For gallium-67 tumor imaging, breastfeeding should be discontinued for at least 1 month to avoid exceeding dose of 100 mrem to the breastfeeding infant [73]. Food and liquid restrictions are not mandatory, and bowel preparation is optional [29]. Normal colonic radiopharmaceutical activity may interfere with evaluation of abdominal disease; mild laxatives (given at least 18 hours prior to imaging) or enemas may occasionally be necessary for colon cleansing. Vigorous catharsis should probably be avoided in patients who are on chemotherapy or are otherwise immunosuppressed. The procedure should be avoided within 24 hours after blood transfusion or gadolinium-enhanced MRI scanning, which may alter gallium-67 biodistribution [29].

Imaging Technique: Imaging is normally performed 48 to 96 hours after administration and may be repeated daily for as long as 7 to 10 days afterwards, using the lower 2 or lower 3 photopeaks (93, 184, and 300 keV [29,31]). The patient should be instructed to fully empty the bladder, change incontinence pad, or empty urine drainage bag immediately prior to positioning on the imaging table. Whole body imaging is obtained, supplemented by spot images or a series of static planar images of the whole body. For whole body imaging, anterior and posterior views are obtained; with approximately 1,500,000 counts; matrix 256 x 512 x 16; scan speed 5 to 10 cm/min. For spot images of the chest, abdomen, and pelvis, at least 500,000 counts should be obtained, with desirable counts.

Radiopharmaceuticals made from murine sources may cause immunologic response in some patients. Anaphylactic reactions are uncommon, but injection should be carried out where resuscitation equipment and personnel are available. Some patients develop human antihuman antibodies (HAMA), and this may interfere with subsequent imaging.

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PRACTICE PARAMETER 6 Neuroendocrine Tumor Scintigraphy 2020 Resolution No. 14
ranging between 1,000,000 and 2,000,000; matrix 256 or 512 x 512 x 16. Due to moderate hepatic activity, images
of the chest and pelvis should avoid including the liver. Single photon emission computed tomography (SPECT)
imaging can be performed to increase contrast resolution for detecting disease in deep structures to better separate
intraluminal gallium in the gastrointestinal tract from intra-abdominal lesions and to correlate with other cross-
sectional imaging modalities. For single-headed SPECT cameras, a 64 x 64 matrix, 360° rotation, and 64 or 128
steps with 20 to 25 seconds per step are recommended. For multiheaded SPECT cameras, a 128 x 128 matrix, 360°
of data collection with 2° steps, and 20 to 40 seconds per step are suggested. SPECT/CT imaging of relevant sites
may be of additional diagnostic benefit, providing attenuation correction of the SPECT image data and improving
anatomic lesion localization and characterization.
C. Indium-111 Capromab Pendetide
For indium-111 capromab pende tide imaging, no patient preparation is required, although bowel cleansing may
be useful. Newer indium-111 capromab pender tide imaging protocols performed 5 to 7 days after the
radiopharmaceutical injection, combining delayed planar whole body imaging (scan speed 5 cm/min) with limited
area SPECT/CT, provides attenuation correction for SPECT imaging data and may improve anatomic lesion
localization and characterization and thus obviate the need for immediate imaging and technetium-99m RBC
imaging [74-76]. The field of view (FOV) should include the penile blood pool at the bottom of the FOV and as
much of the pelvis and abdomen as possible (early regional nodal and osseous metastatic disease typically occur in
the pelvis). Additional body regions can be included as needed. For multiheaded SPECT systems, a 128 x 128 x 16
matrix, 360° of data collection with 2° steps, and 60 seconds per step are suggested. If SPECT/CT is not available,
2-SPECT imaging acquisition procedures may be utilized [38]. The first, and preferred, technique uses the
simultaneous dual-radiopharmaceutical SPECT acquisition performed 4 to 5 days after the injection of indium-111
capromab pender tide and shortly after technetium-99m autologous labeled red blood cells injection. The abdomen
and pelvis, extending below the level of the pubic symphysis, should be included in the FOV [42]. The technetium-
99m window should be centered 140 keV with a 10% window. The indium-111 windows should be centered at 173
keV and 247 keV with a 10% and 20% window, respectively. The second, and less desirable protocol due to
potential anatomical misalignment, consists of indium-111 capromab pender tide imaging of the abdomen and pelvis
eurial to the symphysis pubis performed 30 minutes after injection of indium-111 capromab pender tide to obtain a
blood pool image set; the second imaging session is performed 4 to 5 days after injection and should be as identical
as possible in position and location of the abdomen and pelvis as the first day. Another consideration should be
taken into account on day 4 to 5 imaging secondary to the activity in the bladder. If filtered back projection (FBP)
reconstruction is utilized for the SPECT images, then consideration should be taken for the use of a catheter with
bladder wash. If iterative reconstruction (IR) is utilized, then a bladder catheter may not be as important. Planar
imaging with SPECT or SPECT/CT imaging practice parameters are similar to those described in sections VII.A
and VII.C.
E. Thallium-201 (Thallous Chloride)
For thallium-201 tumor imaging, no special patient preparation is required. Breastfeeding should be discontinued
for 2 weeks after thallium-201 [73]. No special preparation is required. Imaging may be performed 15 to 20 minutes
(early) or 2 to 4 hours (delayed) after injection. Imaging at multiple time points might be helpful in distinguishing
benign and malignant tumors or assessing tumor aggressiveness or response to therapy [77]. Planar and SPECT or
SPECT/CT imaging is performed using low-energy high-resolution parallel hole collimator with 20% windows
centered at 80 and 167 keV. Imaging may be limited to the area of interest (eg, brain). Alternatively, whole-body
planar imaging (scan speed 5 to 10 cm/min) with SPECT (64 x 64 x 16 matrix; 360° in 64 projections of 40 seconds
each) or SPECT/CT of areas of interest may be performed.
E. Technetium-99m Sestamibi
The whole-body radiation doses from scintimammography are substantially higher than the dose of a digital
mammogram, thus scintimammography is not indicated for routine breast cancer screening in its present form [78-
80]. However, scintimammography may be useful in selected patients (eg, breast cancer screening in selected
patients, evaluation of indeterminate breast abnormalities, initial staging, and recurrence detection) [81].
Patient Preparation: For scintimammography, no special patient preparation is required. Known hypersensitivity to
technetium-99m sestamibi and pregnancy are contraindications. Scintimammography should preferably be
performed between days 2 and 12 of the menstrual cycle in premenopausal patients and at least 3 months after
cessation of lactation. To minimize false positive results, scintimammography ideally should be performed either
prior to interventional procedures or at least 2 weeks after fine-needle aspiration of a cyst and at least 3 weeks after core or excisional biopsy. False positive results also are less likely if scintimammography is performed within 72 hours of an interventional procedure.

Imaging Technique: Prior to imaging, the patient should remove clothing from the waist up and should wear a mammography cape or gown. After the venous catheter injection of 20 to 30 millicuries (740 to 1,110 MBq) of technetium 99m sestamibi followed by a 10 to 20 mL flush of normal saline, the intravenous line is removed. To decrease vascular trapping of the radiopharmaceutical, patients may raise their arm above their head for one minute while squeezing a ball. Radiopharmaceutical injection should be in the arm opposite the side of clinical concern or in a foot vein if bilateral disease is suspected.

For image acquisition, the sitting position is preferred; however, the patient may need to stand to optimize lesion detection. Imaging is performed 5 to 10 minutes after radiopharmaceutical injection with a low energy high-resolution small field of view (FOV) gamma camera dedicated for breast imaging (140 keV photopeak, 20% energy window). Planar images are acquired with light breast compression for 10 minutes each or 175,000 counts (7-minute minimum), with acquisition mimicking the mammographic projections (eg, craniocaudal—detector inferior to the breast; mediolateral oblique—detector positioned at an oblique inferior lateral angle aligning to the long axis of the pectoralis muscle). Routine 4 views include right and left craniocaudal and right and left mediolateral oblique; additional views, most often mimicking mammographic views, may be obtained to optimize lesion detection.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [82].

The report should include the radiopharmaceutical used, the administered activity, and route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

A relevant oncologic history should also be included with a brief overview of any prior oncologic treatments, emphasizing the specific indication for the current study.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [83].

A gamma camera with low energy collimation is used for thallium 201 and technetium 99m sestamibi imaging (including scintimammography). For gallium 67 citrate and For In111-labeled radiopharmaceuticals, medium-energy collimation (up to about 300 keV) is used. For I-123-iodide, a low-energy high-resolution or medium-energy collimator may be used. A SPECT/CT hybrid camera may provide additional diagnostic benefit, as discussed above.

VII. RADIATION SAFETY

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)

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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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

1996 (Resolution 10)
Revised 2000 (Resolution 28)
Revised 2005 (Resolution 23)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 28)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 48)
BE IT RESOLVED,  
that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Radionuclide Cystography

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 47) *

ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF RADIONUCLIDE CYSTOGRAPHY

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 Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to guide interpreting physicians in performing radionuclide cystography (RNC) in adult and pediatric patients. Properly performed imaging of the bladder with radiopharmaceuticals provides a sensitive means of detecting, evaluating, and following certain conditions of the bladder and ureters. As with all scintigraphic examinations, correlation of findings with the results of other imaging and nonimaging procedures, as well as clinical information, is necessary for maximum diagnostic yield.

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

RNC involves filling the urinary bladder with a radiopharmaceutical, either by direct (retrograde) administration via urethral catheter or by indirect (antegrade) drainage of an intravenously administered radiopharmaceutical that is excreted by the kidneys and subsequent imaging with a gamma camera.

(For pediatric considerations see sections VI and VII.)

III. GOAL

The goal of RNC is to enable the performing/interpreting physician to detect and quantify physiologic and anatomic abnormalities of the urinary system by producing diagnostic-quality images.

II. INDICATIONS

Clinical indications [2-4] for RNC in evaluating vesicoureteral reflux (VUR) include, but are not limited to, the following:

1. Initial diagnosis of vesicoureteral reflux in female patients with urinary tract infection
2. Diagnosis of vesicoureteral reflux in asymptomatic children with a family history of VUR
3. Diagnosis of vesicoureteral reflux in renal transplant recipients
4. Diagnosis and follow-up of vesicoureteral reflux in infants (including persistent antenatal hydronephrosis) and children with hydronephrosis (eg, persistent prenatal hydronephrosis)
5. As a Follow-up examination to assess spontaneous resolution of known vesicoureteral reflux
6. As a Follow-up examination to evaluate resolution of vesicoureteral reflux after medical or surgical antireflux procedures management
7. Serial evaluation of vesicoureteral reflux in patients with bladder dysfunction
8. Quantification of postvoid residual urine in bladder

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For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [5].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

IV. RADIOPHARMACEUTICALS

The direct (retrograde) technique (see Section VII.A.) employs technetium-99m (Tc-99m) sodium pertechnetate, Tc-99m sulfur colloid, or Tc-99m diethyleneetriamine penta-acetic acid (DTPA). Tc-99m sodium pertechnetate should not be used in individuals who have undergone bladder augmentation with gastric or intestinal tissue. An administered activity of 18.5 ± 7.4 to 37 MBq (0.5 ± 0.2-1.0 mCi) is introduced aseptically into the urinary bladder via a urethral catheter. Administered activity in children should be as low as reasonably achievable (ALARA) for diagnostic image quality. The North American Consensus Guidelines for Administered Radiopharmaceutical Activities in Children and Adolescents recommend no more than 37 MBq (1 mCi) for each cycle of filling in pediatric patients. No weight-based administered activity has been defined for RNC [6].

The indirect (antegrade) technique (see Section VII.B.) may employ Tc-99m mercaptoacetyltriglycine (MAG-3) or Tc-99m DTPA.

V. SPECIFICATIONS OF THE EXAMINATION

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

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). 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. Retrograde (Direct) Technique

1. Patient preparation/catheterization

To measure In male patients, application of urethral anesthesia (eg, lidocaine jelly) before catheterization may decrease discomfort [7]. If direct measurement of the postvoid residual bladder volume directly is needed, adults and toilet-trained pediatric patients should be asked to void immediately before catheterization. Urine collected during catheterization represents the residual bladder volume [4] [4]. Latex materials should be avoided and should not be used in patients with a known latex allergy or who are at high risk for latex allergy (eg, older patients with multiple surgical procedures of the spine or genitourinary tract). In male patients, application of urethral anesthesia (eg, lidocaine jelly) before catheterization may decrease discomfort [8]. Sedation should be avoided because it precludes obtaining the voiding phase of the examination. Sedatives relax the ureterovesicular junction musculature, interfering with the normal ureterovesicular valvular mechanism and potentially causing pharmacologically
induced reflux. Bladder catheterization should be performed by an individual trained in the procedure using aseptic technique and, if clinically desired, a urine specimen for analysis or culture can be obtained at this time. The bladder is catheterized for culture.

2. Radiopharmaceutical infusion

The radiopharmaceutical is administered aseptically into the bladder through the urinary urethral catheter and then sterile normal saline is infused until the bladder reaches its estimated capacity with the patient either lying supine or in the sitting or semirecumbent position. Bladder capacity (in mL) in children can be approximated with a reference table [8] or calculated as follows [9]:

\[
\begin{align*}
< 1 \text{ year of age}: & \quad \text{weight in kg} \times 7 \\
> 1 \text{ year of age}: & \quad (\text{age} + 2) \times 30
\end{align*}
\]

During infusion, the saline container typically is placed no more than 100 cm above the tabletop. Warming the saline solution to room or body temperature and infusing at a slow rate may improve the patient’s comfort. Alternatively, in adults, the radiopharmaceutical may be added to 500 mL of sterile normal saline for infusion. Patients with neurogenic a neuropathic bladder might require more than 500 mL. It is, however, a less suitable alternative, as some of the radiopharmaceutical does not arrive in the bladder until maximal filling.

A cyclic (more than one filling and voiding) examination may increase sensitivity for both children and adults [10] and can be considered in patients with a high pretest probability of having reflux. Repeat filling and voiding cycles are obtained with the catheter remaining in place for all cycles.

3. Image acquisition

In all patients during filling, the pelvis and abdomen are imaged continuously in the posterior projection, with the patient lying supine. During voiding, images are obtained continuously, either in the seated upright position in adults and toilet-trained children who are able to sit on the bedpan or in the supine position in patients who are unable to sit. A low-energy collimator should be used. Digital data acquisition is recommended.

If reflux occurs during filling of the bladder, the volume at which reflux occurred should be recorded. The end of the filling phase usually is indicated by a reduction or cessation of the infusate’s rate of flow or by achieving maximum bladder capacity [4] [4]. In children, bladder volume can be approximated either with the formula ((age in years + 2) \times 30 \text{ mL} = \text{bladder volume}) or with a reference table [8].

When the bladder fills to maximum capacity, the patient is should be instructed to void or when the patient begins to void spontaneously, imaging is continued with continuous image acquisition until the bladder is empty. In patients able to cooperate, voiding images may be obtained with the patient upright. Postvoid posterior images of the bladder should be obtained in either the supine or upright position after bladder emptying is complete. If the patient cannot void upon request or if the patient voids incompletely, the bladder should be emptied emptying the bladder via the urinary catheter will reduce radiation exposure.

In infants and children, a cyclic (more than one filling and voiding) examination may increase sensitivity. Repeat filling and voiding cycles are obtained with the catheter remaining in place for all cycles.
4. Processing

For visual analysis of digital images, a consistent image display technique capable of contrast enhancement and cine mode should be used to maximize the sensitivity of the test. and by detecting the smallest amounts of reflux. Quantification of reflux during the bladder-filling phase and during the voiding phase may be achieved using region-of-interest (ROI) analysis, with ROI placed over the kidneys and the ureters.

For quantification of postvoid residual volumes, prevoid and postvoid images of the bladder should be acquired anteriorly or posteriorly. ROIs are drawn over the bladder on both sets of the pre- and postvoid images. The volume of voided urine is recorded. Residual volume (RV) can be estimated by the following formulas:

\[
RV \text{ (mL)} = \frac{(\text{voided vol [mL]}) \times (\text{postvoid bladder ROI count})}{(\text{initial prevoid bladder ROI count}) - (\text{postvoid bladder ROI count})}
\]

RV may be calculated if the volume to which the bladder was filled is known. The equation then becomes:

\[
RV \text{ (mL)} = \frac{(\text{initial prevoid bladder vol [mL]}) \times (\text{postvoid bladder ROI count})}{\text{initial prevoid bladder ROI count}}
\]

5. Interpretation

The degree of reflux is estimated using a visual grading scale with RNC grades 1 to 3 as below [4,11-13]:

<table>
<thead>
<tr>
<th>RNC Grades</th>
<th>Finding</th>
<th>Analogous Radiographic Grades</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Mild)</td>
<td>Activity limited to ureter</td>
<td>I</td>
</tr>
<tr>
<td>2 (Moderate)</td>
<td>Activity reaching the renal collecting system</td>
<td>II and III</td>
</tr>
<tr>
<td>3 (Severe)</td>
<td>Activity in dilated renal collecting system and ureter</td>
<td>IV and V</td>
</tr>
</tbody>
</table>

Careful review of available previous radiographic, ultrasound, and radionuclide examinations will add to the accuracy of interpretation of the current examination.

The presence of incomplete drainage of refluxed radiotracer, particularly from a dilated renal pelvis, after complete voiding and/or drainage of the bladder should be noted because it could be indicative of coincident ureteropelvic junction obstruction.

6. Instructions to patient/parent

The radiation exposure to the bladder although is small low and well within accepted diagnostic imaging levels. It can be further reduced by complete drainage of any unvoided activity and by encouraging hydration and voiding after the examination. Instruction to drink fluids by mouth for several hours with frequent voiding following the examination should be given to the patient, parent, or caregiver.
B. Indirect (Antegrade) Technique

This test usually is performed as the final part of a dynamic renal scan. **No additional radiotracer is administered beyond what was already administered.** Administered activity is the same for renal scintigraphy (see the ACR–SPR Practice Parameter for the Performance of Renal Scintigraphy [14]), which can be combined with this technique.

The advantages of the indirect technique are that it is noninvasive (ie, does not require catheterization) and it provides information about renal function. A disadvantage of the indirect technique is a lower sensitivity than direct RNC because a) the bladder may only partially fill, b) reflux can be detected only during the voiding phase, and c) it may be difficult to differentiate between reflux and residual antegrade excretion [15-17]. Use of ROIs over the collecting systems and time-activity curves may enhance the sensitivity of indirect RNC for detecting vesicoureteral reflux. Indirect cystography should not be used if the patient has not been toilet trained or has impaired renal function [12,15-17].

For infants and children, refer to the ACR-SPR Practice Parameter for the Performance of Voiding Cystourethrography in Children [7].

VI. DOCUMENTATION

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

The report should include the radiopharmaceutical used, the administered activity, and route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [19].

A gamma camera with a low-energy all-purpose/general all-purpose (LEAP/GAP) or high-resolution collimator (LEHR) may be desirable. If the clinical question relates to vesicoureteral reflux, the field of view (FOV) must be large enough to include both the bladder and kidneys. For infants and small children, magnification may be used if a large FOV camera head (400 mm) is employed.

Digital acquisition may be desirable, and is necessary if quantification is performed. A 64 × 64 acquisition matrix is sufficient for detectors up to 400 mm in diameter. For larger detectors, a 128 × 128 matrix is needed. A framing rate of 10 to 30 seconds per frame is suggested during the filling phase of the study and no more than 5 seconds per frame during micturition. The collimator face and the entire imaging field must be protected from radiopharmaceutical contamination using plastic-backed absorbent pads or other similar material. Plans for collection, disposal, storage, or decontamination of radioactive urine and materials must be considered.

VIII. RADIATION SAFETY

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...

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](http://www.imagegently.org)) and Image Wisely® for adults ([www.imagewisely.org](http://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. 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](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](https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards)) by the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the SNMMI, and the SPR.
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REFERENCES


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

1996 (Resolution 12)
Revised 2000 (Resolution 26)
Revised 2005 (Resolution 24)
Amended 2006 (Resolution 17, 35)
Revised 2010 (Resolution 25)
Amended 2012 (Resolution 8 – title)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 47)
RESOLUTION NO. 16

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Gastrointestinal Tract, Hepatic, and Splenic Scintigraphy

Sponsored By: ACR Council Steering Committee

PRACTICE PARAMETER

ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF GASTROINTESTINAL TRACT, HEPATIC, AND SPLENIC SCINTIGRAPHY

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.
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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 Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to guide physicians performing and interpreting gastrointestinal tract, hepatic, and splenic scintigraphy in adult and pediatric patients. Gastrointestinal scintigraphy involves the intravenous (IV), oral, transcatheter (to include enteric tubes), or intraperitoneal administration of a radiopharmaceutical that localizes in or transits the salivary glands, gastrointestinal tract, or peritoneal cavity. Hepatic and splenic scintigraphy involves IV administration of radiopharmaceuticals that localize in the reticuloendothelial system (RES) or blood pool of the liver and/or spleen. Imaging is performed with a gamma camera and may also include additional hybrid scintigraphic and anatomical imaging, such as single-photon emission computed tomography (SPECT) with or without computed tomography (CT) imaging, which assists with further localization of an abnormality [1]. As with all scintigraphic studies, correlation of findings with the results of other imaging and nonimaging procedures, as well as clinical information, is necessary to achieve maximum diagnostic yield. Properly performed imaging with radiopharmaceuticals that localize in or are introduced into the gastrointestinal tract or peritoneum is a sensitive means for detecting, evaluating, and quantifying numerous conditions affecting the gastrointestinal tract and peritoneum.

Imaging of the hepatobiliary system is discussed separately in the ACR–SPR Practice Parameter for the Performance of Hepatobiliary Scintigraphy [2]. Imaging of radiopharmaceuticals delivered via the hepatic artery in preparation for yttrium-90 ($^{90}Y$) radioembolization of primary and metastatic liver tumors is discussed separately in the ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization for Treatment of Liver Malignancies [3].

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4].

II. INDICATIONS

Clinical indications are varied and include, but are not limited to, the following:

A. Gastrointestinal Tract

1. Salivary Gland
   a. Demonstration of salivary gland function and/or tumors

2. Gastrointestinal Transit
   a. Verification of suspected aspiration
b. Evaluation and quantification of esophageal motility and transit through and reflux into the esophagus

c. Evaluation of gastroesophageal and enterogastric reflux

d. Quantification of the rate of gastric emptying of liquid solid and/or solid liquid meals from the stomach

e. Demonstration of intestinal transit through the small and large intestine

3. Gastrointestinal Bleeding
a. Demonstration of the presence and site of acute gastrointestinal bleeding
b. Detection of ectopic functioning gastric mucosa as seen in Meckel's diverticulum

4. Peritoneum
a. Assessment of peritoneovenous shunt patency
b. Detection of congenital or acquired perforation of the pleuroperitoneal diaphragm (pleuroperitoneal fistula)
c. Demonstration of the presence or absence of peritoneal loculations prior to intraperitoneal chemotherapy or radiopharmaceutical therapy

B. Liver and Spleen

1. Assessing the size, shape, and position of the liver and/or spleen
2. Differentiation of hepatic or splenic hemangiomas and other mass lesions, such as focal nodular hyperplasia (FNH)
3. Evaluating for residual or ectopic functioning splenic tissue and suspected functional asplenia

9. Detection of ectopic functioning gastric mucosa
10. Demonstration of the presence and site of acute gastrointestinal bleeding

For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [5].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for gastrointestinal, hepatic, and splenic scintigraphy 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. Radiopharmaceuticals

Several radiopharmaceuticals are currently available. The radiopharmaceutical used should be chosen based on the clinical indications and circumstances. Administered activity for children should be based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality as outlined in the 2016 Update of the North American Consensus Guidelines for Pediatric Administered Radiopharmaceutical Activities [6]. In the United States, technetium-99m (Tc-99m) sulfur colloid (SC) is the only FDA-approved agent for oral administration, and the additional radiopharmaceuticals mentioned below for oral administration may require specific radioactive licensing amendments.

1. Gallium-67 Citrate (Ga-67)

Ga-67 is not commonly used and is not first line, but it is an alternative radiopharmaceutical in certain circumstances when others are not available. Given orally, Ga-67 is not absorbed from the gastrointestinal tract and may be used as a liquid-phase marker of gastric emptying. Like indium-111 (In-111) diethylenetriamine-penta-acetic acid (DTPA), this radiopharmaceutical can be used with a concomitant solid meal labeled with Tc-99m SC for gastric imaging and measurement of small-bowel or colon transit. Its long half-life (physical half-life: 78.3 hours) allows extended imaging of the abdomen up to 96 hours or longer. Administered activity is typically 0.056 kBq/kg (0.0015 mCi/kg) for dual-phase gastric emptying examinations in pediatric patients. For adults needing evaluation of colonic transit or liquid gastric emptying, a dosage of 3 to 7 MBq (0.08-0.2 mCi) can be used [7,8]. For a liquid-only gastric emptying examination, Tc-99m SC should be used instead of Ga-67 to reduce radiation exposure.

2. In-111 DTPA

Given orally, with an administered activity of 5.55 to 18.5 MBq (0.15-0.50 mCi), In-111 DTPA may be used to evaluate liquid gastric emptying when a concomitant solid meal labeled with Tc-99m SC is used. Also, due to its longer half-life (physical half-life: 67.3 hours), additional imaging of the abdomen is possible up to 72 hours for measurement of small-bowel or colon transit. Administered activity of In-111 DTPA in water for colon transit is 3.7 to 37 MBq (0.1-1.0 mCi) [9-11]. However, for a liquid-only gastric examination, Tc-99m SC should be used instead of In-111 DTPA to reduce radiation exposure.

3. Tc-99m (Stannous - Sn) DTPA

Given orally, Tc-99m DTPA may be used for liquid gastric emptying evaluation or for small-bowel transit when only a single liquid meal transit examination is performed. It cannot be used simultaneously for a combined liquid- and solid-phase gastric emptying examination when a Tc-99m solid-phase radiopharmaceutical is also used. When dual-phase (solid and liquid) gastrointestinal examinations are performed, In-111 DTPA (or Ga-67 citrate) is used to measure the liquid phase, and Tc-99m SC is used for the solid phase. Tc-99m DTPA in water can also be used for esophageal transit time evaluation. The administered activity for Tc-99m DTPA is 18.5 to 37 MBq (0.5-1.0 mCi) for adults. The administered activity of the radiopharmaceutical and the volume to be fed to the pediatric patient should be based on patient factors such as age, body weight, and the usual feeding volume [12].

4. Tc-99m Macroaggregated Albumin (MAA)

Given intraperitoneally, Tc-99m MAA is not absorbed and is used as a qualitative marker of the movement of ascitic fluid through peritoneovenous shunt devices or congenital/traumatic diaphragmatic fenestrations. The usual adult administered activity is 18.5 to 185 MBq (0.5-5.0 mCi) in 3 to 5 mL of 0.9% saline [12].
5. **Tc-99m Red Blood Cells (RBCs)**

   Tc-99m RBCs remain intravascular and are commonly used for detecting and localizing the source of an active gastrointestinal bleed. The usual adult IV-administered activity for gastrointestinal blood loss detection is 555 to 1,100 MBq (15-30 mCi) [13]. For pediatric patients, the recommended administered activity is 11.39 to 26.67 MBq/kg (0.31-0.72 mCi/kg). The highest RBC-labeling efficiency is achieved with the in vitro method (≥ 97%), which is recommended and widely used [14]. See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals for handling of radiolabeled cells [4].

   The usual IV-administered activity of Tc-99m–labeled autologous RBCs for hepatic hemangioma evaluation ranges from 740 to 925 MBq (20-25 mCi).

6. **Tc-99m RBCs (autologous and heat-damaged)**

   Autologous RBCs are radiolabeled, preferably by the in vitro method, with an activity of 37 to 222 MBq (1-6 mCi) for planar imaging or 555 to 1,110 MBq (15-20 mCi) for SPECT or SPECT/CT imaging and heated for 15 minutes in a preheated water bath between 49.0°C and 50.0°C. After cooling to at least body temperature, the heat-damaged RBCs are administered intravenously (IV), with imaging performed 20 to 30 minutes postinjection. The heat-damaged RBCs will be preferentially sequestered by splenic tissue. See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4] for handling of radiolabeled cells.

7. **Tc-99m Sodium Pertechnetate**

   During the first 1 or 2 minutes after IV administration, Tc-99m sodium pertechnetate may be used as a blood flow and blood pool marker. Within minutes after injection, this radiopharmaceutical begins to concentrate normally in the salivary glands and in mucin-producing cells of the gastric mucosa, making it suitable for evaluation of salivary gland function and for detection of ectopic gastric mucosa. The usual adult IV-administered activity is 296 to 444 MBq (8-12 mCi). For pediatric patients, 1.85 MBq/kg (0.05 mCi/kg) is recommended. Physiologic renal excretion results in visualization of the kidneys and bladder. Rapid absorption by the stomach and peritoneum makes Tc-99m sodium pertechnetate unsuitable for oral or intraperitoneal administration [15].

8. **Tc-99m SC**

   Tc-99m SC, when administered orally, is not absorbed and is an excellent radiopharmaceutical for imaging and quantification of numerous parameters of swallowing and gastrointestinal motility and transit. A small volume (up to 1 mL) of Tc-99m SC containing no more than 18.5 MBq (0.5 mCi) can be used for gastropharyngeal aspiration imaging. In adults, 10 to 30 mL of water containing 3.7 to 11.1 MBq (0.1-0.3 mCi) of Tc-99m SC or Tc-99m DTPA can be given for esophageal transit studies [16]. For gastric emptying, an administered activity of 18.5 to 74 MBq (0.5-2 mCi) is generally used as a radiolabel for liquid and solid meals in adults. The affinity of this radiopharmaceutical for the protein matrix of egg whites facilitates the egg white labeling as the solid phase component of the meal [17]. There is no weight-based dosage for children, but 9.25 to 37 MBq (0.25-1.0 mCi) can be used to label a liquid meal and 9.25 to 18.5 MBq (0.25-0.5 mCi) for a solid meal.

   When administered IV, Tc-99m SC is also utilized for functional imaging of the RES of the liver, spleen, and bone marrow. Tc-99m SC consists of particles composed of Tc-99m sulfide stabilized with gelatin. These particles range in size from 0.1 to 1.0 μm. Given IV, they are phagocytized by the RES cells of the liver, spleen, and bone marrow in proportion to relative blood flow, functional capacity of the phagocytic cells, and particle size. Maximum concentration in the liver and spleen occurs within 10 to 20 minutes, and the rate of biologic clearance from the RES is very slow. The usual administered activity is 111 to 222 MBq (3-6 mCi) for planar imaging in adults and up to 370 MBq (10 mCi) for SPECT imaging.
If administered intraperitoneally, Tc-99m SC is not absorbed and becomes a qualitative marker of movement of ascitic fluid through congenital or traumatic diaphragmatic fenestrations and peritoneovenous shunts. It can be used to assess for free flow or loculation prior to P32 colloidal therapy for malignant ascites. The administered activity of 18.5 to 185 MBq (0.5-5.0 mCi) Tc-99m SC is used [12].

Although less superior to Tc-99m RBCs (autologous), Tc-99m SC can also be utilized to identify a gastrointestinal bleed.

**B. Imaging and Patient Preparation**

1. **Gastrointestinal Imaging**
   
a. **Salivary Gland**
   
   Salivary gland imaging may help in the differential diagnosis of salivary gland disorders and certain masses. A sialogogue, such as lemon juice, may be given to stimulate salivary gland emptying in cases of salivary duct obstruction or ligation, sialadenitis, or suspected Warthin’s tumor. The collimator surface should be protected from contamination by using a plastic-backed pad or other similar material. The patient should lie supine in a Water’s position in front of a gamma camera (chin and nose touching the collimator). During the IV administration of Tc-99m sodium pertechnetate, a 1 to 2 minute radionuclide angiogram of the face (3-5 seconds/frame) is followed by serial dynamic imaging for 20 to 30 minutes (2-3 minutes/frame). Additional planar views may also be obtained in the oblique and lateral projections as needed [18]. The position of palpable nodules should be identified using a radioactive source marker. Computer-generated regions of interest can be drawn over the salivary glands to produce time-activity curves to demonstrate the pattern of accumulation and clearance over time. Quantitative analysis can be applied to the time-activity curves [16].

2. **Gastrointestinal Transit**
   
a. **Aspiration (Gastric or Pharyngeal Contents)**
   
   These examinations are usually limited to pediatric patients or as a preoperative pulmonary evaluation prior to lung transplantation. The patient should have nothing by mouth or by tube-feeding prior to the study. The length of time that the patient should refrain from intake depends upon the patient’s age and the clinical circumstances, but in most cases, 4 hours should be sufficient. The patient should be in the supine position, and images should include the mouth and stomach in the field of view (FOV). Radioactive source markers are placed for anatomic reference (eg, shoulder markers as reference of the relative location of the lungs). An alternative for pediatric patients is administration of a radiolabeled liquid meal at bedtime with imaging performed the following morning [19].

   i. **Aspiration of pharyngeal contents**
   
   A small volume of activity of Tc-99m SC is placed on the dorsal surface of the posterior portion of the tongue or in the buccal fossa. Images are obtained in the posterior projection over the course of 30 to 60 minutes. Delayed images can also be acquired up to 24 hours. Radioactivity detected in the bronchi or lungs confirms aspiration.

   ii. **Aspiration of gastric contents**
   
   An appropriate amount of Tc-99m SC is placed in a small amount of the patient’s feeding, administered orally or by tubing (nasogastric, gastrostomy) depending on the clinical
situation and in consultation with the referring provider. If the material is administered orally, once the feeding is completed, an additional nonradioactive liquid feeding is given to clear any remaining radioactivity from the esophagus. Images are obtained immediately after ingestion (baseline), and serially for 60 minutes thereafter. Additional planar imaging at 4 hours or 24 hours may be helpful. In infants and children, evaluation for aspiration of gastric contents is included as a routine component of nuclear gastric emptying and gastroesophageal reflux examinations. Radioactivity seen in the lungs confirms the diagnosis of aspiration. Imaging is terminated after the radioactivity has cleared from the stomach.

b. Esophageal Transit
Scintigraphy of esophageal transit may yield unique and useful physiologic information about esophageal motility in patients with conditions that cause impaired transit of esophageal contents from the pharynx to the stomach (eg, scleroderma, stricture, achalasia) or following therapy for these conditions [20]. This can be by qualitative or quantitative global or regional (dividing the esophagus into thirds) esophageal evaluation. The patient should have nothing by mouth or by tube-feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient's age and the clinical circumstances, but in most cases, 4 hours is sufficient. The patient typically is studied in the supine position, and data are collected in the anterior projection to include the entire esophagus and proximal stomach in the FOV. As with barium esophagography, use of multiple (up to 6) swallows can increase the sensitivity of the examination in detecting an abnormal swallow. The patient swallows the appropriate administered activity of Tc-99m SC in water or a semisolid as a bolus. The initial rapid bolus transit should be recorded in a dynamic mode of 0.25 to 0.5 seconds per frame up to 30 seconds [21] and reviewed using a cinematic (movie) display to evaluate the bolus transit. Additional data acquisition for up to 10 minutes is also helpful, during which time the patient is asked to perform serial dry swallows to measure clearance from the esophagus and to look for possible gastroesophageal reflux. Comparison of at least one upright and one supine swallow can be helpful to differentiate disorders such as achalasia from scleroderma. Time-activity curves may be generated regionally for the proximal, middle, and distal portions of the esophagus, but visual inspection of the entire cine bolus transit is more important for differentiating the various primary esophageal motor disorders. Esophageal transit time (ETT) is the time from initial bolus entry into the esophagus until clearance of 90% of peak activity [22]. The normal value for esophageal transit time is generally under 14 seconds [16], although each facility should validate its own normal range for its specific technique or closely follow a validated technique and normal range from literature. No significant activity should be in the esophagus after 10 minutes [21,22].

c. Gastroesophageal Reflux
Scintigraphy for gastroesophageal reflux may yield unique and useful physiologic information in patients whose history, signs, or symptoms suggest possible incompetence of the gastroesophageal sphincter associated with acute or chronic reflux of gastric contents into the esophagus [20]. Observation of gastroesophageal reflux, however, during an esophageal transit examination can be important as an etiology to reflux esophagitis and associated esophageal dysmotility. In infants and children, a gastroesophageal reflux examination (also called milk scan) is often combined with a liquid gastric emptying examination. The patient should have nothing by mouth or by tube-feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient's age and the clinical circumstances, but in most cases, 4 hours would be sufficient. A liquid consisting of formula, milk, or orange juice containing an appropriate amount of Tc-99m SC is administered orally or by tubing (nasogastric, gastrostomy). If feasible, when the liquid is introduced via an orogastric or nasogastric tube, the tube should be removed prior to image acquisition. The patient is then positioned supine in a left anterior oblique position beneath the gamma camera, and dynamic images (5-10-second frame images) of the
esophagus and stomach are obtained for 60 minutes [23]. Further delayed images can also be obtained for gastric emptying and possible aspiration evaluation. It is often appropriate to image small children in the supine position with the gamma camera under the imaging table. In adults, a Valsalva maneuver or an abdominal binder may be of benefit. Use of an abdominal binder is contraindicated in children. The number of recorded reflux events detected during the recording session should include the duration and the proximal extent of reflux. Gastroesophageal reflux greater than 4% is considered abnormal. This is determined by dividing the maximum counts in the esophagus by counts in the stomach at the beginning of the study [16]. The examination may be repeated to assess the effectiveness of medical therapy.

d. Gastric Emptying
Evaluation of gastric motility utilizing a radiolabeled meal provides functional information that is indispensable in the management of patients presenting with various upper gastrointestinal signs and symptoms [24]. The patient should have nothing by mouth or by tube-feeding prior to the examination. This is typically done by instructing the patient to have nothing by mouth overnight prior to the examination. The patient’s glucose level should be below 200 mg/dL. Prokinetics and medications that delay gastric emptying must be discontinued 2 days prior to the examination [25]. Three approaches are used: liquid phase, solid phase, and combined liquid-solid phase. In general, the liquid phase is preferred in infants and in neurologically impaired children, whereas the solid phase is used when the patient is capable of ingesting solid food. In both cases, the “meal” needs to be introduced into the stomach fairly quickly (ie, within 10 minutes). It is a good general practice to cover the camera detectors with protective wrap to prevent contamination. A large FOV camera should be used to include the distal esophagus, entire stomach, and proximal small bowel. A region of interest (ROI) is drawn around the stomach, and the counts are decay-corrected. The gastric emptying time-activity curves, half-time of emptying and/or percent of emptying are provided. Anterior posterior imaging to provide for geometric mean attenuation correction should be applied [26]. Posterior projection imaging only may be sufficient in children. Currently, there are no published standardized protocols or normal values for pediatric examinations, and there is a lack of age-related normal values [27].

i. Solid-phase meal gastric emptying in adults
The Consensus Recommendations for Gastric Emptying Scintigraphy: a Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine [28] details recommendations for normal values, patient preparation, image acquisition, and data processing. The ACR supports adoption of the recommendations of this consensus guideline and recommends adoption of its recommended normal values, patient preparation, image acquisition, and data processing. Various solid meals have been evaluated. However, the standardized solid radiolabeled meal per consensus guidelines published in 2008 consists of Tc-99m SC mixed and cooked in 120 g of scrambled liquid egg whites and then ingested along with 2 slices of white toast with 30 g of strawberry jelly and 120 mL of water [29]. Subsequently, 1-minute static imaging at 0, 1, 2, and 4 hours is performed with the patient upright. A dual-head gamma camera can be used in order to obtain simultaneous anterior and posterior projections [17,25]. Alternatively, the patient can rotate from an anterior image to a posterior image if a dual-head camera is not available. The geometric mean of the anterior and posterior counts is calculated from a ROI drawn over the stomach. The percentage remaining at each time point is compared with established normal ranges to determine the presence or absence of gastroparesis. Details can be found in the appendix to the consensus guideline, Consensus Recommendations for Gastric Emptying Scintigraphy: a Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine [28].
ii. **Liquid-phase gastric emptying in adults and children**

Liquids may detect abnormal gastric emptying in some patients when solid gastric emptying scintigraphy is normal. The liquid-phase study can be performed on a separate day, immediately before or concurrently with a solid-phase study. Tc-99m SC (alternatively, Tc-99m DTPA or In-111 DTPA) is mixed with an appropriate volume of a liquid carrier and introduced into the stomach by swallowing or tubing (nasogastric, orogastric, or gastric depending on the clinical situation) and in consultation with the referring clinician. In adults, the liquid meal typically consists of the radiopharmaceutical mixed in 300 mL of water. Imaging with a single-head gamma camera in the left anterior oblique projection is performed over the course of 30 to 60 minutes (1-minute frames continuously). A geometric mean should also be calculated for a liquid meal study [25]. In adult patients, the liquid meal exits from the stomach in a monoexponential fashion. In children, imaging is usually performed during the first hour, and the percent of emptying is obtained at 60 minutes or later, if indicated. For normal values, details can be found in a 2009 publication by Ziessman et al [26].

iii. **Liquid-phase gastric emptying in infants**

Liquid-phase gastric emptying may be combined with evaluation of esophageal motility, gastroesophageal reflux, and aspiration. The radiopharmaceutical esophagram may be performed initially or following the completion of the gastric emptying portion of the examination. For the esophagram, the patient is placed in the supine position with the gamma camera posteriorly positioned. Dynamic images of the esophagus at 5 seconds/frame for 2 to 3 minutes are obtained for evaluation of esophageal motility and possible aspiration. If the patient is normally fed by mouth, this may be accomplished as the initial part of the gastric emptying procedure that is then followed by continuous imaging of the chest and abdomen for 60 minutes for evaluation of the presence and severity of gastroesophageal reflux. Gastric emptying at 60 minutes and at 2 or 3 hours after completion of feeding is calculated. If the patient is not orally fed, the esophagram should be performed at the end of the gastric emptying examination using a small volume of radiolabeled sterile water or saline.

iv. **Combined liquid- and solid-phase gastric emptying**

For this purpose, In-111 DTPA should be utilized for the liquid meal portion of the study, and Tc-99m SC for the solid meal portion [19,30].

e. **Intestinal Transit (Small and/or Large Bowel)**

Although small- and/or large-bowel transit can be performed separately or in conjunction with gastric emptying scintigraphy, they are most commonly combined with a radiolabeled solid-liquid gastric emptying examination. Medications that may affect transit should be discontinued prior to the examination. No change in diet is necessary. These scans are not commonly performed in pediatric patients. The imaging FOV should include the entire area of interest if possible.

i. **Small-bowel transit**

This study is performed to evaluate for possible dysmotility of the small bowel. Tc-99m SC or Tc-DTPA in water can be utilized for a single-isotope study. Imaging occurs over 6 hours and is considered normal if > 40% of the radiolabeled liquid has progressed into the terminal ileum reservoir and/or progressed beyond the terminal ileum into the cecum and colon [31].

ii. **Large-bowel transit**

This study is most commonly utilized for evaluation of constipation or for the effectiveness of prokinetic medications. In-111 DTPA is the preferred radiopharmaceutical for this purpose.
3. Gastrointestinal Bleeding

a. Acute Gastrointestinal Bleeding

Diagnosis and localization of an active bleeding site requires that the patient be actively bleeding and imaged during the time the radiopharmaceutical is present in the blood pool. Although this procedure is generally used for gastrointestinal bleeding, it can be useful for other sites of active bleeding. The use of Tc-99m RBCs (autologous) is the recommended method because they remain intravascular and permit a longer imaging time. The clinical detection rate for a gastrointestinal bleed with Tc-99m RBCs can be as low as 0.04 mL/min [26]. Tc-99m SC is an alternative radiopharmaceutical but is less superior to Tc-99m RBCs for this purpose, and if utilized, imaging is usually performed for 20 to 30 minutes because of the rapid clearance of SC from the intravascular space. No patient preparation is required. The patient should void immediately before imaging. The radiolabeled cells are injected IV and dynamic imaging of the anterior abdomen is then performed to first include a blood flow/angiographic phase (rate of 1 frame per 1-3 seconds for 60 seconds) and then for another 60 to 120 minutes (preferably 1 frame per 10-20 seconds) [13]. Oblique, lateral, or delayed static abdominal images may be obtained to supplement the basic examination. If the examination is negative, continued imaging may be appropriate for up to 24 hours. SPECT/CT, although not routinely performed, can be of value to more definitively localize the site of bleeding. If gastric activity is noted, further static images of the head and neck can be acquired to assess for possible thyroid and salivary gland uptake to help differentiate between gastric bleeding versus the presence of free pertechnetate.

b. Ectopic Gastric Mucosa (Meckel's Scan)

Pharmacologic enhancement prior to radiopharmaceutical administration with H2 blockers (cimetidine, famotidine, or ranitidine) or proton pump inhibitors (omeprazole) to enhance free pertechnetate retention and/or glucagon to decrease gastrointestinal peristalsis can be used. Although not required, the patient should fast for 3 to 4 hours prior to imaging to increase sensitivity for detection of ectopic gastric mucosa. The radiopharmaceutical Tc-99m pertechnetate is given IV, and then dynamic imaging of the abdomen is performed. A rapid sequence of images (blood flow/angiographic phase) taken at 1 to 3 seconds per frame over 60 seconds is obtained in the anterior projection to evaluate the presence of hypervascular abdominal lesions that could be mistaken for ectopic gastric mucosa. Subsequent imaging for 30 to 60 minutes is then acquired as serial static views or continuous dynamic imaging (30-60 seconds per image). Continuous dynamic imaging is preferred to better visually discriminate normal...
physiologic activity (such as renal activity) from ectopic gastric mucosa. A lateral view can be
useful to distinguish renal activity and identify retrovesical ectopic gastric mucosa. Additional
SPECT/CT imaging may help localization. Prone or right anterior oblique positioning can be
used to delay gastric emptying into the small bowel if the patient has not been pretreated with H2
blockers. A urinary catheter or administration of 1 mg/kg of IV furosemide may be needed to
help clear activity from the ureters and bladder [14].

4. Peritoneal Imaging

No specific preprocedure patient preparation is required. A local anesthetic may be administered
prior to injection of the radiopharmaceutical.

a. Evaluation of patency of peritoneovenous shunt
Tc-99m SC or Tc-99m MAA is directly administered into the peritoneal cavity using aseptic
technique. An immediate image of the abdomen may be helpful to determine whether the
radiopharmaceutical is free in the peritoneum and not loculated. The patient may need to roll
from side to side to mix the radioactivity within the ascites. Also, normal saline (50-200 mL) can
be infused intraperitoneally to facilitate distribution. Static anterior images are typically
acquired at 10, 30, 60, and 120 minutes. If the shunt is functioning correctly, activity will
eventually appear in the liver and spleen (with Tc-99m SC) or lungs (with Tc-99m MAA) over 1
to 2 hours. Activity in the shunt tubing may or may not be visualized [12,33].

b. Detection of congenital fenestrations or traumatic perforations of the diaphragm
Tc-99m SC or Tc-99m MAA is administered intraperitoneally. The radiopharmaceutical can also
be instilled with up to 500 mL of sterile normal saline in order to facilitate movement of the
radiopharmaceutical into the pleural cavity. If activity appears in the pleural space, the diagnosis
of fenestrated or perforated diaphragm is confirmed [34-36].

c. Demonstration of peritoneal loculation of fluid
Tc-99m SC or Tc-99m MAA is administered intraperitoneally. Immediate and delayed static
images over the abdomen will reveal the pattern of distribution of the radiopharmaceutical in the
peritoneal cavity.

C. Liver and Spleen Imaging

1. Assess size, shape, and/or position of the liver and/or spleen
Tc-99m SC can be used to identify the size and location of functional hepatic and splenic tissue.
Approximately 10 to 20 minutes after IV administration of Tc-99m SC, static planar images of the
liver and spleen are obtained. Anterior, posterior, right anterior oblique (RAO), left anterior oblique
(LAO), right posterior oblique (RPO), and right lateral images should be acquired. Additional views
(left posterior oblique [LPO] and left lateral) may be indicated for more comprehensive evaluation
of the spleen. Another anterior image may also be acquired with a lead marker of known length to
help determine organ sizes. Additional SPECT or SPECT/CT localizes any focal abnormality seen
on planar imaging. The normal distribution of Tc-99m SC in the RES is approximately 85% to the
liver, 10% to the spleen, and 5% to the bone marrow. A shift away from the normal biodistribution
can be seen in severe liver dysfunction and is termed “colloid shift” in which there is greater splenic
and marrow uptake [37].

2. Differentiation of hepatic or splenic hemangiomas and other mass lesions
Hepatic or splenic hemangiomas are conspicuous with Tc-99m RBCs imaging because of their relatively greater blood volume than that of the surrounding parenchyma. They are typically identified when the radiolabeled RBCs reach equilibrium within the intravascular space of the hemangioma, which may take between 30 and 120 minutes postinjection or longer (may require up to 24 hours or more for larger hemangiomas [12]). Following IV administration of Tc-99m RBCs (autologous), immediate angiographic images (1-second intervals for 60 seconds) may yield useful information on the vascularity of particular lesions. Hemangiomas show typical low flow in the arterial phase with late “filling in” on delayed images. This is followed by blood pool imaging (eg, delayed imaging). SPECT or SPECT/CT imaging is particularly helpful in identifying lesions smaller than 3 cm.

Depending upon whether there are functioning or nonfunctioning Kupffer cells, the uptake pattern with Tc-99m SC can help differentiate between different types of mass lesions in the spleen and liver. Types of photopenic lesions include infarcts, cysts, hepatic adenoma, etc. FNH typically has increased uptake in the liver [16]. Up to 30% FNH will be photopenic on a liver scan.

3. Evaluating for residual or ectopic functioning splenic tissue and suspected functional asplenia

The radiopharmaceutical Tc-99m RBCs (autologous and heat damaged) is administered IV (preparation technique in Welch et al [38]). Imaging of the abdomen may commence 30 to 120 minutes later. Planar and SPECT or SPECT/CT imaging parameters are similar to those for liver and spleen imaging. If the test is being performed to identify residual or ectopic splenic tissue, the abdomen and pelvis should be imaged. If the patient has had prior trauma that might have ruptured the diaphragm, the chest should be imaged as well. Alternatively, Tc-99m SC can be utilized instead, but it is less sensitive and specific as compared with Tc-99m heat-damaged RBCs [12].

A. Technetium 99m Sodium Pertechnetate

During the first 1 or 2 minutes after intravenous administration, technetium-99m pertechnetate may be used as a blood flow and “blood pool” marker. Within minutes after injection, this radiopharmaceutical begins to concentrate in the salivary glands and gastric mucosa, making it a suitable radiopharmaceutical for evaluation of the salivary glands and for detection of ectopic gastric mucosa. The usual adult administered activity is 296 to 444 MBq (8 to 12 mCi) intravenously. Lower administered activity (111 to 185 MBq [3 to 5 mCi]) may be used if flow imaging is not performed. For pediatric patients, 1.85 MBq/kg (0.05 mCi/kg) is recommended. Physiologic renal excretion results in visualization of the kidneys and bladder. Rapid absorption by the stomach and peritoneum makes technetium-99m pertechnetate unsuitable for oral or intraperitoneal administration.

B. Technetium 99m Sulfur Colloid

Technetium-99m sulfur colloid, when administered orally, is not absorbed and is an excellent radiopharmaceutical for imaging and quantification of numerous parameters of swallowing and gastrointestinal motility and transit. A small volume (up to 1 mL) of technetium-99m sulfur colloid containing no more than 18.5 MBq (0.5 mCi) can be used for pharyngeal aspiration imaging. Administered activity of 18.5 to 74 MBq (0.5 to 2 mCi) is generally used as a radiolabel for liquid and solid meals in adults. There is no weight-based dosage for children, but 9.25 to 37 MBq (0.25 to 1.0 mCi) of administered activity can be used to label a liquid meal, and 9.25 to 18.5 MBq (0.25 to 0.5 mCi) can be used to label a solid meal. The affinity of this radiopharmaceutical for the protein matrix of egg whites makes it easy to use to label egg as a solid-phase radiopharmaceutical [17]. The administered activity of the radiopharmaceutical and the volume to be fed to the patient should be based on patient factors such as age, body weight, and the usual feeding volume.

Administered intraperitoneally, it is not absorbed and becomes a qualitative marker of movement of ascitic fluid through congenital or traumatic diaphragmatic fenestrations and peritoneovenous shunts. For this purpose, the administered activity of 18.5 to 185 MBq (0.5 to 5.0 mCi) technetium-99m sulfur colloid is used.

C. Technetium 99m (Stannous – Sn) Diethylenetriamine Pentaacetic Acid (DTPA)
Given orally, technetium-99m (Sn) DTPA may be used as a liquid-phase marker of gastric emptying or of small-bowel transit when only a single liquid meal transit examination is performed. It cannot be used simultaneously for a combined liquid-phase and solid-phase gastric emptying examination when a technetium-99m solid-phase radiopharmaceutical is also used. When dual-phase (solid and liquid) gastrointestinal examinations are performed, indium-111 DTPA or gallium-67 citrate is used to measure the liquid-phase, and technetium-99m sulfur colloid is used for the solid-phase.

The administered activity for technetium-99m DTPA is 18.5 to 37 MBq (0.5 to 1.0 mCi) for adults. The administered activity of the radiopharmaceutical and the volume to be fed to the patient should be based on patient factors such as age, body weight, and the usual feeding volume.

D. Indium-111 DTPA

Given orally, with an administered activity of 5.55 to 18.5 MBq (0.15 to 0.50 mCi), indium-111 DTPA may be used as a liquid-phase marker of gastric emptying when a concomitant solid meal labeled with a technetium-99m radiopharmaceutical is used. Due to the longer half-life of indium-111, additional imaging of the abdomen is possible up to 72 hours and allows measurement of small bowel or colon transit [10, 25]. Administered activity of indium-111 DTPA for colonic transit is 3.7 to 37 MBq (0.1 to 1.0 mCi). For a liquid-only gastric examination, technetium-99m sulfur colloid should be used instead of indium-111 DTPA to reduce radiation exposure.

E. Gallium-67 Citrate

Given orally, gallium-67 is not absorbed from the gastrointestinal tract and may be used as a liquid-phase marker of gastric emptying. Like indium-111 DTPA, this radiopharmaceutical can be used with concomitant solid meal labeled with technetium-99m for imaging and measurement of small bowel or colon transit. Its long-half-life allows extended imaging of the abdomen up to 96 hours or longer. Administered activity is typically 0.056 kBq/kg body weight (0.0015 mCi/kg) for dual-phase gastric emptying examinations in pediatric patients. For adults needing evaluation of colonic transit, a dosage of 3 to 7 MBq (0.08 to 0.2 mCi) can be used [7, 8].

For a liquid-only gastric emptying examination, technetium-99m sulfur colloid should be used instead of gallium-67 to reduce radiation exposure.

F. Technetium-99m Autologous Red Blood Cells (RBCs)

Technetium-99m RBCs remain intravascular and are commonly used for detecting and localizing active gastrointestinal bleeding. The usual adult intravenous administered activity for gastrointestinal blood loss detection is 740 to 1,010 MBq (20 to 30 mCi). The highest RBC labeling efficiency is achieved with the in vitro method, which is recommended and widely used.

G. Technetium-99m Macroaggregated Albumin (MAA)

Given intraperitoneally, technetium-99m MAA is not absorbed and is used as a qualitative marker of the movement of ascitic fluid through peritoneovenous shunt devices or congenital/traumatic diaphragmatic fenestrations. The usual adult administered activity is 0.5 to 5.0 mCi (18.5 to 185 MBq).

A. Salivary Gland Imaging

The collimator surface should be protected from contamination by using a plastic-backed pad or other similar material. The patient’s face is positioned in front of a gamma camera in the Water’s (nose-chin) position. Technetium-99m pertechnetate is given intravenously. Serial anterior images of the face are obtained over a period of 30 minutes. If needed, these views may be supplemented by oblique or lateral static images of the head and neck.

A sialogogue, such as lemon juice, may be given to stimulate salivary gland emptying in cases of salivary duct obstruction or ligation, sialadenitis, or suspected Warthin’s tumor. The position of palpable nodules should be identified using a radioactive source marker.

B. Aspiration of Gastric or Pharyngeal Contents

These examinations are usually limited to pediatric patients or as a preoperative pulmonary evaluation prior to lung transplantation. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours should be sufficient.

1. Aspiration of pharyngeal contents

A small volume of appropriate administered activity of technetium-99m sulfur colloid is placed on the dorsal surface of the posterior portion of the tongue or in the buccal fossa. Images of the chest are obtained.
in the posterior projection over the course of 30 to 60 minutes. Radioactivity detected in the bronchi or lungs confirms aspiration.

2. Aspiration of gastric contents

Radioactive source markers are placed for anatomic reference (eg, shoulder markers as reference of the relative location of the lungs). Appropriate administered activity of technetium-99m sulfur colloid is placed in a small amount of the patient’s feeding, administered orally, by nasogastric tube, or by gastrostomy tube depending on the clinical situation and in consultation with the referring provider. If the material is administered orally, once the feeding is completed, an additional nonradioactive liquid feeding is given to clear any remaining radioactivity from the esophagus. Images of the thorax are obtained immediately after ingestion (as a baseline) and serially for 60 minutes thereafter. Additional planar imaging at 4 hours or 24 hours may be helpful. In infants and children, evaluation for aspiration of gastric contents is included as a routine component of the radiopharmaceutical gastric emptying and gastroesophageal reflux examinations (see VII.D and VII.E). Radioactivity seen in the lungs confirms the diagnosis of aspiration. Imaging is terminated after the radioactivity has cleared from the stomach.

C. Esophageal Transit

Scintigraphy of esophageal transit may yield unique and useful physiologic information about esophageal motility in patients with conditions (eg, scleroderma, stricture, achalasia) that cause impaired transit of esophageal contents from the pharynx to the stomach or following therapy for these conditions [20]. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours would be sufficient.

Data are collected in the posterior projection. As with barium esophagography, use of multiple (up to 5) dry swallows can increase the sensitivity of the examination in detecting an abnormal swallow. Comparison of at least one upright and one supine swallow can be helpful to differentiate disorders such as achalasia from scleroderma.

The examination involves the patient swallowing the appropriate administered activity of technetium-99m sulfur colloid in 10 to 15 mL of water or a semisolid as a bolus. The initial rapid bolus transit should be recorded in a dynamic mode of 0.25 to 1 second per frame and reviewed using a cinematic (movie) display to evaluate the bolus transit. Additional data acquisition for up to 10 minutes is also helpful, during which time the patient may be asked to dry swallow to measure clearance from the esophagus and to look for possible gastroesophageal reflux.

The normal value for esophageal bolus transit time is generally under 5 seconds, although each facility should validate its own normal range for its specific technique, or it should closely follow a validated technique and normal range from the literature.

Time activity curves may be generated for the proximal, middle, and distal portions of the esophagus, but visual inspection of the cine bolus transit is more important for differentiating the various primary esophageal motor disorders.

D. Gastroesophageal Reflux

Scintigraphy for gastroesophageal reflux may yield unique and useful physiologic information in patients whose history, signs, or symptoms suggest possible incompetence of the gastroesophageal sphincter associated with acute or chronic reflux of gastric contents into the esophagus [20]. Observation of gastroesophageal reflux, however, during an esophageal transit examination can be important as an etiology to reflux esophagitis and associated esophageal dysmotility.

In infants and children, a gastroesophageal reflux examination is often combined with a liquid gastric-emptying examination. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours would be sufficient. A liquid meal consisting of formula, milk, or orange juice containing an appropriate concentration of technetium-99m sulfur colloid is administered orally, by nasogastric tube, or by gastrostomy tube. If feasible, when the meal is introduced via an oro gastric or nasogastric tube, the tube should be removed prior to image acquisition. The patient is then positioned supine beneath the gamma camera detector, and serial 10-second to 30-second images of the esophagus and stomach are obtained. It is often appropriate to image small children in the supine position with the gamma camera detector under the imaging table. In adults, a Valsalva maneuver or an abdominal binder may be of benefit. Use of an abdominal binder is contraindicated in children.
The number of reflux events detected during the recording session, the duration, and the proximal extent of reflux are reported. The examination may be repeated to assess the effectiveness of medical therapy.

E. Gastric Emptying

Evaluation of gastric motility through a radiolabeled meal provides functional information that is indispensable in the management of patients presenting with various upper gastrointestinal signs and symptoms [24,37]. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours should be sufficient. Three approaches are used: liquid phase, solid phase, and combined liquid-solid phase.

In general, the liquid phase is preferred in infants and in neurologically impaired children, whereas the solid phase is used when the patient is capable of ingesting solid food. In both cases, the “meal” needs to be introduced into the stomach fairly quickly (ie, within 10 minutes). It is a good general practice to cover the camera detectors with protective wrap to prevent contamination. Digital acquisition is required to determine the half-time of emptying and/or percent of emptying and to generate gastric emptying time activity curves. Given the oblique lie of the stomach in the abdomen, images should be acquired in both the anterior and posterior projection with gastric emptying determined based on the geometric mean. Posterior-projection imaging only may be sufficient in children.

Currently there are no published standardized protocols or normal values for pediatric examinations [27].

1. Solid-phase gastric emptying in adults

ACR supports the published consensus guideline on the scintigraphic measurement of gastric emptying in adults by the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the American Neurogastroenterology and Motility Society (ANMS) [28]. The ACR supports adoption of the recommendations of this consensus guideline and recommends adoption of its recommended normal values, patient preparation, image acquisition, and data processing. Following ingestion of a radiolabeled low-fat, egg-white meal, 1 minute static imaging at 0, 1, 2, and 4 hours is performed with the patient upright, if possible [17]. The percentage remaining at each time point is compared with established normal ranges to determine the presence or absence of gastroparesis. Details can be found in the appendix to the consensus guideline [28].

2. Liquid-phase gastric emptying in adults and children

For some time liquid-phase gastric emptying examinations have not been used since it was believed that abnormal liquid gastric emptying was a late phenomenon and that a solid meal would detect abnormal gastric emptying better than a liquid meal. Recent studies suggest that liquids may detect some patients with abnormal gastric emptying when solid gastric-emptying scintigraphy is normal [26]. There are, however, no consensus recommendations at present on the best liquid-phase gastric-emptying meal or protocol.

Technetium-99m sulfur colloid or technetium-99m (Sn) DTPA is mixed with an appropriate volume (30 to 240 mL) of liquid carrier (eg, orange juice, formula, milk) and is introduced into the stomach by swallowing, nasogastric tube, orogastric tube, or gastric tube depending on the clinical situation, in consultation with the referring clinician. Sequential imaging and computer data acquisition are performed over the course of 30 to 60 minutes. A region of interest (ROI) is drawn over the stomach, and a decay-corrected time-activity curve is generated. In adult patients, the radiopharmaceutical exits from the stomach in an approximately monoexponential fashion for liquid meals. In children, imaging is usually performed during the first hour, and the percent of emptying is obtained at 60 minutes and later, if indicated. Unfortunately, there are currently no well-defined normal values for the various liquid meals used. Each facility must validate its own normal range for its specific meal and technique.

3. Liquid-phase gastric emptying (“milk scan”) in infants

Liquid-phase gastric emptying may be combined with evaluation of esophageal motility, gastroesophageal reflux, and aspiration. The radiopharmaceutical esophagram may be performed initially or following the completion of the gastric emptying portion of the examination. For the esophagram, the patient is placed in the supine position with the gamma camera posteriorly positioned. Dynamic images of the esophagus at 5 seconds/frame for 2 to 3 minutes are obtained for evaluating esophageal motility and possible aspiration. If the patient is normally fed by mouth, this may be accomplished as the initial part of the gastric emptying procedure, which is then followed by continuous imaging of the chest and abdomen for 60 minutes for...
evaluation of the presence and severity of gastroesophageal reflux. Gastric emptying at 60 minutes and at
2 or 3 hours after completion of feeding is calculated. If the patient is not orally fed, the esophagram should
be performed at the end of the gastric emptying examination using a small volume of radiolabeled sterile
water or saline.

4. Combined liquid-phase and solid-phase gastric emptying and small bowel and colon transit studies
A solid-phase examination (see section VII.E.1 above) may be combined with the liquid-phase examination
(see section VII.E.2 above), using technetium 99m sulfur colloid for the solid phase and indium 111 DTPA
or gallium 67 for the liquid phase. With the use of proper administered activity of dual
radiopharmaceuticals and availability of simultaneous dual-isotope-image acquisition and processing
capability, it is possible to acquire data simultaneously using photopeaks of both radiopharmaceuticals. An
added advantage provided by this combined solid-phase and liquid-phase technique includes the ability to
follow the liquid phase to measure small bowel and colon transit resulting in evaluation of the whole gut
[10]. There are increasing reports on the utility of whole-gut scintigraphy using simultaneous dual
radiopharmaceutical solid-liquid meal in patients with various abdominal symptoms but no consensus
recommendations on its use exist to date [37,38].

F. Ectopic Gastric Mucosa (Meckel’s scan)
The radiopharmaceutical technetium 99m pertechnetate is given intravenously. A rapid sequence of images (blood
flow/angiographic phase) taken at 1 to 2 seconds per frame, over 1 minute, may be obtained in the anterior projection
to evaluate the presence of hypervascular abdominal lesions that could be mistaken for ectopic gastric mucosa.
Immediate serial imaging for 30 to 45 minutes can then be acquired as serial static views (300,000 to 500,000 counts
per image) or continuous dynamic imaging (30 to 60 seconds per image). Continuous dynamic imaging is preferred
better visually discriminate normal physiologic activity (such as renal activity) from ectopic gastric mucosa. A
lateral view can be useful to distinguish renal activity and identify retrovesical ectopic gastric mucosa. The
examination may be supplemented with oblique, postvoid single photon emission computed tomography (SPECT)
imaging or delayed views of the abdomen, as indicated. Pharmacologic enhancement prior to administration of the
radiopharmaceutical with H2 blockers (cimetidine, famotidine, or ranitidine) to enhance free pertechnetate retention
and/or glucagon to decrease gastrointestinal peristalsis can be used. Prone or right anterior oblique positioning can
be used to delay gastric emptying into the small bowel if the patient has not been pretreated with H2 blockers.

G. Gastrointestinal Blood Loss
All methods for diagnosing and localizing an active bleeding site require that the patient be actively bleeding and
imaged during the time the radiopharmaceutical is present in the blood pool. Although this procedure is generally
used for gastrointestinal bleeding, it can be useful for other sites of active bleeding.
The use of technetium-99m labeled autologous RBCs is the recommended method because they remain
intravascular and permit a longer imaging time. The radiolabeled cells are injected intravenously. Blood
flow/angiographic phase and continuous cine or images of the abdomen are obtained for 60 to 120 minutes. Cine
images (maximum of 15 seconds per image) and display are preferred as these improve the initial detection and
more accurate localization of subtle gastrointestinal bleeding sites. Oblique, lateral, or delayed static abdominal
images may be obtained to supplement the basic examination. If the examination is negative, continued imaging
may be appropriate. SPECT/CT, although not routinely performed, can be of value to more definitively localize
sites and identify the cause of gastrointestinal hemorrhage.

H. Peritoneal Imaging
1. Evaluation of patency of peritoneovenous shunts
Technetium-99m sulfur colloid or technetium-99m MAA is directly administered into the peritoneal cavity,
using aseptic technique. An immediate image of the abdomen may be helpful to determine that the
radiopharmaceutical is free in the peritoneum and not loculated. On occasion, normal saline (50 to 200 mL)
can be infused intraperitoneally to facilitate distribution. If the shunt is functioning correctly, serial images
obtained over 1 or 2 hours will reveal radiopharmaceutical in the shunt tube, and radioactivity will
eventually appear in the liver and spleen (with technetium-99m sulfur colloid) or lungs (with technetium-
99m MAA).

2. Detection of congenital fenestrations or traumatic perforations of the diaphragm
Technetium-99m sulfur colloid or technetium-99m MAA is administered intraperitoneally as described in section VII.H.1. Occasionally, the radiopharmaceutical can be instilled with up to 500 mL of sterile normal saline in order to facilitate movement of the radiopharmaceutical into the pleural cavity. If activity appears in the pleural space, the diagnosis of perforated diaphragm is confirmed.

3. Demonstration of peritoneal loculation of fluid

Technetium-99m sulfur colloid or technetium-99m MAA is administered intraperitoneally as described in section VII.H.1. Immediate and delayed static images over the abdomen will reveal the pattern of distribution of the radiopharmaceutical in the peritoneal cavity.

V. DOCUMENTATION

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

The report should include the radiopharmaceutical used, the administered activity, and the route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [40].

A gamma camera with a low-energy all purpose (LEAP) or high-resolution collimator is used for Tc-99m–labeled radiopharmaceuticals. A medium-energy collimator is needed for In-111 and Ga-67. SPECT or SPECT/CT may also be useful in select cases.

VII. RADIATION SAFETY

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).

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 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).

II. DEFINITION

Gastrointestinal scintigraphy involves the intravenous, oral, transcatheter (to include enteric tubes), or intraperitoneal administration of a radiopharmaceutical that localizes in or transits the salivary glands, gastrointestinal tract, or peritoneal cavity, followed by gamma camera imaging with digital acquisition [5]. (For scintigraphy of the hepatobiliary tract or liver and spleen, see the ACR–SPR Practice Parameter for the Performance of Hepatobiliary Scintigraphy [2] and the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy [6].)

III. GOAL

The goal of gastrointestinal scintigraphy is to enable the interpreting physician to identify and/or quantify anatomic or physiologic disturbances of the salivary glands, gastrointestinal tract, or peritoneum.

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 and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the SNMMI, and the SPR.

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Collaborative Committee – members represent their societies in the initial and final revision of this practice parameter

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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.

Development Chronology for this Practice Parameter

1996 (Resolution 16)
Revised 2000 (Resolution 22)
Revised 2005 (Resolution 20)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 29)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 45)
RESOLUTION NO. 17

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–ASTRO–SNMMI Practice Parameter for Lutetium-177 (Lu-177) DOTATATE Therapy

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.

NEW

ACR–ACNM–ASTRO–SNMMI PRACTICE PARAMETER FOR LUTETIUM-177 (Lu-177) DOTATATE THERAPY

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.

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 developed collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

This practice parameter is intended to guide appropriately trained and licensed physicians performing therapy with lutetium-177 (Lu-177) DOTATATE. Such therapy requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient, those who administer radiopharmaceutical therapy and those who manage the attendant side effects. Adherence to this parameter should help to maximize the efficacious use of these procedures, maintain safe conditions, and ensure compliance with applicable regulations.

Application of this parameter should be in accordance with the ACR–AAPM–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals [1], in so far as that standard relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public. There must also be compliance with applicable laws and regulations.

The goal of therapy with Lu-177 DOTATATE is to provide either cure, extended time to disease progression, or effective palliation of disease while minimizing untoward side effects and complications.

Neuroendocrine tumors (NETs) are relatively rare and typically slow-growing neoplasms that originate in neuroendocrine tissue distributed throughout the body. They secrete bioactive amines and hormones, giving rise to variable clinical presentations [2]. Surgical resection of the tumor is the preferred initial therapy; however, because of the indolent course and nonspecific presentation of the disease, many patients are diagnosed with locally advanced or metastatic disease, making curative resection difficult or impossible. Alternative conventional treatments include use of nonradioactive somatostatin analogues that take advantage of the overexpression of somatostatin receptors (SSRs) by these NETs. Use of other agents, including cytotoxic chemotherapy, can be limited because of the unwanted side effects and minimal effectiveness in certain grades of tumor. Despite use of these currently available conventional treatments, many patients continue to progress with life-altering signs and symptoms, such as unrelenting diarrhea, flushing, or right-sided heart disease [3,4].

Lu-177 DOTATATE is an effective therapy for patients with inoperable, locally advanced, or metastatic NETs that progress on conventional treatments [3-6]. Improvement in disease control rates, progression-free survival, overall survival, and quality of life have advanced this radiopharmaceutical agent to a place of primary consideration in advanced disease management [7]. Lu-177 DOTATATE specifically binds to the SSRs that are overexpressed on the cell surfaces of most NETs, with highest affinity for subtype 2. The complex formed is chemically stable and is internalized into the cell resulting in a favorable position to irradiate the nucleus to induce DNA damage–related inhibition of growth and death [8]. This treatment process is called peptide receptor radionuclide therapy (PRRT). Beta (β-) emission from Lu-177 has a maximum energy (Q-value) of 0.5 MeV, range in soft tissues of 2 mm, and half-life of 6.7 days. Lu-177 also emits low-energy gamma rays at 208 keV (11% abundance) and 113 keV (6.4% abundance) that can be used for gamma camera imaging and dosimetry if desired [9]. Although PRRT with Lu-177
DOTATATE has been proven to be effective in NET, there are adverse side effects and safety issues that must be understood and taken into consideration by the treating physicians so that appropriate plan and required interventions can be instituted [5].

Side effects associated with PRRT with Lu-177 DOTATATE can be categorized as acute, subacute, or delayed [5]. It is highly advisable that a multidisciplinary team coordinate the care of a patient being considered for treatment with Lu-177 DOTATATE [6].

General: Abdominal pain, nausea, and vomiting can occur typically within 24 hours of treatment. In addition, patients can also experience fatigue and diarrhea. In most cases, these symptoms are self-limiting and rarely require more than supportive therapy.

Nephrotoxicity: Lu-177 DOTATATE is excreted by the kidneys through glomerular filtration and is reabsorbed by the proximal tubules where radiation damage can occur [9]. Reduction of proximal tubular reabsorption has been effectively achieved with use of other ligands that can competitively bind to the receptors in the proximal tubular cells without affecting the SSR targets of Lu-177 DOTATATE in the circulation [10]. The most efficacious solution to date to reduce renal uptake of somatostatin analogues consists of a combination of basic amino acids lysine (25 g) and arginine (25 g) [9,11]. Renal toxicity is generally mild and well-tolerated with amino acid co-infusions. However, grade 1 nephrotoxicity in 20% and grade 2 nephrotoxicity in 4% of patients has been reported [5,7]. Higher-grade toxicities are rare (0% to 0.4%) [4,5]. Many studies have shown improvement of renal function over time, but long-term renal impairment remains a clinical concern, with some studies reporting an annual decrease in creatinine clearance of 3.4% to 3.8% [12,13]. Details on administration are provided in the “Specific Procedures” section of this document (IV.B).

Hematologic: The bone marrow is a rapidly dividing organ and is thus radiosensitive. Mild subacute myelosuppression can be seen in the first days to weeks after treatment and typically reverses within weeks after cessation of treatment [5]. The most frequently seen effects include anemia, thrombocytopenia, and leukopenia. Grade 3 and 4 bone marrow toxicity are seen less frequently and are generally reversible without intervention within 2 to 3 months but may take up to 12 months [4,14,15]. Bone metastases can increase the likelihood of myelotoxicity [15,16]. Rarely, 1% to 2% of patients can develop leukemias and myelodysplastic syndrome (MDS), which can lead to a fatal outcome in patients heavily pretreated with myelosuppressive therapies prior to receiving Lu-177 DOTATATE [4,5,13,14].

Hepatic: Liver dysfunction has been noted with increase in bilirubin and transaminases. A few patients have developed grade 3 toxicity that progressed to liver failure and death within one year after PRRT [5].

Hormonal Crisis: This is a rare complication that presents as flushing and significant diarrhea and, less frequently, heart failure, emesis, and bronchoconstriction. It typically occurs within 48 hours of infusion, with greater likelihood in patients with large tumor burden [17,18]. This is a serious adverse side effect requiring prompt in-hospital care for continuous somatostatin analogue infusion and supportive care.

Risk of Infertility: The recommended cumulative activity of 800 mCi (29.6 GBq) Lu-177 DOTATATE results in radiation absorbed dose to the testis and ovaries within the range where temporary or permanent infertility may ensue, such as seen following pelvic external-beam radiotherapy [4,6,7,19].

Facilities and their responsible staff should consult with their radiation safety officer (RSO) to ensure that there are policies and procedures specific to Lu-177 DOTATATE that address 1) required instrumentation, calibration, and calibration frequency and 2) ordering and receiving, recordkeeping, safe use, and waste disposal in compliance with the applicable laws and regulations as described in ACR–AAPM Radiation Safety Officer Resources [19].
II. INDICATIONS

Lu-177 DOTATATE is indicated for the treatment of SSR-bearing gastroenteropancreatic NETs (GEP-NETs), including foregut, midgut, and hindgut NETs in adults [6].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The qualifications and responsibilities of physicians and other personnel performing these therapeutic procedures should be in accordance with the ACR–AAPM–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [1,20].

In addition, training and experience must be in compliance with the applicable laws and regulations.

IV. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

The written or electronic request for a Lu-177 DOTATATE procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance.

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

The request for the procedure 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. Clinical Evaluation:

The clinical evaluation should be in concordance with the ACR–ASTRO Practice Parameter for Radiation Oncology and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [20,21]. The treating physician’s initial evaluation of the patient must include review of the patient’s history, physical examination, pertinent diagnostic studies, laboratory reports, and complete history of all previous pertinent therapies, including, but not limited to, myelosuppressive systemic therapy and/or radiotherapy.

1. Verification of Pathology and Indication for Therapy: A pathology report confirming diagnosis of GEP-NET should be reviewed and included in the patient’s record. Efficacy of Lu-177 DOTATATE is well documented, particularly in well-differentiated NET often with Ki-67 index of <20% [22]. Because Lu-177 DOTATATE localizes to NET expressing SSR, it is of paramount importance to confirm that the NET being treated expresses the required SSR through positive indium-111 octreotide scan or gallium-68 DOTATATE PET/CT (see ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Neuroendocrine Tumor Scintigraphy and ACR Practice Parameter for the Performance of Gallium-68 DOTATATE PET/CT for Neuroendocrine Tumors) [23,24].

2. Discontinuation of Somatostatin Analogue Therapy with Baseline Laboratory Evaluation: If the patient is being treated with long-acting somatostatin analogue, this should be stopped for 4 weeks prior to Lu-177 DOTATATE infusion. Short-acting analogues can be stopped 24 hours prior to PRRT. In anticipation of possible side effects, each patient should have a complete blood count with differentials and metabolic panel including renal and hepatic function tests. Such monitoring should be performed before each infusion and as needed for hematologic monitoring in between treatments. Dose reduction based upon laboratories is discussed in Section IV.B.2. Although institution and patient-specific considerations take precedence,
creatinine clearance >50 mL/min and grade 1 to 2 or less hepatic enzyme elevation or myelosuppression is sufficient to allow therapy. Women of childbearing age should undergo pregnancy testing [6].

3. **Special Populations:** Lu-177 DOTATATE has not been tested in lactating patients, and these patients should be advised to stop breastfeeding while receiving treatment and for 2.5 months after the last treatment fraction, as effects on infants have not been determined. For patients of reproductive potential, discussion should be carried out to use effective contraceptive measures during and after PRRT. For female patients, because of the possibility of fetal harm, effective contraception should be continued for 7 months following the last treatment fraction of PRRT. For male patients with female partners, contraception should be continued until 4 months following the last treatment fraction [6]. Sexual activity should be avoided following therapy for 7 days. The radiopharmaceutical has not been tested in pediatric (<18 years old) and pregnant patients. Caution should be exercised in these patient populations, with extensive discussion regarding risk of radiation.

4. **Quality Management:** In order to use radiopharmaceuticals as unsealed sources for therapy, including Lu-177 DOTATATE, a “quality management” program must be in place as required by applicable state and federal regulations. (An Agreement State is any state with which the Nuclear Regulatory Commission (NRC) or the US Atomic Energy Commission has entered into an effective agreement under subsection 274.b of the Atomic Energy Act of 1954 as amended, 73 Stat, 689). Key elements of such a program include written directives, duplicative procedures for identifying patients, careful record keeping to ensure prescribed administered activity, minimization of the possibility of infiltration for radiopharmaceuticals that are administered intravenously (IV), procedures for minimizing radiation exposure or radiopharmaceutical contamination of personnel, family members of patients, and the public (eg, alerts regarding possible current or future pregnancy), procedures for containment of radioactivity; and an audit mechanism to ensure compliance with the program.

5. **Informed Consent:** Informed consent must be obtained and documented. See the ACR Practice Parameter on Informed Consent – Radiation Oncology [25].

6. **Treatment:** The procedure and follow-up should be performed according to an established system of procedural steps unique for Lu-177 DOTATATE [26].

7. **Radiation Precautions:** Radiation precautions and patient release criteria may be regulated federally by the NRC in many states or by the state (with regulations that are closely patterned on the federal regulations and may be more restrictive). The radiation safety officer, medical physicist, or health physicist for the local facility can provide information on the applicable regulations. Details on the federal regulations can be obtained at the NRC website (www.nrc.gov).

Under the guidelines of federal code 10 of the Code of Federal Regulations (CFR) 35.75 [27] and key sections of NUREG-1556 [28], a patient may be released to the public if the total effective dose equivalent to any other individual (including any caregiver or family member) who is exposed to the patient is not likely to exceed 5 mSv (0.5 rem). If the total effective dose equivalent is likely to exceed 1 mSv (0.1 rem) to any individual, instructions (including written instructions) must be provided to the patient on actions to limit radiation exposure to others by utilizing the “as low as reasonably achievable” (ALARA) principle. Some states may have specific rules and regulations regarding release of patients with significant residual activity.

The dose limits specified by the National Council on Radiation Protection and Measurements (NCRP) differ somewhat from the NRC regulations [29]. Because the fetus and children are more sensitive to radiation injury than adults, the NCRP specifies that children and pregnant women, whether or not they are members of the patient’s household, should be limited to 1 mSv (0.1 rem). Any individual who has no familial

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connection to the patient and whose presence offers no emotional benefit should also be limited to 1 mSv, which is also the NRC dose limit to a member of the public.

Many radiation meters measure exposure rates in milliroentgens per hour (mR/h). For purposes of radiation protection and for low linear energy transfer (LET) radiation (including beta particles and most x-rays and gamma rays), the authors of this document accept the approximation that 1 mR, 0.01 mSv, and 1 mrem are equivalent. Thus, an exposure rate of 7 mR/h at 1 m is an adequate approximation to the dose rate, 0.07 mSv/h (7.0 mrem/h) at 1 m.

Specific Considerations During Lu-177 DOTATATE Therapy and Patient Release:
According to radiation exposure calculations based on whole-body clearance data, patients may need to be kept in radiation isolation for 4 to 5 hours following the administration of the typical dose of 200 mCi (7.4 GBq) Lu-177 DOTATATE [30]. Postinfusion survey by physics or other radiation safety is performed to determine an acceptable maximum exposure rate that conforms to the 10 CFR 35.75 requirement of <5 mSv exposure anticipated to other individuals. An established protocol for documenting this survey result should be used and available. Until the patient has been released, the patient must be kept in an area with suitable radiation shielding to protect others from unnecessary exposure. An administration of 200 mCi Lu-177 DOTATE typically results in exposure levels on the order of 2 mR/h at 1 m immediately after administration, declining to 1 mR/h after 24 hours, allowing outpatient treatment in most cases with appropriate training, protocols, infrastructure, and patient counseling. The procedures and practical example guidance for instruction of patients upon discharge have been reviewed in published literature [31]. For further information, see Appendix A.

Modeling per the NUREG-1556 assumption of 0.25 occupancy factor estimates 1.8 mSv exposure dose to other individuals, thus requiring written instructions be given to the patient on ALARA principles. During therapy, involvement of trained radiation safety personnel qualified in safe management of unsealed sources, waste, accidental contamination, and counseling of patients is important. The patient and, as relevant, caregivers should be compliant with all radiation safety precautions and instructions. Education should occur before treatment, preferably at the time of consultation so that the patient and caregivers can plan ahead. Inability to comply with the precautions may require an admission or other special accommodations to account for the realities of patient life at home, as determined by the authorized user. The specific instructions and considerations for admission or other special accommodations will vary from institution to institution, but key features are summarized below.

Urinary Contamination:
Specific concern is paid to disposal of urine as the most common potential source of contamination. During therapy, a dedicated toilet is preferred, and although lead shielding is not needed because of the short range of beta emission, disposable lining of the floors and toilet/sink surfaces is recommended to contain radioactive urine or other contamination [31]. Urinary incontinence, if present, would require catheterization prior to administration and for at least 2 days thereafter to minimize radiation contamination. Other simple measures used to minimize urinary contamination upon discharge include:

- Use of private room with its own bathroom
- Washing of hands for 20 seconds after each use of the restroom
- Instructing the patient to urinate while seated
- Flushing 2 to 3 times with the toilet lid closed
- Rinsing of sinks and showers after use
- Cleanup of urinary spills with damp toilet paper that can be flushed down the toilet (to minimize accumulation of waste product trash requiring long-term storage).
**Other Potential Sources of Contamination:**

Peritoneal and hemodialysis are not contraindications for treatment, but they may impact the administered activity of Lu-177 given the prolonged residence time within the patient and complicate handling of hemodialysis machines because of the likelihood of retained radioactivity after use, thus requiring logistics planning with dialysis facilities and the patient. Another infrequent but special consideration for Lu-177 DOTATATE therapy given its target population is in patients with indwelling drains, such as biliary drains, which require confirmation of ability of caregivers to safely manage disposal of waste with the same precautions applied to urine. When possible, these sources of waste should be flushed down the toilet similar to urine, with use of disposable gloves by the caregiver when handling and cleaning drain equipment and collection bags.

**Release to Health Care Facility/Admission to Hospital Considerations:**

If confinement in a health care facility is needed, it is not usually necessary to store body effluents, such as urine, stool, or vomitus. In general, for patients who have been released to the public, precautions for the patient should be according to ALARA principles and universal precautions. A discussion should be had in such cases with a facility or hospital’s radiation safety department and/or involved parties (clinical leadership) to determine any additional precautions that will be taken for care workers. Furthermore, should a patient receiving Lu-177 DOTATATE require admission to a hospital or transfer to an emergency department, it is highly recommended that the administering team contact the receiving personnel for a “signout.”

Although not explicitly required, examples of “extra” precautions include the following. For effluent disposal where acceptable under state or federal regulations, the toilet can be flushed two or three times after each use to ensure sufficient dilution of radioactivity. Food trays, linens, and all other contaminated products may be stored in the patient’s room until monitored and cleared by radiation safety staff. The patient must stay in the room except in a medical or nonmedical (eg, fire) emergency, and access by personnel and visitors can be limited. All trash and residual nondisposable items can be monitored after the patient’s release and stored until radiation levels reach the statutory level defined for safe disposal or reuse. In some jurisdictions, items in decay storage must reside there for 10 half-lives (67 days for Lu-177) or until radiation levels are indistinguishable from background. Once all known contamination is removed from the room, the room must be surveyed to verify that the radiation levels and removable contamination are sufficiently low to permit its general use. The room may not be used until this survey is performed and safe level documented. Individual institution’s radiation safety procedures may vary somewhat.

If the admitting physician is different from the physician who administers the radiopharmaceutical, there must be a mechanism to prevent premature discharge or release of the patient from confinement.

**Waste Disposal:**

As above, trash and nondisposable items contaminated by patient fluids must be stored and monitored until their radiation levels reach safe disposal limits, which may vary between institutions and jurisdictions, with one prominent guideline being 10 half-lives (67 days for Lu-177).

**Distance of Caregivers and Considerations for Travel:**

There is no specific regulation on required distance of caregivers following discharge. However, to meet guidance from NUREG-1556’s use of a 0.25 occupancy factor for estimating exposure of public allowing safe discharge of patients after administration, it is assumed that exposed persons will maintain a distance of 1 m (3 ft) for at least 3 days and not sleep in the same bed as the patient for 7 days. There is a further assumption of following ALARA principles to minimize exposure to potential contamination, such as may occur during use of the same toilet facilities.
Prolonged use of personal or public transportation (bus, train, etc) in the company of others for more than one hour is discouraged for the first 3 days following therapy. Although Title 10 of the CFR, part 35.75, does not expressly prohibit release of a radioactive patient to a location other than a private residence such as a hotel, the NRC strongly discourages this practice because it can result in radiation exposure to members of the public for which the licensee may not be able to assess full compliance with the code.

Nonetheless, when travel is unavoidable in the first 3 days after therapy, the patient should be instructed to discuss the matter with treating personnel.

Furthermore, although patients are recommended to travel immediately home, it is acknowledged that some patients may need to reside in a hotel or other public facility. Again, precautions to maximize distance from other members of the public are recommended (>1 m at a minimum) in the 3 days after Lu-177 DOTATATE administration.

B. Treatment Procedures for Infusion of Lu-177 DOTATATE

1. Preparation:

Before ordering Lu-177 DOTATATE solution for PRRT, confirm that treatment with Octreotide analogues has been discontinued for at least 4 weeks for long-acting preparation and for 24 hours for short-acting preparation before scheduled therapy.

Lu-177 DOTATATE is a radiopharmaceutical that requires effective radiation shielding before handling. The vial containing the radiopharmaceutical is delivered in a lead- or Plexiglas-shielded container. It is highly advised that the personnel assigned to prepare or infuse the radiopharmaceutical wear double gloves.

Before the actual administration of Lu-177 DOTATATE, patients should be started on a renoprotective amino acid infusion and may be premedicated with antiemetics according to institutional/physician preference. Depending on institutional preferences and resources, coordination should be made between all involved staff, including the referring physician and the physician administering the radiopharmaceutical to ensure that the steps and processes involved with PRRT are carried out. Two separate IV access sites are preferred: one for the amino acid infusion and one for Lu-177 DOTATATE infusion.

2. Dosage:

The recommended dosage is 200 mCi (7.4 GBq) Lu-177 DOTATATE, administered every 8 weeks for a total of 4 doses as tolerated. Dosage can be halved, according to the US Food and Drug Administration (FDA)–approved clinical notes, in special clinical situations, such as hematological toxicity [32].

**Prophylaxis: Amino Acid Solution and Antiemetics:**

The Lu-177 DOTATATE solution needs to be administered with concomitant amino acid infusion to reduce radiation absorbed dose and toxicity to the kidneys. Amino acid infusion should be initiated 30 minutes prior to infusion of Lu-177 DOTATATE and continued for at least 4 to 5 hours after completion of PRRT. There are different amino acid formulations available. The extemporaneously compounded formulation contains only 25 g lysine HCl and 25 g arginine HCl with 1 L of appropriate sterile solvent (eg, water for injection). This formulation has lower osmolality and less patient emetic effects. The commercially available amino acid solutions have a lysine content between 18 and 24 g and arginine content between 18 and 25 g in a volume of 1.5 - 2.2 L of solution having <1,050 mOsmol/L. Aminosyn II 10% used in clinical trials in the United States contained additional essential and nonessential amino acids as well as electrolytes resulting in osmolality of 1,040 mOsmol/L. This preparation was associated with a high incidence of nausea and vomiting. Choice of amino acid formulations depends on institutional resources.
Due to nausea with or without vomiting observed in some patients receiving amino acid infusion, it is advised that use of prophylactic antiemetic medications be considered, as used in each institution with any chemotherapy, 30 minutes prior to commencing amino acid solution administration. Other adjunct treatment for persistent vomiting is reasonable depending on physicians’ experiences.

3. Infusion Methods:
It is highly preferred that the IV access for administration of Lu-177 DOTATATE solution be separate from IV access for amino acid infusion. Separate access allows removal of the radiopharmaceutical access materials from the patient after PRRT, ensuring no radioactive medical line leaves the confines of the administering facility. Prior to infusion, measure the source activity to confirm prescribed activity. In some centers, a double lumen peripherally inserted central catheter (PICC) line is preferred can be used for infusion to avoid delivery failures.

Lu-177 DOTATATE is delivered in a vial under positive pressure. It can be administered via gravity method, infusion pump method or via automated syringe pump injector, as detailed with illustrative figure at the available link: http://jnm.snmjournals.org/content/60/7/937/F3.expansion.html [26]. Each institution can choose the best technique of radiopharmaceutical administration.

**Gravity Method:**
- Insert a 2.5-cm-long, 20-gauge needle (short needle) into the Lu-177 DOTATATE vial, ensuring that the beveled tip inside the vial does not touch the solution at any time during the infusion. The hub of the short needle is fastened to the IV tubing of a previously prepared 500-mL sterile 0.9% sodium chloride solution. Keep the IV tubing clamped close until the entire setup has been completed and is ready for infusion.
- Insert a second needle that is 9 cm long, 18 gauge (long needle) into the Lu-177 DOTATATE vial, ensuring that the beveled tip of this long needle touches and is secured to the bottom of the vial during the entire infusion. Fasten a connecting tube prefilled with sterile 0.9% sodium chloride to the hub of the long needle, ensuring that there are no air bubbles inside the plastic tubing. Check the designated IV access for Lu-177 DOTATATE to ensure patency; once confirmed, fasten the male Lauer lock of the connecting tube to the IV access, keeping clamp closed.
- Do not remove the needles to reposition once the seal is punctured, as this may make the seal ineffective and prevent dose delivery by this method.
- Open the clamp in the connecting tube from the vial to the patient, and then open the clamp of the tubing from the bag of normal saline solution. Regulate the flow of the sodium chloride solution via the short needle into the Lu-177 DOTATATE vial at a rate of 50 mL/h to 100 mL/h for 5 to 10 minutes and then 200 mL/h to 300 mL/h for an additional 25 to 30 minutes. During infusion, ensure that the level of solution in the Lu-177 DOTATATE vial remains constant and that the vial does not fill up completely. Total duration of infusion is about 30 to 40 minutes.
- Do not administer Lu-177 DOTATATE as an IV bolus.
- Clamp the saline line once the level of radioactivity is stable for at least five minutes.
- Clamp the connecting line from the vial and disconnect from the long needle, taking care that no fluid spills out. Open the connecting tube again and flush with 25 mL of 0.9% sterile sodium chloride to wash off any radiopharmaceutical remaining within the tubing into the patient.
- Remove the IV access used. Measure the remaining activity in the setup, including the vial, and subtract from the measured preinfusion activity to obtain the net activity administered.

**Infusion Pump Method:**
For the infusion pump method, the short and long needles are also used. The tubing that connects to the long needle should be primed with normal saline solution before attachment to an infusion pump. The other end of this tubing is attached to the IV access of the patient. A 3-way stopcock is connected to the hub of the tubing from the vial to the patient. A 3-way stopcock is connected to the hub of the connecting tube to the IV access ensuring that the beveled tip of this long needle touches and is secured to the bottom of the vial during the entire infusion. Fasten a connecting tube prefilled with sterile 0.9% sodium chloride to the hub of the long needle, ensuring that there are no air bubbles inside the plastic tubing. Check the designated IV access for Lu-177 DOTATATE to ensure patency; once confirmed, fasten the male Lauer lock of the connecting tube to the IV access, keeping clamp closed.

- Do not remove the needles to reposition once the seal is punctured, as this may make the seal ineffective and prevent dose delivery by this method.
- Open the clamp in the connecting tube from the vial to the patient, and then open the clamp of the tubing from the bag of normal saline solution. Regulate the flow of the sodium chloride solution via the short needle into the Lu-177 DOTATATE vial at a rate of 50 mL/h to 100 mL/h for 5 to 10 minutes and then 200 mL/h to 300 mL/h for an additional 25 to 30 minutes. During infusion, ensure that the level of solution in the Lu-177 DOTATATE vial remains constant and that the vial does not fill up completely. Total duration of infusion is about 30 to 40 minutes.
- Do not administer Lu-177 DOTATATE as an IV bolus.
- Clamp the saline line once the level of radioactivity is stable for at least five minutes.
- Clamp the connecting line from the vial and disconnect from the long needle, taking care that no fluid spills out. Open the connecting tube again and flush with 25 mL of 0.9% sterile sodium chloride to wash off any radiopharmaceutical remaining within the tubing into the patient.
- Remove the IV access used. Measure the remaining activity in the setup, including the vial, and subtract from the measured preinfusion activity to obtain the net activity administered.
the short needle before it is inserted into the vial with a filter attached to the vent tip. Again, the tip of the short needle should stay above the fluid level, whereas the tip of the long needle is at the bottom of the vial. The positive pressure within the Lu-177 DOTATATE vial drives fluid into the patient and is controlled by the infusion pump, which is usually programmed to deliver 0.8 to 0.9 mL/min for total infusion time of 25 to 30 minutes. Remove the IV access used. Measure the remaining activity in the setup, including the vial, and subtract from the measured preinfusion activity to obtain the net activity administered.

**Automated Syringe Pump Injector Method:**

Another method involves drawing the Lu-177 DOTATATE solution from inside the vial into a sterile lead-shielded syringe that is then mounted on an automated syringe pump injector to administer the Lu-177 DOTATATE. This method exposes the individual drawing the solution to radiation risk. A connecting tube prefilled with sterile 0.9% sodium chloride solution is used to connect the syringe containing the radiopharmaceutical to the IV access of the patient. Before starting the infusion, confirm patency of patient’s IV access. The pump is programmed to deliver the contents of the syringe over 30 minutes, eg, 30 mL at 60 mL/h. Once infusion is completed, the connecting tube can be flushed with 25 mL of 0.9% sterile sodium chloride to wash off any radiopharmaceutical remaining within the tubing into the patient. Attention is required to safely handle the setup to avoid spillage as well as minimize radiation exposure by using tongs. Remove IV access used and measure remaining radioactivity in the setup and vial, and subtract it from preinfusion activity to determine net activity administered.

C. Posttherapy Survey

All personnel involved with Lu-177 DOTATATE therapy should perform a survey of their hands and clothing for any contamination, and appropriate measures should be performed if such contamination is discovered. The room used for infusion should be surveyed for contamination before releasing the room to another patient. All medical wastes associated with the PRRT should be stored as required by radiation safety procedures, making sure that they are separated from other wastes associated with short-acting radiopharmaceuticals.

Care of the patient after Lu-177 DOTATATE therapy follows established institutional protocol for care of patient after radionuclide therapy with special consideration to ALARA principles. Therapy with octreotide LAR or lanreotide is usually given 4 to 24 hours after Lu-177 DOTATATE at the discretion of the attending oncology physician and stopped 4 weeks prior to subsequent PRRT. Short-acting octreotide maybe given for symptomatic management during PRRT cycles and withheld 24 hours prior to next dose of Lu-177 DOTATATE after determination by treating team of physicians.

If desired, posttherapy 3-D imaging may be obtained for the purposes of dosimetry. Personalized dosimetry may be used to assess and estimate potential risk to organs for the individual patient, as data collection for correlative studies seeking to establish maximum organ dose thresholds or lesion treatment efficacy thresholds, or for dose reporting in case of future radiation treatments [26].

V. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [21].

A summary of the patient’s history, pathologic findings, imaging results and laboratory findings should be included in the report to document the indication and tolerability for treatment with Lu-177 DOTATATE. The report should include the radiopharmaceutical used, the administered activity, site and route of administration, safety precautions for other staff involved in the patient’s care, and any associated incident encountered during therapy. If dosimetry is performed, salient organ absorbed dose values, both in directly calculated dose and in equivalent dose (EQD2), should be reported, and, if available, a dose map in DICOM format with the associated CT. On subsequent PRRT,
interval history should include a summary of prior Lu-177 DOTATATE treatments, interval imaging to assess treatment efficacy, and pertinent laboratory findings to determine and confirm appropriateness and safety of additional therapy [26].

VI. STATEMENT ON THERAPEUTIC USE OF UNSEALED RADIOPHARMACEUTICAL SOURCES

On the basis of their education, training pathway(s), initial board certification(s), and maintenance of certification(s), NRC or Agreement State Authorized User (AU) status, and clinical work experience, diagnostic radiologists (DRs), nuclear radiologists (NRs), nuclear medicine physicians (NMs), and radiation oncologists (ROs) may have the qualifications to supervise and perform therapy with Lu-177 DOTATATE. Although it is recognized that individual physician variations and state and federal regulatory requirements may, of necessity, dictate site-specific practice patterns, these physicians may best participate in the practice according to their special interests and qualifications. In most clinical settings, one of the following common practice paradigms generally applies:

- Physicians who are NRC and/or Agreement State recognized, board-eligible or board-certified in DR, NR, NM, or RO but do not hold AU status. These physicians may participate in the practice of PRRT under the supervision of an AU. Although they may not issue written directives for Lu-177 DOTATATE, they may administer such a dosage as designated and supervised by an AU.
- Physicians who are NRC and/or Agreement State–recognized and board certified in DR, NR, NM, or RO and hold AU status based on that certification and site-specific credentialing: These physicians may administer Lu-177 DOTATATE therapy under their own AU qualifications and licensure.
- Physicians who are NRC and/or Agreement State–recognized and board certified in DR, NR, NM, or RO and hold the appropriate AU statuses and site-specific credentialing. These physicians may practice parenteral Lu-177 DOTATATE therapy as permitted by their own specific training leading to such AU statuses.

VII. RADIATION SAFETY

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 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.imagemgently.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).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality control and improvement, 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).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [33].

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PRACTICE PARAMETER

Lutetium (Lu-177 DOTATATE)

2020 Resolution No. 17

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REFERENCES


Post Treatment Instructions to Patient Following Lu-177 DOTATATE Therapy

Name of Patient: __________________________    Medical Record Number: ___________

Last name, First name

Date of Treatment: __________________________  Isotope: Lu-177    Activity: __________

Before this date: ______________, please show this form to every physician, healthcare worker or emergency personnel that provide you care.

Special Precautions

1. Maintain a distance of at least 3 feet (1 meter) from others for 3 days since radiation exposure decreases with distance, the further away you are from others, the less radiation they get.

APPENDIX A
2. Minimize visits by family or friends for 3 days. If you have visitors, try to stay at least 3 feet away.

3. Minimize close contact with others at work for 3 days.

4. For woman of childbearing age (<55 years old), pregnancy must be excluded before initiating the treatment. Both men and women of child-bearing potential must refrain from procreation by using effective contraceptive methods during the treatment and for 6 months after.

5. For women who are breastfeeding, discontinue breast feeding for this child.

6. Sleep alone for at least 7 nights. Sleeping together with another adult exposes them to the radiation coming from you. Sexual activity is not advised for 7 days after LUTATHERA administration.

7. No children should sleep with you for 7 days. No pregnant person should sleep with you for 15 days. Children and fetuses are much more sensitive to radiation than adults, and special care is needed. Limit close contact to brief periods for 7 days.

8. Take particular care when urinating for 3 days. Toilets must be used in a seated position, even for men. Use private bathroom or flush 2 to 3 times and clean any spills with disposable gloves and damp cloth after each use. Wash hands thoroughly. The radiation leaves your body mainly from your urine.

9. Wash dishware and utensils and bathroom accessories separately for 3 days.

10. Do not travel by public transportation (bus, train, plane) for more than 1 hour for 3 days. If you are planning to travel while radiation safety precautions are in effect, please inform Nuclear Medicine or Radiation Facility personnel at (area code) ______-______.

**For flights, travelers may call TSA Cares toll free at 1-855-787-2227 prior to traveling with questions about screening policies, procedures, and what to expect at the security checkpoint. For more information, visit https://www.tsa.gov/travel/special-procedures.

11. No prolonged car trip (more than 1 hour) with others for 3 days.

12. Drink plenty of fluid (4-8 glasses) per day for 3 days.

If you are admitted to the ER or hospitalized while radiation safety precautions are in effect, inform the hospital staff to notify the above contact person immediately. During off-hours, contact Nuclear Medicine or Radiation Facility via the operator at _______________________.

Instructions for Radioactive Trash Generated by patient

Please be aware that the following items that may be contaminated with urine and blood cannot be disposed into regular trash:

1. Pads, tampons
2. Toilet papers, tissue
3. Towels, linens, sheets
4. Any other items that are contaminated with urine, blood, and wound or drainage secretions for the first 3 days post treatment

Towels, linens and sheets can be washed separately and reused.
Toilet paper and tissue need to be flushed down the toilet.
Any other contaminated items that cannot be washed or flushed down the toilet needs to be kept for at least 70 days or bring it to the Nuclear Medicine or Radiation Oncology Facility to be stored.

I have read the above precautions and instructions and have spoken with the Nuclear Medicine or Radiation Facility personnel and agree to comply.

Patient (print name): ______________________________
Signature: _______________________________ Date/time: ________________
*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.
RESOLUTION NO. 19

Extension of Review Cycle for One Practice Parameter

WHEREAS,
the language in some MRI practice parameter documents that indicates that “the supervising radiology physician must have complete understanding of the indications, risks and benefits of the examination” (e.g. lines 41-42 of the liver MRI parameter) might be interpreted to represent the individual patient’s clinical indications, risks, benefits; therefore,

BE IT RESOLVED,
that the language in the ACR MRI practice parameter documents be revised to include the word “imaging” before the word examination to clarify that this phraseology is intended to indicate complete familiarity with the imaging examination being performed rather than the individual patient being examined, and therefore read as follows “The supervising radiology physicians must understand the indications, risks, and benefits of the imaging examination, as well as alternative imaging procedures”; and

BE IT FURTHER RESOLVED,
that working with the appropriate ACR members, staff will identify all relevant practice parameters in which the edits should be implemented.

Sponsored by:  Texas Radiological Society
Supervising Radiologist Understanding for Imaging Indication

To support the resolution Supervising Radiologist Understanding for Imaging Indication, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
RESOLUTION NO. 20

Extension of Review Cycle for One Practice Parameter

WHEREAS,
the policy governing the revision cycle of the ACR Practice Parameters and Technical Standards as published in the Digest of Council Actions (see Section II-Provisional and Public Policy Statements, 1.-Radiological Practice and Ethics, 2.-ACR Policy on Development of Practice Guidelines and Technical Standards, r. Revision of Practice Guidelines and Technical Standards Review Cycle) states, ‘ACR practice guidelines and technical standards will be reviewed by the Council every five years, or sooner if directed by the Council Steering Committee, the Board of Chancellors, or the Commission on Quality and Safety; 2000, amended 2010 (Res. 10-d).’; and,

WHEREAS,
after initial review of the thirty-nine (39) practice parameters and technical standards to be revised for the 2021 cycle, and consultation with staff and respective commission and committee chairs, the Chair of the Practice Parameters and Technical Standards Committee and the Chair of the Commission on Quality and Safety, identified one (1) document whose review cycle could be extended, and

WHEREAS,
there is no significant scientific reason compelling the review of these document for presentation at the 2021 annual meeting; therefore,

BE IT RESOLVED,
that the review cycle for the practice parameters listed below is hereby extended by one additional year and that these practice parameters are to be presented for consideration at the 2022 ACR Annual Meeting:

(a) ACR–ASNR–ASSR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Spine

Sponsored by: Council Steering Committee
Fiscal Note

Extension of Review Cycle for One Practice Parameter

To support the resolution Extension of Review Cycle for One Practice Parameter, the ACR would incur the following estimated costs:

Costs:

De minimis (<$10,000)
RESOLUTION NO. 21

ACR Conflict of Interest Policy

WHEREAS, physicians in the United States have confronted increased scrutiny of their relationships and interests that might affect their service to organized medicine, including medical specialty societies; and

WHEREAS, such scrutiny increases organizational risk to the American College of Radiology (ACR) and individual risk to its members and others who are serving in an official capacity; and

WHEREAS, these factors motivated the ACR Board of Chancellors to form a Workgroup to study whether ACR had sufficient processes to evaluate risk stemming from potential Conflict of Interest (COI) issues relating to members’ outside relationships and financial interests; and

WHEREAS, the BOC Workgroup undertook a comprehensive review and recommended a new approach to address identified gaps in prior ACR processes; and

WHEREAS, the BOC acted on the recommendation by adopting a COI policy in May 2018, which the Council Steering Committee supported; and

WHEREAS, the Council Steering Committee then appointed a Workgroup to consider an organizational COI policy that is based on the BOC COI policy; and

WHEREAS, the ACR’s legislative body should join in affirming a unified organizational position for managing relationships and interests that may pose a risk to the College and its’ members; therefore,

BE IT RESOLVED, that the Council of the American College of Radiology adopt the revised Conflict of Interest Policy in lieu of the Conflict of Interest Disclosure provision adopted in 2011 as Resolution 47-h.

Sponsored by: Board of Chancellors
Council Steering Committee
ACR Conflict of Interest Policy

To support the resolution for **ACR Conflict of Interest Policy**, the ACR would incur the following estimated costs:

**Costs:**
- De minimis (< $10,000)
American College of Radiology: Conflict of Interest (COI) Policy

I. INTRODUCTION

The American College of Radiology (ACR) has the fiduciary responsibility to hold the public trust in fulfilling its charitable mission. ACR meets this responsibility in abiding by applicable laws and regulations, and striving to foster professionalism and the integrity of professional judgment in support of its core purpose to serve patients and society by empowering members to advance the practice, science, and professions of radiological care. ACR demonstrates its commitment to these values by disclosing, managing, and, in some cases, restricting relationships that could be perceived to compromise its objective voice.

The Council of Medical Specialty Societies (CMSS) Code for Interactions With Companies (“CMSS Code”) is a set of principles that requires signatory societies to adopt policies for transparency and independence in transactions and activities involving for-profit entities that develop, produce, market, or distribute drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions. ACR signed on to the CMSS Code in April 2010 and has adopted policies and practices in compliance with the Code.

The following Conflicts of Interest Policy (“Policy”) describes ACR’s comprehensive approach to addressing relationships held by ACR and its affiliates, its key leaders and volunteers, or any other person serving in an official ACR capacity.

II. SCOPE

This policy applies to the activities of the ACR and its affiliates including but not limited to the American College of Radiology Association, the American College of Radiology Foundation, the American Institute for Radiologic Pathology (herein referred to as ACR), and all interested persons as defined unless specific terms or the context dictates otherwise. For purposes of this Policy, the term “ACR” refers to all of these entities and related activities, collectively and as applicable.

III. POLICY STATEMENT

All ACR interested persons must complete annually, and update if there are any changes to prior disclosures, a COI Questionnaire through ACR’s electronic system. Interested persons must comply with this Policy to participate in ACR activities.

IV. INFORMATION TO BE DISCLOSED

Disclosures under this Policy generally includes but may not be limited to the following: professional relationships, financial interests, leadership positions, consulting and advisory activities, honoraria, speaking engagements, business courtesies, sanction and exclusions, expert testimony, research funding (to the individual or the institution), and licensing fees and royalties associated with intellectual property interests. Such disclosures
extend to individuals with whom an interested person has a close personal relationship. ACR interested persons are not required to disclose information pertaining to direct clinical or patient care administrative services. (Certain terms are further defined in the Glossary.)

Collection of disclosures from all interested persons emphasizes ACR’s commitment to transparency, objectivity, and to fulfill its legal obligations. Disclosures of relationships or financial interests do not create a presumption of impropriety.

V. Potential Conflicts of Interest

Disclosures will assist the ACR to identify actual, potential, and perceived conflicts of interest based on an interested person’s service to the ACR. Submitting and keeping current, a COI questionnaire is sufficient to resolve many potential COIs.

Listed below are types of services to the ACR and outlines of COI expectations in these areas, including any legal or external obligations. When a potential conflict has been identified that may affect an interested person’s service to the ACR, various activity-specific management strategies may be employed.

Leadership and Key Persons

For the purposes of this Policy, Leadership and Key Persons are defined as Board of Chancellors (BOC), Board members of ACR affiliates, Council Steering Committee members, the Chief Executive Officer, and the Editor-in-Chief and Deputy Editor of the Journal of the American College of Radiology (JACR). These individuals are required to disclose relationships and other financial interests for themselves and individuals with whom they have a close personal relationship. The BOC Chair or Chief Executive Officer (CEO) may identify others as ACR Key Persons for purposes of this policy.

Councilors, Alternate Councilors, and All Other Annual Meeting Attendees

ACR Councilors and Alternate Councilors serve unique and vital roles participating in the ACR’s Council. Elected and selected by state chapters and specialty societies, they represent those constituencies at the ACR Annual Meeting. Other ACR members and non-members also participate in the Annual Meeting, representing themselves and other constituencies. All attendees must ensure the integrity, independence and objectivity of Council activities. As a condition of attendance, all Annual Meeting attendees must complete a conflict of interest questionnaire as approved by the Council Steering Committee. All potentially relevant disclosures must be verbally conveyed when addressing the Council. Summary information from COI questionnaire disclosures will be available to all Annual Meeting participants. Councilors and Alternate Councilors with potential conflicts may address the Council on relevant matters but should recuse themselves from voting on them.

Officers, Directors, and Key Employees

As a 501(c)(3) tax-exempt organization, the ACR is subject to Internal Revenue Service (IRS) regulations governing "Transactions With Interested Persons". Should a covered transaction, as defined by the IRS, be under consideration, any affected Officer, Director or Key Employee must follow ACR processes for covered transactions.

Continuing Medical Education Activities

As an accredited provider of continuing medical education (CME) for physicians, the College offers CME in accordance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support.
All interested persons serving as planners, presenters, and other individuals who are in a position to control the content of ACR CME, or an activity jointly sponsored by ACR must meet disclosure requirements and management strategies as outlined by ACCME and ACR’s CME compliance program.\(^3\)

**Journal Manuscripts**

The mission of the Journal of the American College of Radiology (JACR, or “the Journal”) is to fill the gap for information on health services research and policy, clinical practice management, training and education, and leadership. The ACR supports the International Committee of Medical Journal Editors (ICMJE) COI process that requires all disclosures pertaining to the planning, implementation, writing, peer review, editing, and publication of scientific work are submitted according to these standards.\(^4\)

**Clinical Research Activities**

The development of new devices and pharmaceuticals and increasingly sensitive and quantitative methodologies for the diagnosis, monitoring, and treatment of human disease is dependent on partnerships among industry, academia, and government. It is essential that these relationships are guided by integrity, transparency, and consideration for the public trust.

ACR participates in numerous federally supported grants through the National Institutes of Health (NIH) and other federal agencies. All Interested Persons participating in federally funded Clinical Research Activities must submit all federally mandated disclosures through the annual ACR COI process. Additionally, all Interested Persons who participate in private (non-federally supported) research activities must disclose relationships and other financial interests according to the ACR Financial Conflict of Interest in Research Policy.

**ACR Practice Parameters, Technical Standards and Appropriateness Criteria and Accreditation Activities**

ACR sponsors the development of radiology practice documents and materials based on scientific evidence and consensus in a manner that minimizes the risk of actual or perceived bias, including intended or unintended influence introduced by an individual’s interests. All committee members and others participating in drafting, reviewing, and approving radiology practice documents and other Committee activities must complete a COI questionnaire annually. Additionally, the majority of committee members, including the committee chair, must not hold relationships or financial interests with a company where there is a reasonable likelihood of direct regulatory or commercial impact on the entity as a result of care delivered in accordance with Committee published guidance documents. ACR does not accept Company funding to support the development or initial publication or dissemination of ACR Documents or their updates.

**Grants Selection**

In support of its Core Purpose, the ACR has established various grant programs. To minimize the potential for bias in awarding ACR supported grants, those serving in a grant decision making capacity must complete a COI Questionnaire annually. Those individuals serving in any grant decision making capacities are not eligible to serve as the Principal Investigator in grants they oversee.

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**VI. ENFORCEMENT OF POLICY**

Failure to comply with this policy may result in disciplinary action up to and including removal from ACR service. Noncompliance includes failure to disclose, in good faith, an accurate and complete questionnaire, timely reporting of any changes to a previously submitted questionnaire, or failure to comply with a management plan.
VII. EFFECTIVE DATE OF POLICY

This Policy is effective on the date of publication. Earlier ACR Conflict of Interest policies are no longer in effect.

VIII. GLOSSARY

COMPENSATION – Direct and indirect remuneration as well as gifts or favors in aggregate received by interested persons and their close personal relationships.

CONFLICT OF INTEREST – A COI occurs whenever an interested person or someone with whom they have a close personal relationship has a direct or indirect interest or relationship, financial or otherwise, which may conflict or be inconsistent with the interested person’s duties, responsibilities, or independent judgment in any transaction or matter involving ACR.

CLOSE PERSONAL RELATIONSHIP – Any relationship that may create an actual, potential or perceived COI. These may include immediate family members, other relatives, or other persons close to you where you know about their relationships or other financial interests.

COVERED TRANSACTIONS – Any transaction in which there may be an actual, potential or perceived conflict of interest, which occurs when the interests of an Officer, Director, or key employee may be seen as competing with the interests of the ACR.

FINANCIAL INTEREST – Financial relationships of interested persons or those of their close personal relationships with any entity related to or doing business with ACR or to any activities associated with research, practice, or education, in the fields of diagnostic radiology, radiation oncology, interventional radiology, nuclear medicine and medical physics. Financial interests include, but are not limited to:

- Salary
- Consulting fees
- In-kind donations
- Honoraria
- Speaker’s bureau payments

- Equity interest
- Ownership or intellectual property rights, including copyrights, patents, and royalties
- Research grant funding

- Reimbursement for travel or other expenses
- Investment income such as stocks, bonds, mutual funds
- Other payments viewed as compensation

INTERESTED PERSON – Any officer, chancellor, councilor, alternate councilor, member of an ACR commission, committee or task force, persons responsible for public or private research activities related to ACR, annual meeting attendee, or any other person serving in an official ACR capacity.

Whereas certain interested persons are further defined in this policy as ACR Leadership and Key Persons, this group includes officers, members of the Board of Chancellors (BOC), Board members of ACR affiliates, Council Steering Committee members, and the Editor-in-Chief and Deputy Editor of the Journal of the American College of Radiology (JACR). The BOC Chair or Chief Executive Officer (CEO) may identify others as ACR Key Persons for purposes of this policy.
REFERENCES


RESOLUTION NO. 22

Paid Family/Medical Leave in Radiology and Radiology Oncology Practices

WHEREAS, the American College of Radiology (ACR) is “committed to the radiologist’s well-being as an integral part of high quality and safe patient care and the health of our members” [1]; and

WHEREAS, both men and women and their family members may experience serious medical conditions during the course of a professional career, and that pregnancy and childbirth are a biologic necessity for the continuation of the human race; and

WHEREAS, the federal Family Medical Leave Act (FMLA) of 1993 [2] requires private employers with 50 or more employees within 75 miles of the eligible employee’s worksite and all public agencies to provide eligible employees* up to 12 work weeks of unpaid leave in a 12-month period for reasons including:**

- the birth of a child and to care for the newborn child within one year of birth;
- the placement with the employee of a child for adoption or foster care and to care for the newly placed child within one year of placement;
- to care for the employee’s spouse, child, or parent who has a serious health condition; and
- a serious health condition that makes the employee unable to perform the essential functions of his or her job. [2]; and

WHEREAS, since 2016, the U.S. Department of Defense has offered 12 weeks of fully paid maternity leave as “an incentive for attracting and retaining talent…[and] also promotes the health and wellness of mothers through facilitating recovery and promoting feeding and bonding with the infant.” [4]; and

WHEREAS, in December 2019, the President signed into law legislation for federal employees to fund 12 weeks of paid leave to mothers and fathers of newborns, newly adopted children or foster children [5, 6].

WHEREAS, additionally, certain states have passed legislation that require employers to provide to their employees either paid or unpaid family leave under similar circumstances [7]; and

WHEREAS, the Society of Chairs of Academic Radiology Departments (SCARD) pledges “to strive for departmental, institutional, and organizational change that provides 12
weeks of paid parental leave for eligible (as defined per the Family Medical
Leave Act) faculty members of all genders.” [8]; and

WHEREAS,
the American Board of Radiology’s (ABR’s) revised Core Examination
eligibility policy allows “residents who are in or beyond their 32nd month of DR
training to take the examination if (1) the program director attests that the
resident is believed to have sufficient knowledge and experience, and (2) the
candidate attests that he or she understands the potential consequences of taking
the examination early. This policy change would allow up to a 4-month leave of
absence, in addition to standard vacation and meeting time, during the first 3
years of radiology residency.” [9]; and

WHEREAS,
the Department of Labor considers medical residents to be employees under the
FMLA [10]; and

WHEREAS,
the Association of Program Directors in Radiology (APDR) “recognizes that
under the FMLA, eligible* radiology trainees of all genders have the right to take
up to 12 weeks of unpaid family leave, and encourages program directors to
make this right known to their trainees, as indicated by federal law [11], and to
provide notice of any additional rights under relevant state family leave laws.”
[12]; and

WHEREAS,
we believe it is essential for the success and well-being of the members of our
practices and departments, including our members in training, that when they
experience the significant life events of welcoming a new child or dealing with
serious illness, they must have sufficient leave from work consistent with federal
law and that they should not endure the financial burden of loss of income;
therefore,

BE IT RESOLVED,
that the American College of Radiology (ACR) recommends that radiology
and radiation oncology practices, departments and training programs strive
to provide 12 work weeks of paid family/medical leave in a 12-month period
for radiologists, radiation oncologists, nuclear medicine physicians and
medical physicists of all genders, including members in training.

Sponsored by: Susan Ackermann MD, FACR, Councilor, American Association for Women
Radiologists
California Radiological Society
Colorado Radiological Society
Delaware Radiological Society
Kansas Radiological Society
Kentucky Radiological Society
Maryland Radiological Society
Massachusetts Radiological Society
Minnesota Radiological Society
New York State Radiological Society
Texas Radiological Society
Utah Radiological Society
Virginia Radiological Society
Andrew Moriarity MD, Councilor, ACR Young and Early Career Professional Section (YPS)
Amy Patel, MD, Councilor, ACR YPS
Patricia Balthazar MD, Councilor, ACR Resident and Fellow Section (RFS)
Jamaal Benjamin MD, Councilor, ACR RFS
Anna Laucis MD, Councilor, ACR RFS
Daniel Ortiz MD, Councilor, ACR RFS
Monica Wood MD, Councilor, ACR RFS
To support the resolution **Paid Family/Medical Leave in Radiology and Radiology Oncology Practices**, the ACR would incur the following estimated costs:

**Costs:**

- **De minimis (<$10,000)**

**Defined, per FMLA, as “Employees are eligible for leave if they have worked for their employer at least 12 months, at least 1,250 hours over the past 12 months, and work at a location where the company employs 50 or more employees within 75 miles.”** [3]

**Additional reasons under the FMLA include:**

- any qualifying exigency arising out of the fact that the employee’s spouse, son, daughter, or parent is a covered military member on “covered active duty”; and
- to care for a covered service member with a serious injury or illness if the eligible employee is the service member’s spouse, son, daughter, parent, or next of kin (leave entitlement is up to 26 weeks in a 12-month period). [2]

**REFERENCES**


5. Yen H, Olson A. Paid parental leave for fed workers could spur wider changes. Associate Press. 16 December 2019. [https://apnews.com/7b5095225350e53850fb05e2b88a0da5](https://apnews.com/7b5095225350e53850fb05e2b88a0da5). Accessed December 17, 2019.


REFERENCE COMMITTEE III

COMMISSIONS, COMMITTEES & TASK FORCES:

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<p>| 24. | ACR–SAR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Enterography | REVISED PP |
| 25. | ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Abdomen (Excluding the Liver) | REVISED PP |
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RESOLUTION NO. 23

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) I. RADIOLOGICAL PRACTICE AND ETHICS

2. ACR POLICY ON DEVELOPMENT OF PRACTICE PARAMETERS AND TECHNICAL STANDARDS

b. ACR Radiation Oncology Practice Parameters and Technical Standards

After completion of field review and the CSC chaired conference call, the proposed collaborative radiation oncology practice parameter or technical standard work product will then be reviewed by the ACR Commission on Radiation Oncology and ACR Commission on Medical Physics.

After review and approval by the ACR Commission on Radiation Oncology and the ACR Commission on Medical Physics, it will next be reviewed by the ACR Council Steering Committee.

After review and approval by the ACR Council Steering Committee it will be sent to the ACR Board of Chancellors for final review and approval by the College; adopted 2010 (Res. 8).

(b) I. RADIOLOGICAL PRACTICE AND ETHICS

2. ACR POLICY ON DEVELOPMENT OF PRACTICE PARAMETERS AND TECHNICAL STANDARDS

y. Revision of Practice Parameters and Technical Standards Review Cycle

ACR practice parameters and technical standards will be reviewed by the Council every five years, or sooner if directed by the Council Steering Committee, the Board of Chancellors or the Commission on Quality and Safety; 2000, amended 2010 (Res. 10-d).

(c) I. RADIOLOGICAL PRACTICE AND ETHICS
f. Direct Patient Communication

Radiologists are encouraged to increase direct communication with their patients in a manner appropriate to the clinical circumstances and in accordance with the patient's wishes; adopted 2000, 2010 (Res. 10-e).

n. Conflict of Interest Disclosure

All ACR leaders (including BOC and CSC members and those running for office in the above) must comply with the disclosure requirements of ACR Conflict of Interest Policies, with such required disclosures, including, but not limited to, all management, board membership or ownership relationships with companies that consult with hospitals or provide radiology services. These disclosures should be listed prominently in the election manual and ACR meeting materials; adopted 2010 (Res. 53-a).

q. Efficacy

2. Thermography Efficacy

The position of the American College of Radiology is that thermography has not been demonstrated to have value as a screening, diagnostic, or adjunctive imaging tool; adopted 1990, 2000, 2010 (Res. 1-d).

J. TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS

7. OTHER NON-PHYSICIAN RADIOLOGY PROVIDERS (NPRP) PERFORMING FLUOROSCOPIC PROCEDURES

It is the policy of the American College of Radiology that other ancillary personnel Non-Physician Radiology Providers (NPRP) who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform fluoroscopic examinations or fluoroscopically guided imaging procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal
All ancillary personnel, non-physician radiology providers (NPRP), using fluoroscopy should be credentialed for those fluoroscopic examinations or procedures and should have completed 40 hours of didactic education or its equivalent CME that meets applicable state or other laws and regulations to become competent in the following:

digital image acquisition and display, contrast media, fluoroscopic unit operation and safety, image analysis, radiation biology, radiation production and characteristics, and radiation protection.

Additionally, NPRP using fluoroscopy should have sufficient clinical experience and be supervised by a radiologist or medical physicist to demonstrate competency in those fluoroscopic examinations or procedures for which they are credentialed. Medical physicists should be involved in the radiation safety and image quality aspects of fluoroscopy. Required CME for other ancillary personnel NPRP performing fluoroscopy should include education in radiation dosimetry, radiation protection, and equipment performance related to the use of fluoroscopy; adopted 2010 (Res. 52).

Sponsored by: ACR Council Steering Committee
To support the resolution for **Ten Year Extension of Policy**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Enterography

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 18)*

ACR–SAR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF COMPUTED TOMOGRAPHY (CT) ENTEROGRAPHY

PREAMBLE

These Practice Parameters are 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 cautions against the use of these Practice Parameters 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the Practice Parameters, 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 the Practice Parameters 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 the Practice Parameters. However, a practitioner who employs an approach substantially different from these Practice Parameters is advised to document in the patient record information sufficient to explain the approach taken.

1Iowa 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 these Practice Parameters 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 these Practice Parameters is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was developed revised collaboratively by the American College of Radiology (ACR), Society for Pediatric Radiology (SPR), and the Society of Abdominal Radiology (SAR) (authors are members of both organizations).

CT enterography (CTE) is an examination using neutral oral contrast agents (with density of <20-30 HU) as well as and intravenous (IV) contrast medium, with multidetector CT (MDCT) in the evaluation of small-bowel diseases, primarily Crohn’s disease and obscure gastrointestinal bleeding [1-20]. Currently, this examination is also used worldwide for evaluating acute and chronic mesenteric ischemia (in acute cases, oral contrast media administration may not be necessary), detection of small-bowel neoplasms (often in the setting of obscure gastrointestinal bleeding), and evaluating celiac disease, as well as in the nontraumatic patients who have acute abdominal pain [20]. In most active large centers caring for patients with Crohn’s disease patients, CT and now MR enterography (MRE) has have become the standard of care and have supplanted traditional barium-based fluoroscopic techniques (small-bowel series and enteroclysis) [21] (see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance (MR) Enterography [22]).

II. INDICATIONS AND CONTRAINDICATIONS

Clinical indications and contraindications for CTE include, but are not limited to, the following:

A. Indications

1. Known Crohn’s inflammatory bowel disease not in the perioperative period
2. Suspected Crohn’s disease or other causes of small-bowel inflammation
3. Suspected small-bowel bleeding (formally obscure gastrointestinal bleeding). This study should be performed if upper and lower endoscopy fail to identify bleeding source. Note: Suspected acute as well as small-bowel bleeding should be evaluated with multiphasic technique and not uniphasic CTE.
4. Suspected small-bowel disease (eg, celiac disease)
5. Chronic diarrhea and/or abdominal pain
6. Suspected chronic mesenteric ischemia

B. Contraindications (most are relative) when Other Examinations may be more Efficacious

1. Patients with a known, severe iodinated contrast media allergy who are able to undergo a contrast-enhanced MRE
2. Patients with chronic kidney disease whose estimated glomerular filtration rate (eGFR) is < 30 mL/min/1.73 m², in whom iodinated contrast material or oral fluid volume is considered harmful. In these patients, consider hydration or MRE.
3. Patients who have had multiple CT examinations in their lifetime and in whom the examination is not considered urgent or emergent. In such cases, consider MRE, especially in younger patients with Crohn’s disease
4. Patients in the postoperative period (within 2-3 weeks) in whom an abscess or anastomotic leak is considered more likely; this will require the use of a positive oral contrast agent, generally iodinated contrast either orally and/or rectally if there is an anastomosis, rather than CTE. In the acute, emergency department setting, the choice of a conventional CT with positive or high attenuation oral contrast or a CTE should be based upon whether the patient is in the postoperative period or not. If the patient is not in the postoperative period and there is a history of Crohn’s disease, a CTE should be considered.

5. In pediatric patients, the relative advantages and disadvantages of CTE and MRE should be considered. In particular, the potential need for sedation/anesthesia should be weighed cautiously.

Clinical Scenarios in which CTE may not be Efficacious

Patients with an eGFR <30 mL/min/1.73 m², who should not receive gadolinium agents, will likely be better assessed with nonenhanced MRE (relying on T2-weighted pulse sequences and diffusion-weighted imaging) rather than unenhanced CTE.

CTE is not efficacious without IV contrast. The issues related to the use of gadolinium-based and iodinated contrast media in patients with acute and chronic kidney disease have recently been addressed and significantly changed when compared with prior recommendations. It is beyond the scope of this practice parameter to address these issues. Any questions concerning the appropriate use of these contrast agents for CTE and MRE should be addressed in the ACR Manual on Contrast Media [23]. It documents the use of low and iso-osmolality iodinated contrast media in CTE in patients with stable renal function and an eGFR of >30 mL/min/1.73 m². The risk of contrast-induced nephropathy is low or nonexistent, all other factors being equal. The use of group II gadolinium-based contrast agents in MRE in any patient with acute or chronic kidney disease is now considered to be safe.

Crohn’s Patients with inflammatory bowel disease who have had multiple prior CT examinations and are not acutely ill may be better evaluated with contrast-enhanced MRE rather than with enhanced CTE. This particularly applies in the pediatric population, for whom efforts to apply ALARA principles should be maintained. In the perioperative period, even in patients with Crohn’s disease, an anastomotic leak may not be identified when neutral oral contrast medium is used. Lastly, there is no evidence that CTE can detect the cause of incomplete, low-grade, or recurrent small-bowel obstructions, which are commonly due to adhesive disease. These patients are better evaluated with either a standard, fluoroscopic small-bowel follow-through series or CT enteroclysis [24].

In this patient cohort, an MRE without intravenous IV contrast may be preferred.

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 [25].

III. QUALIFICATIONS OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [26].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for CT enterography should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.
Oral Contrast Media Ingestion Regimens

CTE oral contrast ingestion protocols vary between institutions \([11,30-38]\). Regardless, oral contrast must be ingested over 30 - 60 minutes. CT image acquisition is generally begun after 45 to 70 minutes for patients with an intact gastrointestinal system and 30–45 minutes for patients with surgically altered intestinal anatomy, ileocecal resections, ileostomies, multiple small bowel resections, or total proctocolectomies with ileo-anal pouch anastomoses. The volume of contrast ingested varies, but most adult protocols require the ingestion of at least 1350 mL of contrast agent, and in pediatric patients, the volume varies and is prescribed according to patient weight, eg, 20 mL/kg, up to adult dose (corresponds to 3 bottles of the commercially available 0.1% barium suspension), and often supplemented at the end by water. Immediately before the scan acquisition in an attempt to distend the stomach and duodenum and jejunum since water absorption is not a concern at this time. It is best for the patient to consistently and slowly ingest the oral contrast material over the time period, rather than rapidly ingest each bottle of contrast. This method will facilitate consistent proximal-to-distal small-bowel distension. For the most consistent bowel distension, it is optimal that Ideally, the patients ingesting the contrast should be located in the radiology department such while ingesting the contrast so that a technologist, or nurse, or designated individual can directly observe the patients both to encourage them to drink and to identify those patients who are having trouble ingesting the agent, and provide encouragement. Patient compliance with enteric contrast drinking can be enhanced by contrast refrigeration or addition of sugar-free fruit flavoring. Ideal distension appears to improve when the patient ingests the agent while sitting or supine, as opposed to in the right lateral decubitus position \([37]\). If the patient cannot ingest the oral contrast agent, either a feeding tube or NG (nasogastric) tube an enteric tube can be placed to allow for administration or the patient can be encouraged to drink the balance of and removed prior to imaging. Alternatively, if the patient has ingested some contrast medium, the required volume balance can be completed with water. Some sites encourage patients to ingest a few sips of water between bottles of the commercially available 0.1% barium suspension, to aid patient compliance. They have found that this simple method improves patient compliance. If only water is used, imaging should be performed earlier (ie, 30 minutes after beginning drinking) as water is rapidly absorbed. If patients are unable to drink the prescribed volume of neutral oral contrast agent, the
supervising physician should make the determination whether the patient should substitute water for the remaining volume of contrast or continue the study.

IV Contrast Enhancement for CTE

For CTE, IV intravenous contrast enhancement is essential for the assessment of bowel wall enhancement pattern, enhancing bowel wall lesions and/or intraluminal contrast extravasation, and in the case of acute gastrointestinal bleeding. Scan timing relative to the start of iodinated contrast injection for CTE is somewhat variable. Schindera et al reported that the normal small-bowel wall appears to have the greatest level of enhancement during the enteric phase (approximately 40-50 seconds postinitiation of contrast injection) [39]. This investigation did not take into account the location of the small bowel when assessing bowel wall enhancement, which is relevant because the normal number of folds decreases from duodenum to ileum, and the duodenum enhances more than the jejunum and the jejunum more than the ileum [1]. Thus, some investigators believe that the ideal time to scan in patients with Crohn’s disease is at 50 seconds (or 14 seconds after peak abdominal aortic enhancement) after initiating contrast injection, although if the injection rate is limited by technical factors, timing should be delayed. Other investigators using timed MR scanning after an injection of contrast have shown that the maximal difference between normal and active inflammatory small-bowel Crohn’s disease occurs much later, even several minutes after contrast injection [40]. Furthermore, an investigation of CTE showed that the detection of active inflammatory small-bowel Crohn’s disease did not differ was not different between scans obtained after 40 seconds and 70 seconds post contrast enhancement [41]. In most academic institutions, CTE obtained for assessment of Crohn’s disease is performed using a single phase of enhancement acquired between 50 and 70 seconds post contrast injection (ie, either the enteric or portal venous phase). Recently, a split-bolus technique has been investigated, yielding a greater contrast-to-noise ratio for active Crohn’s disease and improving disease detection [42].

In the evaluation of suspected small-bowel bleeding obscure gastrointestinal bleeding, suspected acute or chronic mesenteric ischemia, and suspected small-bowel masses, multiphasic scanning is essential [7-10]. Some centers perform a low-dose precontrast evaluation in order to eliminate the confusion that high-attenuation, intraluminal objects, such as pills, may cause (any intraluminal high-attenuation object that does not change during multiple postcontrast phases postcontrast must be considered as inert and not significant). Most perform an arterial phase examination, with scan timing based on bolus tracking techniques, with a region of interest placed over the aorta at the diaphragmatic hiatus. This is followed by an enteric phase examination at approximately 50 seconds post contrast injection as well as a more delayed portal venous phase for even longer, >70–80 seconds. Some centers only perform arterial and portal venous phase scans for these indications. If a dual-energy CT scanner is utilized, the unenhanced portion of the examination can be eliminated because virtual noncontrast images can be generated.

Scan Position and Range

Patients are scanned in the supine position through the abdomen and pelvis. Importantly, technologists should include the perineum in order to identify perianal fistulas and abscesses in patients with known or suspected Crohn’s disease.

Reconstruction Techniques for CTE

For reconstruction purposes, CTE created from MDCT data sets must be processed in orthogonal planes, typically axial and coronal. Some sites routinely reconstruct in the sagittal plane; some only when this plane provides additional information to a specific case, or for presurgical planning. Multiplanar reconstructions facilitate the identification of fistulae and sinus tracts. The sagittal plane is particularly helpful in identifying the origin of the celiac axis and superior mesenteric artery and assessing for stenosis or occlusion in patients with suspected acute or chronic mesenteric ischemia. In patients scanned for vascular disease, 3-D angiograms can be easily reconstructed with various techniques on modern workstations. Modern workstations can also allow for assessment of the scan data in unlimited planes. However, it is best to provide the referring gastroenterologist and surgeon at
least the axial and coronal planes. Specialists are most familiar with evaluating the small bowel in the frontal or coronal plane, the plane that most imitates the overhead films radiographs routinely obtained in a small bowel barium series. The combination of axial, coronal, and sagittal planes can be utilized and helpful in identifying fistulae, sinus tracts, and presurgical planning. Maximum intensity projection (MIP) images are helpful particularly in multiphasic gastrointestinal bleeding studies to quickly assess for sites of active extravasation or focal enhancing masses. In patients with Crohn’s disease, reconstructing 10-mm, coronal, thick MIP images facilitates the detection of chronic mesenteric vein occlusion.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [43].

It is recommended that the 2018 SAR/American Gastroenterological Association (AGA)/SPR consensus document recommends that a templated, standardized reporting method be used for CTE in Crohn’s disease [44]. Others recommend this as well [18,19,45-47]. Systematic reporting using a template and standardized terms for the findings and conclusions will facilitate communication and allow for outcomes measures. Findings on CTE and MRE are increasingly important in directing both medical and surgical management [48-52]; therefore, consistency in reporting is critical. The report should indicate that CTE was performed specifically indicate that the abdomen and pelvis CT with oral and IV contrast was a CTE examination utilizing neutral oral contrast media. Additionally, every effort should be made to use the standardized terms for radiographic findings of Crohn’s disease as well as the accepted impressions summarizing those findings [44].

As an example, the report should address the following for patients with Crohn’s disease (for non-Crohn’s patients, the template can be adjusted to the specific disease process (eg, suspected small-bowel obscure gastrointestinal bleeding):

- Presence, location, number, and length of disease segments (describe where wall thickening and abnormal enhancement are present)
- Presence of luminal narrowing without and with upstream dilation
- Presence of penetrating disease, including sinus tracts and fistulae
- Presence of inflammatory mass (or phlegmon, a term no longer recommended) and abscess
- Presence of ancillary findings: vasa recta distension, fibrofatty proliferation, perienteric edema, or inflammatory mass, gallstones, renal stones, mesenteric venous thrombosis, saccroiliitis, or avascular necrosis of hips

In the conclusion, the following terms can be used (it should be noted that these terms are currently under consideration by a multidisciplinary group of gastrointestinal radiologists, gastroenterologists, and bowel surgeons and may change over time):

- Active inflammatory small-bowel Crohn’s disease
- Quiescent or inactive small-bowel Crohn’s disease
- Strictures disease with or without findings of active inflammation (This term should only be used if there is both luminal narrowing and upstream bowel dilation ≥3 cm.)
- Penetrating Crohn’s disease (in addition to active or strictureing disease, most often occurs with strictureing disease)

A standardized nomenclature and reporting template for findings is being developed by the Small Bowel Special Interest Group of the SAR in conjunction with gastrointestinal and colorectal surgery societies in order to achieve effective communication. The use of a standardized nomenclature and reporting template will address the important issues in Crohn’s disease.
The impressions for CTE recommended by the SAR/AGA/SPR consensus are:

- Nonspecific small-bowel inflammation
- Active inflammatory small-bowel Crohn’s disease without luminal narrowing
- Active inflammatory small-bowel Crohn’s disease with luminal narrowing
- Crohn’s disease with no imaging signs of active inflammation
- Stricture with imaging findings of active inflammation
- Stricture without imaging findings of active inflammation
- Penetrating Crohn’s disease (often with luminal narrowing or stricture with imaging findings of active inflammation)
- Perianal Crohn’s disease
- Other complications of Crohn’s disease (eg, gallstones, nephrolithiasis, primary sclerosing cholangitis, or aseptic necrosis of femoral heads)
- Other important non-Crohn’s disease findings

For specific issues regarding CT quality control, see the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [26].

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 [53].

A. Performance Parameters

To achieve acceptable clinical CT scans of the small bowel, a CT scanner should meet or exceed the following capabilities [18]:

1. MDCT with detector row ≥16
2. Helical or volume acquisition with appropriate adaptation of pitch so that images of the abdomen and pelvis are acquired in a single breath-hold
3. Scan rotation time: ≤1 sec
4. Minimum slice thickness: <2 mm; maximum slice thickness: 3–4 mm with overlapping reconstructions
5. Limiting spatial resolution: ≥8 lp/cm for ≥32 cm display field of view (DFOV) and ≥10 lp/cm for <24 cm DFOV
6. Creation of multiplanar images (minimum axial and coronal; sagittal images added for disease process)

With the proliferation of dual-energy CT scanners (fast-switch kVp, dual-source or dual-layer, detector based), many sites are beginning to scan patients to create monoenergetic low keV (generally 50 keV) and iodine-map images. Some have found that these scanners more easily and accurately detect disease yet with no increased radiation exposure and with the ability to decrease the volume of iodinated contrast media administered [54,55]. An alternate solution is to utilize low kVp to accentuate areas of abnormal enhancement. This approach is especially useful in smaller patients, whereas in larger patients this may result in greater noise.

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 soft-copy workstation (PACS station) review capability should be available to radiologist and clinicians. CD
or DVD capability also should be available. For additional information on image sharing and security, see the
ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging [56] and the ACR–AAPM–
SIIM Practice Parameter for Electronic Medical Information Privacy and Security [57].

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

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)

Radiation Exposure Dose Issues with CTE

CT contributes the single source of man-made ionizing radiation to the American public, and this
contribution continues to has substantially increased since 2009 [58]. This is of special concern in patients with a
chronic illness such as Crohn’s disease, which often starts in childhood or adolescence, and who are more likely to
undergo frequent imaging examinations.

Several studies have shown that some patients with Crohn’s disease patients can receive large cumulative
exposures doses (over 100 mSv) over the course of their disease and often are examined with CT 2–3 times a year
[59-65]. In one series encompassing a 15-year period of time, the mean ionizing radiation dose was 36.1 mSv. Over
the entire study period there was an increasing use of CT, and although CT accounted for only 16.2% of all imaging
studies, it accounted for 77.2% of the radiation dose. Further in this study, the total ionizing radiation exceeded 75
mSv in 15.5% of the patients [61]. Crohn’s patients with onset of disease before 17 years of age, who have upper
gastrointestinal tract or penetrating disease, who require intravenous steroids or infliximab, or who have had
multiple surgeries receive higher doses. [59,61]. Given the recent evidence that radiation exposure from CT scans in children may result in an increased risk of brain tumors and leukemia [66,67], CT dose optimization reduction remains at the forefront of quality efforts in radiology, especially in pediatric patients. Notwithstanding these observations, however, the benefits of CT far outweigh potential risks in symptomatic patients with Crohn’s disease. Two recent studies have shown that CT in emergency department patients with Crohn’s disease results in substantial patient management changes in a large proportion of these patients (particularly in patients with bowel obstruction and abscesses) [68,69]. Another study showed that about 50% of outpatients with known or suspected Crohn’s disease had their management plans changed as a result of CTE [49]. One of these groups consequently concluded, “These numbers reflect the fact that patients with Crohn’s disease are at high risk for complications given the nature of the disease and the risks of immunosuppression. Although radiation exposure in patients with Crohn’s disease is a concern, clinicians must also weigh the risk of missing a potential urgent diagnosis when they forego a CT” [69]. The medical justification for CTE depends upon the perceived benefit versus risk for any particular patient as well as the availability and clinical feasibility of alternative imaging modalities, such as MRE.

Efforts to reduce the dose from CT are ongoing and include In the last decade, there have been many investigations comparing full or standard exposure CTE with lower exposure CTE utilizing alterations in kVp and mAs appropriate to body habitus, weight, and body mass index (BMI), and altering the scan pitch. These changes can lead to an increase in the image noise that can be offset with newer image reconstruction algorithms, generally called iterative reconstruction, applied to the initial lower-exposure dose images to reduce noise [70-97]. Dose Reductions from CT dose index (CTDIvol) between 15–20 mGy to < 10 mGy, and even below 5 mGy, have been achieved without apparent loss of efficacy. However, these lower-exposure techniques reconstructed with new noise-reducing algorithms often result in images that are unfamiliar to some radiologists. In the research setting, these examinations are often rated by readers as suboptimal or nondiagnostic [70,82]. What is not known is how these images are interpreted in day-to-day practice and whether these lower exposure examinations result in more equivocal interpretations.

It remains to be seen whether sub-millie Sivert imaging is possible without data loss. Crohn’s disease identification in the small bowel is a high contrast issue with CT (ie, identifying a process with a higher attenuation versus background; small bowel wall hyperenhancement is a primary finding in active inflammatory Crohn’s disease). Recent investigations have shown that low contrast objects (an object of lower attenuation versus background) can be lost with lower-dose CT even using iterative reconstruction techniques, including model-based iterative reconstruction [79,87-93,95].

In this evolving field, when CTE is performed, every effort should be made by the protocelling radiologist to reduce the radiation exposure as low as reasonably achievable (ALARA) dose and still achieve a diagnostic examination as low as reasonably achievable (ALARA). Several investigations have already shown that diagnostic examinations can be achieved using lower dose techniques, techniques that result in doses much lower than many radiologists are familiar with, and resulting in examinations that radiologists unfamiliar with the new changes judge as suboptimal or nondiagnostic [70-78].

For radiation exposure dose reduction in patients with Crohn’s disease, a very appropriate alternative to CTE is MRE. Comparisons of the two techniques show equivalent efficacy in detecting both uncomplicated and complicated Crohn’s disease [44]. The advantage of CT is the rapid scan acquisition time and superior spatial resolution. The 3T magnet technology approaches the spatial resolution of CT, but MRE can be more challenging to perform because it is more likely to be affected by patient motion given the longer acquisition times. This is especially an issue for imaging young children and first-time MRI studies on patients. MRE, especially on a 3T, is more susceptible to bowel peristalsis, a problem that can be improved by the use of antiperistaltic agents such as glucagon, hyoscyamine sulfate, or scopolamine butyl bromide, which is not available in the United States. The challenges of MRE are offset by its superior signal-to-noise ratio and excellent tissue characterization when compared with CTE and avoidance of ionizing radiation. Furthermore, multiple pulse sequences can be performed. These advantages make MRE a feasible and viable alternative to CTE.
In many most institutions, adult patients over the age of 18 years with known or suspected Crohn’s disease are imaged with CTE at presentation. This initial examination offers excellent spatial resolution, is unaffected by motion-related artifacts, and provides a baseline study. If subsequent follow-up examinations are indicated, a CTE can be substituted with MRE (see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance (MR) Enterography [22]), depending upon the clinical presentation and scanner availability. Acutely ill patients require rapid imaging in order to exclude an abscess. Thus, CTE is more appropriate in this population. Postoperative patients are best evaluated with CT using positive oral contrast agents in order to exclude an anastomotic leak (oral and/or rectal, positive contrast administration, depending upon the site of the anastomosis).

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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Development Chronology for this Practice Parameter

2015 (Resolution 18)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Abdomen (Excluding the Liver)

Sponsored By: ACR Council Steering Committee

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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 2) *

ACR–SAR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE ABDOMEN (Excluding the Liver)

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 cautions 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 physician or medical physicist 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 those presented.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 826 N.W.2d 831 (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.
INTRODUCTION

Magnetic resonance imaging (MRI) of the abdomen is a proven and useful tool for the evaluation, assessment of severity, and follow-up of diseases of the abdomen. It should be performed only for a valid medical reason. MRI of the abdomen is an evolving technology involving a variety of pulse sequences and protocols that are continuously being modified and improved. Detailed imaging protocols are not presented here to avoid promoting obsolete methodology. This document pertains to the MRI assessment of the abdomen, excluding the liver. For practice parameters pertaining to the liver, see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Liver [1].

The choice of MRI of the abdomen requires an analysis of the strengths of MRI as well as its suitability for each unique the particular patient and particular clinical situation. In patients without a contraindication (see Section IV below), MRI is appropriately used for For characterization of suspected lesions requiring a technique that offers a high degree of soft tissue contrast (lesion characterization requiring high soft-tissue contrast, ), to provide a multiplanar evaluation of a lesion not well depicted on other imaging modalities, and multiphasic contrast enhanced imaging, to provide intravenous contrast-enhanced abdominal imaging in patients who have, a contraindication to iodinated contrast media, including allergy or renal dysfunction MRI benefits from a lack of ionizing radiation, and to perform cross-sectional abdominal imaging without ionizing radiation, MRI might be the procedure of choice provided that the patient does not have a contraindication (See section IV below). See the ACR Guidance Document on MR Safe Practices: 2013 [2] and the ACR Manual on Contrast Media [3].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [2,4].

INDICATIONS

Indications for MRI of the abdomen (excluding the liver) include, but are not limited to, the following:

A. Pancreas

1. Detection of pancreatic masses and preoperative staging in patients unable to receive iodinated contrast media and preoperative assessment of pancreatic neoplasms
2. Characterization of indeterminate lesions and/or unexplained gland enlargement detected with other imaging modalities
3. Identification of causes of pancreatic duct obstruction, including calculi, stricture, or mass
4. Detection and characterization of pancreatic duct anomalies
5. Evaluation of pancreatic or peripancreatic fluid collections or fistulae
6. Evaluation of chronic pancreatitis, including assessment of pancreatic exocrine function, evaluation of complicated acute pancreatitis, and associated complications
7. Postoperative/treatment follow-up after pancreatic surgery
B. Spleen
1. Characterization of indeterminate lesions detected with other imaging modalities
2. Detection and characterization of suspected diffuse abnormalities of the spleen
3. Evaluation of suspected accessory splenic tissue

C. Kidneys, Ureters, and Retroperitoneum
1. Detection of renal tumors
2. Characterization of indeterminate lesions detected with other imaging modalities
3. Preoperative assessment of renal neoplasms to include evaluation of the arterial supply, renal vein, and inferior vena cava
4. Evaluation of the urinary tract for abnormalities of anatomy or physiology (MR urography)
5. Postprocedure surveillance after renal tumor ablation or surgical extirpation via partial or complete nephrectomy
6. Evaluation of ureteral abnormalities
7. Evaluation of suspected retroperitoneal fibrosis and other benign lesions
8. Characterization and staging of retroperitoneal malignant neoplasms
9. Evaluation or follow-up of lymphadenopathy
10. Surveillance imaging of the upper urinary tract in patients with urothelial carcinoma
11. Characterization of complex congenital anomalies
12. Identification of causes of urinary tract obstruction

D. Adrenal Glands
1. Detection of suspected pheochromocytoma and functioning adrenal adenoma
2. Characterization of indeterminate lesions detected with other imaging modalities
3. Staging of malignant adrenal neoplasms
4. Detection and characterization of congenital anomalies

E. Vascular (see the ACR–NASCI–SPR Practice Parameter for the Performance of Body Magnetic Resonance Angiography (MRA) [5]).

F. Bile Ducts and Gallbladder
1. Detection, staging, and posttreatment follow-up of bile duct and gallbladder cancer
2. Detection of bile duct or gallbladder stones
3. Evaluation of bile duct dilation and/or narrowing
4. Evaluation of suspected congenital abnormalities of the gallbladder or bile ducts
5. Detection and anatomic delineation of bile leaks
6. **Delineation of ductal anatomy prior to liver transplantation**
7. **Assessment of post–liver transplant biliary complications**

G. Gastrointestinal Tract and Peritoneum
1. Preoperative assessment of gastric neoplasms
2. Detection of small-bowel neoplasms
3. Assessment of inflammatory disorders of the small or large bowel and mesenteries (including MR enterography); for MR enterography, see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance (MR) Enterography [6]
4. Assessment of peritoneal adhesive disease
5. Detection and evaluation of primary and metastatic peritoneal or mesenteric neoplasms
6. Detection and characterization of intra-abdominal fluid collections as well as follow-up after percutaneous or surgical drainage
7. Second-line imaging tests after an initial ultrasound for diagnosis of acute appendicitis in children and adults, including pregnant women [7-9]

8. Evaluation and follow-up of lymphadenopathy

H. Other

1. Imaging follow-up of abnormalities of the abdomen deemed indeterminate on initial MRI and for which surgery is not advised

2. Detection and characterization of extraperitoneal neoplasms other than those mentioned above

3. Evaluation of the abdomen as an alternative to CT when radiation exposure is an overriding concern in susceptible patients, such as pregnant or pediatric patients or in patients with a contraindication to iodinated contrast agents

4. Assessment of treatment response to medical therapy of malignant neoplasms of the abdomen

5. Determining organ of origin of an indeterminate (benign or malignant) lesion in the abdomen when the origin is not obvious from other imaging modalities

6. Identification and characterization of vascular malformations (see the ACR–NASCI–SPR Practice Parameter for the Performance of Body Magnetic Resonance Angiography (MRA) [5])

7. Evaluation of abdominal wall abnormalities not adequately assessed by other imaging modalities

8. Assessment of traumatic injury of the abdomen when CT is contraindicated

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [10], the ACR Guidance Document on MR Safe Practices: 2013 [2], and the ACR Manual on Contrast Media [3].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [10].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for MRI of the abdomen 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 adequate complete 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, including potential adverse reactions to contrast media. 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 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 on a regular basis 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 by the technologist performing the examination. Patients and any family members or others who will accompany the patient into the MRI suite must be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment. All sites should have an established and documented screening mechanism for establishing MRI compatibility.

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 use (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [11]).

Patients suffering from anxiety or claustrophobia, or who are unable to cooperate or suspend respiration, may require sedation or additional assistance. Administration of sedation may be necessary to achieve a successful examination. If sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [12].

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. Furthermore, regular training on the use of such equipment and medication is recommended for those providing patient care in the MRI environment.

All sites should employ site-access restrictions, with clear demarcation of safety zones I–IV, utilizing signage and physical barriers as appropriate (see the ACR Guidance Document on MR Safe Practices: 2013 [2]).

C. Examination Technique

A phased array surface coil should be used unless precluded by patient body habitus or condition. In pediatric patients, coil selection will depend on patient size and the region being imaged. In small neonates, a surface coil should be considered, whereas infants and children may be imaged with a cardiac, flex torso, or body coil, depending on the size of the abdomen. The field of view (FOV) should be selected to provide the highest resolution possible to include the entire region or organ of interest, allowing for an adequate signal-to-noise ratio (SNR) and minimization of relevant artifacts. Multiple acquisitions with repositioning of the surface coil may be necessary when the region of interest exceeds the potential FOV of the surface coil. For most applications, evaluation of the abdomen should include T1 and T2-weighted images. Acquisitions in multiple imaging planes may be beneficial in defining anatomic relationships. For most applications, slice thickness for acquisitions should not exceed 8 mm, with the interslice gap not exceeding 3–2 mm, although thinner slices and gaps are desirable. In children, slice thicknesses typically range from 3–8 mm, depending on the size of the area to be imaged.

T1-weighted imaging may be performed using an echo train spin-echo (turbo spin-echo [TSE] or fast spin-echo [FSE]) sequence, although the gradient-echo technique is typically favored because it has a much shorter acquisition time sequence. T2-weighted images may be accomplished using one of the echo train spin-echo sequences (TSE or FSE) or a hybrid gradient and spin-echo technique [13]. Fat suppression is frequently beneficial and may be accomplished using short tau inversion recovery (STIR), chemically selective fat saturation, or spectral presaturation inversion recovery (SPIR), or other forms of fat suppression such as water excitation and chemical shift/Dixon-based techniques [14-16].
Although fast gradient-echo T1-weighted images can usually be acquired during breath-holding, some patients are unable to cooperate with even short breath holds. Compressed sensing, often in combination with parallel imaging (PI) and view sharing or non-Cartesian acquisition, is a technique offered by multiple vendors that allow dramatic reduction in scan time and even free-breathing dynamic postcontrast imaging [17-19]. The duration of conventional and FSE T2-weighted imaging is often too long for complete acquisition during breath holding. Breath-hold techniques can be used for T2-weighted imaging if the scan time is reduced by a) long echo trains, b) partial-Fourier imaging, c) use of PI techniques, and/or d) dividing the volume of interest into several smaller volumes that can each be imaged in individual breath holds. Traditional strategies to reduce respiratory motion during free-breathing image acquisition include respiratory compensation (respiratory-ordered phase encoding), respiratory triggering with respiratory bellows, the use of navigator pulses [20,21], the acquisition of k-space data in concentric rectangular strips [22] and signal averaging. Familiarity with these methods is helpful when scanning young children or other patients who may not be able to follow breath-hold commands, as well as sedated/anesthetized patients. Other advances that can reduce imaging times and/or correct for motion include the acquisition of k-space data in concentric rectangular strips [22].

Inclusion of at least one in-phase and out-of-phase gradient-echo sequence is useful for detecting intracellular lipid within certain adrenal (eg, adenoma) and renal (eg, clear-cell carcinoma) tumors and to confirm fatty infiltration of organs, such as the pancreas [23-27]. The technique can also be useful for the detection of hemosiderin, such as can occur in renal masses, or other sources of susceptibility artifact [28,29]. A single dual-echo gradient-echo sequence is more effective than separate gradient-echo sequences that differ in echo times (TEs) because the former will depict the exact same anatomy, without misregistration artifacts. It is essential that the out-of-phase TE is shorter than the in-phase TE so that signal reduction on the out-of-phase TE will be unambiguous evidence of lipid content. Breath-held dual-echo sequences are generally preferable. These may be either T1-weighted or proton density-weighted sequences.

Three-dimensional (3-D) techniques are available for both T1 and T2-weighted imaging. Numerous advantages over traditional two-dimensional (2-D) sequences include higher inherent SNR, higher in-plane and through-plane resolution, and homogenous fat suppression, most of which are better realized in T1-weighted imaging. Isotropic voxel dimensions allow for multiplanar reconstructions that may obviate the need for additional acquisition in other planes. Several publications have illustrated the value of T2-weighted 3-D imaging for the depiction of complex anatomy and volumetric imaging [30-32].

IV contrast enhancement with gadolinium chelates is gadolinium-based contrast agents (GBCAs) are beneficial to detect and characterize many intra-abdominal neoplasms, vascular abnormalities, and inflammatory processes. However, the use of those agents gadolinium may be omitted when noncontrast images are sufficiently diagnostic if, in the opinion of the supervising physician such that the administration of IV contrast is unlikely to be of further benefit to the patient or where the risks of the administration outweigh the potential benefits. IV contrast may also be omitted when there is a) no IV access, b) a history of prior allergic-like type reaction to GBCAs gadolinium chelates and the patient has not been premedicated, c) a relative contraindication exists to parenteral exposure to gadolinium chelates (such as, eg, pregnancy), d) severe renal insufficiency with an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m² or acute renal injury insufficiency of any severity, or e) known or suspected diagnosis of nephrogenic systemic fibrosis. Of note, is for an eGFR of 15–30, many practices are now opting to perform a clinically indicated contrast-enhanced MR examination utilizing a macrocyclic GBCA gadolinium agent. Detailed information that can help in forming practice-specific policies regarding handling of GBCA gadolinium administration is provided in the ACR Manual on Contrast Media [3].

Multiphase contrast-enhanced sequences acquired through the abdomen are commonly (including composed of precontrast, arterial, venous, and delayed phase images, which are beneficial for evaluating various blood vessels and tumors of the solid organs tumors [33,34]. Subtraction images may also be generated, which can aid in identifying tumor enhancement [35]. Postcontrast enhanced imaging may be performed with a 2-D or 3-D
technique. 3-D imaging allows isotropic or near-isotropic resolution and facilitates multiplanar reconstructions [36]. The use of fat suppression during dynamic contrast-enhanced, T1-weighted imaging is strongly encouraged, as it improves the conspicuity of enhancing structures and abnormalities. Fat suppression can typically be accomplished using chemically selective fat-frequency selective saturation techniques, water excitation, or chemical shift/Dixon techniques. STIR–inversion recovery sequences should be avoided for gadolinium-enhanced T1-weighted postcontrast imaging, as the relative enhancement of tissues due to gadolinium is that falls within the nulling range for fat is also suppressed by this technique.

Specific timings and adjunctive measures in dynamic contrast-enhanced imaging can be employed for particular applications. For instance, delayed postcontrast T1-weighted imaging (5 minutes or later greater after extracellular-gadolinium-based contrast administration of extracellular GBCA) can be useful in excretory MR urography for detecting pathology of the urinary tract (excretory MR urography) [37,38], and IV hydration and/or diuretic administration has been shown to improve visualization of the nondilated collecting system [39] and ureters [40] during excretory MR urography. Delayed imaging with extracellular gadolinium-based agents may also be useful in diagnosing cancer of the biliary system [41]. Note that different GBCAs intravenous gadolinium chelates that allow are targeted toward visualization of particular organs and organ systems are available. Specifically, hepatobiliary agents (eg, gadoxetate disodium, gadobenate dimeglumine) localize to the liver and biliary tree, and fat-suppressed T1-weighted imaging during the hepatobiliary phase (timing varies depending on the agent) provide images based on hepatocyte uptake and biliary excretion of these agents [42]. (See the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Liver [1].) Similarly, blood-pool agents target the vascular system on postcontrast T1-weighted imaging [43].

The addition of a heavily T2-weighted MR cholangiopancreatography (MRCP) sequence may be beneficial for evaluating the biliary and pancreatic ducts [41-43]. Such heavily T2-weighted sequences may also serve to evaluate dilated renal collecting systems (static-fluid MR urography) [34,44] as well as in the evaluation of the lymphatic system to demonstrate pathologic lymphatic structures and the presence and distribution of lymphatic fluid in different body cavities [45,46].

The use of secretin has been shown to significantly improve visualization of the pancreatic duct during MRCP, which can aid in the diagnosis of anatomic variants [44-46], chronic pancreatitis [47,48], and side-branch intraductal papillary mucinous neoplasms [49]. Secretin has also been used to measure pancreatic exocrine function [50,51]. T2-weighted imaging can be performed using a rapid acquisition relaxation enhancement (RARE) or half-Fourier single-shot echo train spin-echo sequence. These sequences can be performed as a thick slab acquisition in multiple projections or as multiple thin (< 5 mm) slices in at least one imaging plane during breath holding. 3-D respiratory triggered T2-weighted FSE techniques can also be used, potentially offering improved SNR and isotropic spatial resolution [52]. Additional sequences, such as postcontrast T1-weighted and FSE T2-weighted sequences, can aid in the assessment of periductal tissues, the evaluation for causes of extrinsic ductal compression, and the staging of cholangiocarcinoma [54,55].

The use of an oral contrast agent for MRI of the abdomen is considered optional but may occasionally be beneficial for gastrointestinal imaging [47]. For MR enterography, see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MR) Enterography [6]. Negative oral contrast agents may be helpful in selected cases to suppress signal and reduce artifact from bowel contents when imaging other organs or structures, such as the peritoneum, pancreaticobiliary tree, or urinary system. When using oral contrast media for assessing the small bowel and its serosal surface, a nonabsorbable agent that produces a dark enteric lumen on T1-weighted images is recommended to distend the bowel and optimize detection of mural enhancement after IV administration of GBCA a gadolinium chelate. Administration of spasmylic agents, such as glucagon [48], can reduce peristalsis and its resultant motion artifact. This can be particularly helpful for contrast-enhanced fast gradient-echo T1-weighted imaging of the bowel [49] or for evaluating the mesentery and peritoneal surfaces [50].
The addition of a heavily T2-weighted magnetic resonance cholangiopancreatography (MRCP) sequence may be beneficial for evaluating the biliary and pancreatic ducts [51-53]. The use of secretin has been shown to significantly improve visualization of the pancreatic duct during MRCP, which can aid in the diagnosis of anatomic variants [54-56], chronic pancreatitis [57,58], and side-branch intraductal papillary mucinous neoplasms [59] and in quantifying pancreatic exocrine function [41,60]. T2-weighted imaging can be performed using a rapid acquisition relaxation enhancement (RARE) or half-Fourier single-shot echo train spin-echo sequence. These sequences can be performed as a thick slab acquisition in multiple projections or as multiple thin (less than 5 mm) slices in at least one imaging plane during breath-holding. Three-dimensional respiratory triggered T2-weighted FSE techniques can also be used, potentially offering improved SNR and isotropic spatial resolution [61]. Such heavily T2-weighted sequences may also serve to evaluate dilated renal collecting systems (static fluid MR urography) [37,62]. Additional sequences, such as postcontrast T1-weighted and FSE T2-weighted sequences, can aid in the assessment of periductal tissues, in the evaluation for causes of extrinsic ductal compression, and in the staging of cholangiocarcinoma [63,64].

Steady-state free-precession (SSFP) sequences display bright fluid and blood while minimizing motion and flow-related artifacts. Such sequences can provide a rapid abdominal survey [65] and can be useful for cine imaging of the bowel during MR enterography and for demonstration of intra-abdominal adhesions [65-68].

3T imaging systems have become widely available, and potential advantages include increased SNR [69], increased conspicuity of enhancement after administration of a gadolinium chelate [70], and more rapid chemical shift-type sequences (based on shorter in-phase and out-of-opposed-phase TEs compared with 1.5T). Potential disadvantages include decreased image contrast on T1-weighted images, increased susceptibility artifact, increased chemical shift artifact, increased specific absorption rate (SAR), and standing wave phenomena from signal B1 inhomogeneity [71]. The latter can be partially compensated for by the use of radiofrequency cushions [72]. In short, 3T imaging can offer substantial improvements in SNR and spatial resolution and/or decreases in imaging times, but careful sequence optimization is required to maintain desired image contrast and reduce artifacts [73,74].

PI techniques take advantage of spatial sensitivity information from multiple independent receiver coil elements in order to reduce the number of phase encoding steps, thereby reducing scan times [75]. Parallel imaging (PI) techniques These can also expand the options for breath-hold imaging and provide shorter effective TEs and decreased blurring on echo-train sequences, such as single-shot FSE. The primary penalty of this method is that this time savings is reduced SNR [76]. However, there is a potentially synergistic effect between PI and imaging at 3T: 1) the decreased SNR inherent to PI is partially offset by the increased SNR of 3T, and 2) the SAR issues inherent to 3T can be offset by a reduced number of excitations [77]. Recently, 2-D PI techniques have become available, which provide higher-order acceleration factors by reducing the number of measurements required to fill k-space in both the phase and partition directions [78,79]. Emerging applications are also being developed with other means of image acquisition acceleration, such as non-Cartesian kernels and simultaneous multislice techniques (SMS) [80].

Diffusion-weighted imaging (DWI) can be utilized for abdominal application [81]. Most research to date has centered on oncologic applications, either for staging disease or monitoring response to therapy [82-88]. The most common technique uses single-shot echo-planar imaging (SS-EPI). Breath-held, free-breathing multiple-averaging, and respiratory-gated SS-EPI techniques have been described [89,90]. PI can be used to decrease imaging time, reduce susceptibility-related signal loss by shortening the effective TE, and has been shown to result in accurate apparent diffusion coefficient (ADC) values [91]. DWI has shown promising results in early research and at least appears to be a value-added adjunct sequence capable of improving lesion detection and characterization, as restricted diffusion can be quite sensitive in suggesting the presence of hypercellularity, such as with small metastases or the purulent core of an abscess, and is useful in examinations for which IV contrast is not or cannot be utilized revealing additional sites of disease in the abdomen [92]. There is also increasing evidence of its utility in the evaluation of infectious and inflammatory processes, possibly obviating the need for IV gadolinium-based contrast in the study of inflammatory bowel disease during MR enterography and for the diagnosis of acute appendicitis and its postoperative complications [93-99]. ADC maps can be generated to help
differentiate between restricted diffusion and T2 shine-through when at least 2 b-values are obtained, including such as \( b = 0 \) to 50 s/mm\(^2\) and \( b = 500 \) to 1,000 s/mm\(^2\). Many vendors offer computed DWI, in which additional higher b-value images are generated from a set of measured \( v \)-values by voxel-wise fitting, thus providing images with greater diffusion weighting in less time and with higher relative SNR than directly acquired DWIs [100]. In addition, more complex models of diffusion, such as the intravoxel incoherent motion (IVIM) model, have shown the potential to separate perfusion effects from true restricted diffusion values and may provide more robust measures of diffusion compared with the ADC model [101].

**V. DOCUMENTATION**

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [102].

**VI. EQUIPMENT SPECIFICATIONS**

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance (MR) Imaging Equipment [103].

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 magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

**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, 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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Collaborative Committee Members represent their societies in the initial and final revision of this practice parameter.

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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 Parameters and Technical Standards was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

2005 (Resolution 5)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 16)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 2)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance (MR) Enterography

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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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.
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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

Magnetic Resonance enterography (MREnt) is a proven and useful tool for the diagnosis, assessment of severity and complications, and follow-up of small-bowel disease of diseases of the small bowel [1-10]. MREnt is especially useful and is most widely used in patients with inflammatory bowel disease (IBD), particularly Crohn’s disease (CD). MREnt is a noninvasive imaging test that does not employ ionizing radiation. For these reasons MREnt may be considered a primary imaging modality for patients, especially the pediatric and young adult population, patients with IBD who require repeated imaging for disease assessment and therapeutic monitoring [11,12]. Performance of MREnt requires adequate technical and clinical expertise and may not be appropriate for routine use in centers that do not possess this skillset.

II. INDICATIONS

Indications for MREnt include, but are not limited to, the following:

1. Diagnosis of IBD, including assessment of disease activity, and extent, and distribution.
2. Follow-up of known IBD, including assessment of disease activity and response to therapeutic intervention.
3. Evaluation of suspected IBD-related complications, such as stricture and obstruction or penetrating disease (eg, fistula, sinus tract, or abscess). High-resolution pelvic MRI sequences may be added to the routine MREnt or obtained as a separate examination for dedicated evaluation of perianal disease.
4. Differentiation of CD from ulcerative colitis in children with “indeterminate colitis,” searching for features that are more characteristic for CD, which include transmural and periserosal disease, terminal ileal or other small-bowel involvement, asymmetric involvement of the mesenteric border of the small bowel, associated penetrating complications (eg, fistulas or sinus tracts), lack of involvement of the rectum and distal large bowel, or skip lesions.
5. Nonemergent evaluation of suspected bowel disease with prior negative computed tomography (CT) examination and/or endoscopy, or in place of these other tests, and including a variety of disease processes, such as subacute bowel obstruction or non-IBD enteritis (eg, due to infection or vasculitis)
6. Evaluation of polyposis syndromes and small bowel mass(es)

MREnt protocols are specifically tailored to allow detailed assessment of the small intestine. However, in some IBD patients, additional evaluation of IBD-related diseases or conditions may be desired at the time of MREnt. Variations in MREnt scanning protocols, usually requiring added pulse sequences, can allow for concurrent appraisal of the pancreatobiliary tree (eg, in the setting of a known or suspected sclerosing cholangitis), perianal/perineal region (eg, in the setting of known or suspected perianal fistula or abscess), and sacroiliac joints. Although additional imaging will lengthen the MREnt examination and increase the likelihood of motion-related artifacts due to patient discomfort and/or pain, this approach may be desired when imaging is to be performed under sedation or general anesthesia (eg, in the pediatric population). However, combined studies should be performed in a manner that does not adversely affect image quality or overall diagnostic performance of either examination.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [13].
IV. SPECIFICATIONS OF THE EXAMINATION

The supervising physician must have complete 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, including potential adverse reactions to contrast media. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing the MRI interpretation must be knowledgeable about have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The written or electronic request for MREnt 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 that are used and their imaging appearance, including the appearance of image artifacts. Standardized imaging protocols should be established but may be 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.

The majority of MREnt examinations require the administration of intravenous (IV) gadolinium-based contrast media (GBCA) [14,15]. IV GBCA administration contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution’s policy on IV contrast utilization (see the ACR-SPR Practice Parameter for the Use of Intravascular Contrast Media [16]). Noncontrast examinations may be considered in select cases in which the presence/absence of active bowel inflammation is the only clinical question and it is felt that the clinical question may be resolved with T2-weighted (T2W) fat-suppressed sequences and/or diffusion-weighted imaging (DWI) [17-19]. Noncontrast examinations may also be considered in patients with contraindications to IV GBCA contrast administration, such as during pregnancy or diminished renal function.

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. Physicians working in or near the MRI area must have current training in MRI safety, preferably Level 2 training [20], as well as the management of contrast reactions.
C. Patient Preparation

Bowel preparation is generally regarded as helpful for improving the diagnostic performance of MREnt [21-24]. The goal of bowel preparation is to 1) achieve maximal distension of bowel loops to minimize false-positive instances of bowel-wall thickening, 2) improve the visibility of mural postcontrast enhancement, luminal disease; 3) reduce bowel peristaltic activity to improve the diagnostic quality of motion-sensitive MR sequences, and 4) displace air within bowel loops that can cause susceptibility artifacts on gradient-echo sequences.

Oral contrast may be administered to patients prior to MREnt to improve small-bowel distension. Patients may be asked to fast 4 to 6 hours prior to the examination to improve compliance with ingestion of enteric contrast preparations and minimize filling defects within the small bowel. Though the types and volumes of enteric contrast may vary across centers, oral contrast agents should provide some osmotic effect to prevent water absorption by the gut, and a viscosity agent to promote distension. In addition, the generally favored contrast agents should be biphasic, demonstrating bright signal on T2W images and dark signal on T1-weighted (T1W) images, to achieve maximum contrast with the bowel wall. This is especially important on T1W postcontrast sequences in which the bowel wall will enhance and the distended lumen will remain low signal [25-27]. Patient compliance with enteric contrast (especially pediatric patients) can be improved by contrast refrigeration and flavor additives, although caution should be employed with color additives if contemporaneous endoscopy is planned. A defined time delay from administration of oral contrast to imaging allows for adequate distal passage of contrast to the terminal ileum prior to image acquisition. The amount of contrast and the specified time delay may vary according to center-specific experience. A recommendation is to follow prescriptions as used for CT oral contrast administration at the corresponding imaging facility. Rectal contrast may assist in visualization of the ileocecal junction [25].

Antiperistalsis medications may also be administered prior to and during the imaging examination. An oral, over-the-counter liquid anticholinergic agent may be mixed with the patient’s enteric contrast to reduce bowel motility [28-31]. Administration of IV glucagon as a spasmylytic agent is a commonly employed method to reduce bowel motion artifact [31]. However, because of the short-acting half-life of glucagon, it is recommended that it be administered immediately prior to motion-sensitive sequences (typically T1W dynamic contrast-enhanced sequences), which may require interruption of image acquisition; both intramuscular (IM) and IV routes of administration are available. IM administration is longer lasting but less reliable [32]. Evaluation for any potential contraindications or drug interactions should be investigated prior to administration.

Enteroclysis is an invasive method for improving small-bowel distension through intubation of the jejunum with a nasojejunal feeding tube and direct administration of enteric contrast through the tube [23,33]. Though enteroclysis may provide increased small-bowel distension more reliably compared with routine oral contrast administration [33], the impact on clinical decision-making pathways has not been well documented [34]. For this reason, enteroclysis is not considered an absolute requirement for routine applications of MREnt. Furthermore, dedicated colon cleansing and administration of rectal contrast is another potential patient preparation step that may be considered on a case-by-case basis [35,36].

D. Examination Technique

A phased array surface coil should be used unless precluded by patient body habitus. The field of view should be selected to cover as much of the bowel as possible, ensuring the inclusion of the anal region while providing the highest possible signal-to-noise ratio with adequate spatial resolution. The patient may be imaged prone or supine. Although some centers have found prone imaging to improve bowel motion artifacts effects and bowel separation, there is no a-consensus on this point, and there are patients who will prefer supine positioning for comfort. Prone positioning may also be uncomfortable for patients with a stoma device and should be avoided in these instances. Adequate performance of MREnt requires imaging in both the axial and coronal planes; imaging in the coronal plane is a key feature of MREnt, allowing for maximum visualization and inclusion of bowel loops in each slice, with optimum display of the terminal ileum. For most applications, MREnt should include both T1W, and T2W, and, if available, DWI [9,14,17,37-40].
T2W imaging may be performed with an accelerated spin-echo sequence (turbo spin-echo (TSE) or fast spin-echo (FSE)), gradient-echo (GRE) sequence, or a hybrid gradient and spin-echo (GRASE) technique. Given the motion effects of a contracting bowel that cannot be corrected with breath-holding or triggering techniques, motion-insensitive fast spin-echo (FSE) T2W imaging with acquisition of all necessary phase lines in one repetition time (TR) interval (“single shot” technique) is the most reliable method for T2W imaging of the bowel. Slice thickness is typically 4 - 7 mm, and the interslice gap should not exceed 10% of the slice thickness.

T2W imaging is a fluid-sensitive sequence that is used for identifying fluid collections, edema, fluid-filled fistulas and sinus tracts. T2W imaging with fat suppression is a key component of MREnt for identifying evaluation of active bowel wall and mesenteric edema, which are signs of active inflammation. Fat suppression may be accomplished through a variety of techniques, including short tau inversion recovery (STIR), chemically selective fat saturation, water excitation, or Dixon-based methods. Spectral adiabatic inversion recovery (SPIRA) fat suppression is a newer technique that combines elements of both inversion recovery and chemical fat suppression techniques to provide an extremely a very reliable and robust degree of fat suppression while continuing to preserve water signal [19,41,42].

T1W imaging may be performed using a 3-D accelerated gradient-echo with fat suppression, or accelerated spin-echo (TSE or FSE) methods. Three-dimensional (3-D) image acquisition methods are available for both gradient-echo or spin-echo sequences, allowing for higher through-plane resolution, improvements in SNR and more homogeneous fat suppression. Use of surface coils is important for improved signal. T1W 3-D gradient-echo acquisitions have the advantage of rapid acquisitions within a breath-hold, reducing breathing-motion artifact without the need for time-consuming respiratory navigation and triggering techniques. These acquisitions should be no longer than 15-19 seconds. However, antiperistaltic agents, administered prior to T1W 3-D imaging, are recommended to reduce bowel peristalsis and bowel wall motion artifacts. These acquisitions should be no longer than 15-19 seconds. Radial acquisition methods, such as radial 3-D gradient-echo (GRE) sequences, are also available for patients that are less sensitive to image deterioration from bowel peristalsis and breathing motion and may be used in patients unable to hold their breath at all [43,44].

IV contrast enhancement with GBCAs gadolinium chelates is an important component of a comprehensive MREnt examination, especially for the accurate diagnosis and detection of bowel wall inflammation delineation of chronic bowel disease and fibrotic strictures, fistulas, abscesses, and perianal fistulas. Every Standard extracellular GBCAs should be used because there is no benefit in using a liver-uptake GBCA or blood pool agent. Attempts should be made to use IV contrast material except when there is 1) no IV access, 2) history of prior allergic-type reactions to GBCAs gadolinium chelates and the patient has not been premedicated, 3) relative contraindication to gadolinium chelates (such as pregnancy), or 4) known or suspected nephrogenic systemic fibrosis (NSF) or particular concerns regarding NSF risk that may outweigh the benefits of a contrast-enhanced MREnt examination. The standard MREnt examination will include multiple dynamic postcontrast phases, which ideally would include a late arterial or enteric phase and portal venous phase usually obtained in the coronal plane. Axial and coronal Venous and delayed phase postcontrast images obtained at least 2 minutes or up to several minutes after the start of the injection in both the axial and coronal plane. are also the key sequences to depict fibrosis within the bowel wall, which will appear thickened and will retain contrast [1,3,45-48]. Similarly, late enhancement is a feature of fibrotic adhesions that may be associated with tethered bowel loops or fistula [49].

DWI can be an important component of an MREnt examination and should be performed if possible. DWI evaluates for abnormal water mobility in tissues. With DWI, ideally, multiple b-values (eg, b-values of 0, 20, and 800 s/mm²) are obtained, having varying degrees of diffusion weighting as well as an apparent diffusion coefficient (ADC) map. Low b-value images (eg, 20 s/mm²) can be used to identify edema and fluid. High b-value images of at least 500 s/mm² can be used to identify bowel wall inflammation, abscesses, and lymph nodes that will have high signal intensity on high b-value images and low signal on the ADC map. DWI sequences may be additionally helpful in MREnt examinations in which IV GBCAs cannot be administered, in addition to fat-suppressed T2W imaging (which is essential for the detection of edema and inflammation).

Additional MR sequences, although considered optional, may provide added value to bowel imaging. Dynamic, real-time cine MRI of the bowel may be obtained by a heavily T2W coronal slab or a single-shot balanced

PRACTICE PARAMETER 5 MR Enterography 2020 Resolution No. 26
steady-state free-precession sequence or a heavily T2W coronal slab centered over a region of interest [50-52]. Repeated image acquisitions over time with these techniques may be used to produce real-time cine imaging of the bowel to evaluate bowel motility and also aid in evaluating of any the potential functional significance of fibrotic strictures and fixed luminal narrowing. However, even in the absence of real-time cine images, comparison of different sequences that are acquired at different time points during the study acquisition or over multiple examinations is helpful to discern bowel peristalsis from a fixed fibrotic stricture. A quantitative perfusion sequences are is an additional MRI technique that may can be performed for bowel imaging [17,53-57]. DWI detects abnormally restricted water motion, and these images can show areas of inflamed bowel wall and adjacent soft tissue. Quantitative perfusion may be able to help discriminate between inflammation or fibrosis in a region of abnormally thickened bowel wall, where inflammation leads to increased vascularity and accelerated contrast arterial phase enhancement.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [58]. 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 the potential hazards associated with 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.

VI. EQUIPMENT SPECIFICATION

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance (MR) Imaging Equipment [16]. 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 magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels. Additional considerations include the use of surface coils that can provide coverage of the entire abdomen and pelvis. In addition, it may be commonly necessary to use at least 2 fields of view (FOV) to capture all of the entire abdomen and pelvis. Acquisition and postprocessing of these images may be facilitated by systems with specific software that allows merging of at least 2 imaging fields.

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, 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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Members represent their societies in the initial and final revision of this practice parameter.

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PRACTICE PARAMETER 7
MR Enterography
2020 Resolution No. 26
NOT FOR PUBLICATION, QUOTATION, OR CITATION

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RESOLUTION NO. 27
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Liver

Sponsored By: ACR Council Steering Committee

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Revised 2015 (Resolution 3) *

ACR–SAR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE LIVER

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.

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I. INTRODUCTION

Magnetic resonance imaging (MRI) of the liver is a proven and useful tool for the evaluation, assessment of severity, and follow-up of diseases of the liver. Although liver MRI is one of the most sensitive diagnostic tests for detection and characterization of hepatic lesions, findings may be misleading if not closely correlated with the results of previous imaging studies, clinical history, physical examination, or laboratory tests. Adherence to the following parameters will enhance the probability of accurately assessing such abnormalities.

II. INDICATIONS

Indications for MRI of the liver include, but are not limited to, the following:

1. Detection of focal hepatic lesions
2. Focal hepatic lesion characterization (eg, cyst, focal fat, hemangiomas, and vascular malformations), hepatocellular carcinoma (HCC), hepatoblastoma, metastasis, \textit{intrahepatic} cholangiocarcinoma, focal nodular hyperplasia, and hepatic adenoma
3. Evaluation for known or suspected metastases, \textit{metastasis including preoperative mapping for liver resection}
4. Evaluation of vascular patency, including Budd-Chiari and portal vein thrombosis
5. Evaluation and \textit{noninvasive quantification} of iron, fat, and fibrosis in chronic liver disease, such as hemochromatosis, hemosiderosis, or steatosis \textit{nonalcoholic steatohepatitis, (NASH) and hepatitis in adults and pediatric patients}
6. Evaluation of cirrhotic liver and HCC surveillance
7. Clarification of findings from other imaging studies, laboratory abnormalities, or alternative imaging for contraindications to CT scans
8. \textit{Staging of liver and biliary cancers, including assessment of vascular and biliary invasion}
9. Evaluation of infection
10. Potential liver donor evaluation, liver resection evaluation, liver transplant evaluation, and evaluation of postsurgical complications
11. Evaluation of tumor response to treatment, eg, image-guided liver interventions/tumor ablation, chemoembolization, radioembolization, chemotherapy, radiotherapy, or surgery
12. Evaluation of known or suspected congenital abnormalities
13. Informing or guiding clinical decision making and treatment planning

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the \textit{ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI)} [1].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for MRI of the liver 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 radiology physician must have complete 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, including potential adverse reactions to contrast media. 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 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. It is also critical to understand the different contrast agents used for liver MRI as well as the basis for choosing between them. 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 (see the ACR Guidance Document on MR Safe Practices: 2003 [2]).

Certain indications require administration of intravenous (IV) contrast media. IV contrast administration should be performed using appropriate injection protocols and in accordance with the institution’s policy on IV contrast utilization (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [3]).

Patients suffering from anxiety or claustrophobia or who are unable to cooperate or suspend respiration, such as children, may require sedation or additional assistance. Administration of sedation may be necessary to achieve a successful diagnostic examination. If sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [4] and the American Academy of Pediatrics (AAP) - American Academy of Pediatric Dentistry(AAPD): Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic procedures [5].

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

A phased array surface coil should be used [6] unless precluded by patient body habitus or scan indication. The field of view should be selected so that it includes the entire liver without introducing undesirable artifacts.

An adequate MRI examination of the liver is typically performed in the axial plane, and coronal plane images are added as necessary to improve the visualization of the liver dome, evaluate vasculature, and bile ducts and to facilitate interventional and surgical planning.

An adequate satisfactory MRI examination of the liver should include T2-weighted imaging, which may be performed with an accelerated fast spin-echo, or single-shot accelerated fast spin-echo (FSE), half-Fourier single-shot turbo spin-echo (HASTE) or single-shot fast spin-echo (SSFSE) or steady-state free precession sequence (in axial and/or coronal planes). T2-weighted images can be obtained using a breath-hold or non-breath-hold technique. When a non-breath-hold technique is used, every effort should be made to minimize the respiratory motion artifacts by using multiple signal averages and/or respiratory compensation or respiratory triggering, which could include bellows or navigator-triggered sequence. Other motion-correction strategies, including periodically rotated overlapping parallel lines, with enhanced reconstruction (PROPELLER), may be useful. For effective T2-weighting, an echo time (TE) between approximately 80 and 100 ms should be used at 1.5T and 70–100 ms at 3T. T2-weighted images are helpful to show abnormal increased fluid or inflammation content in diseased tissue and fluid-containing lesions (eg, cysts, biliary hamartoma, hemangiomas, and vascular malformations) [7]. When using a 2-D technique, the slice thickness and interslice gap in one of the planes should not exceed 8 and 2 mm, respectively. Parallel MRI with suitable phased-array coils is often used to reduce scan time and increase spatial resolution. Fat suppression may be helpful to assess for fluid and inflammation and to improve image contrast and dynamic range.

IV contrast enhancement with gadolinium chelates is critical for accurate diagnosis of various liver pathologies [8]. Every attempt should be made to use of IV contrast should be strongly considered except when there is a) no IV access, b) history of prior allergic-type reaction to gadolinium chelates and the patient has not been premedicated prior to the study, c) contraindication to gadolinium chelates (such as pregnancy), d) known or suspected nephrogenic systemic fibrosis (NSF) or particular concerns regarding NSF risk that outweigh the benefits of a contrast-enhanced liver MR, or e) contrast is not felt to be necessary for the diagnosis in question [2,9,10]. In patients with a high risk of NSF in whom contrast is not used, an unenhanced MR could still be helpful to assess the patient. Long-term safety of gadolinium-based contrast agent (GBCA) administration is not yet established, especially in young infants. A cautious risk/benefit approach is desirable with avoidance of GBCA when feasible in young infants. When contrast administration is required, lower dosing and macrocyclic agents should be considered. Dynamic fat-suppressed MRI should be performed after bolus administration of a gadolinium chelate contrast agent. T1-weighted images should be acquired before gadolinium contrast injection as well as during late hepatic arterial, portal venous, and 2- to 5-minute delayed phases using a 2-D or 3-D technique [11,12]. The 3-D techniques are preferred. Methods to obtain late hepatic arterial phase include using a bolus timing technique, such as automated bolus detection algorithm or fluoroscopic triggering, or obtaining multiple consecutive arterial-phase data sets with higher temporal but lower spatial resolution. An optimal late arterial phase is characterized by the following:

- Hepatic artery and branches are fully enhanced
- Hepatic veins not yet enhanced by antegrade flow
- Portal vein is enhanced

Additional delayed images with delays greater than 2 to 5 minutes may help characterize certain lesions, such as HCC, hemangiomas, and vascular malformations, or intrahepatic cholangiocarcinomas [13-15]. Fat-suppressed volumetric interpolated breath-hold images 3-D T1-weighted gradient-echo images have quality comparable to that of conventional fat-suppressed 2-D gradient-echo images [16]. It is advantageous to acquire 3-D data sets using the smallest voxel dimensions possible to achieve the highest resolution practical in each axis. Minimizing slice
thickness of a volumetric acquisition can reduce truncation artifacts in the axis of slice encoding, which can be a source of boundary artifacts at high-contrast borders. When using a 2-D technique, the slice thickness and interslice gap should not exceed 8 and 2 mm, respectively.

To aid in the detection of contrast-enhanced lesions, subtraction of unenhanced from contrast-enhanced images may be considered for lesions that are hyperintense on T1-weighted images prior to gadolinium administration, for example, in cases of hepatic lesions following locoregional therapy radiofrequency ablation or chemoembolization and T1 hyperintense nodules within cirrhotic livers. Efforts should be made to ensure that patients’ respirations are suspended in an identical manner during precontrast and postcontrast dynamic phases. However, misregistration artifacts have to be excluded to minimize erroneous interpretation of subtraction images. Other methods for postcontrast sequences include the combination of compressed sensing, radial sampling, and parallel imaging, which allow high-quality scans to be obtained during free breathing. This has several advantages; for instance, it is possible to perform free-breathing dynamic contrast-enhanced MRI in children or in patients who are ill, uncooperative, or hard of hearing [17].

The use of Hepatobiliary phase (HBP) images obtained between 45 min and 3 hours after the administration of gadobenate dimeglumine and approximately at least 20 minutes after the administration of gadoxetate disodium revealing retention of contrast within the lesion can confirm the diagnosis of focal nodular hyperplasia [18-20]. HBP images and can also be used to detect and characterize malignant disease and assess its extent [21-23]. The use of hepatobiliary agents partially excreted in the biliary system, such as gadoxetate and gadobenate, can help delineate biliary anatomy [26-28]. When interpreting HBP images, it is important to ascertain the adequacy for diagnosis. For an adequate HBP image in patients without chronic liver disease, the liver parenchyma is unequivocally brighter than the intrahepatic blood vessels; otherwise, the HBP images are considered suboptimal. Poor enhancement of hepatic parenchyma may be seen in some patients with chronic liver disease. The use of hepatobiliary agents may not be advisable in patients with total bilirubin of greater than 2 mg/mL [24-26]. The use of hepatobiliary agents (gadoxetate and gadobenate) partially excreted in the biliary system such as gadoxetate and gadobenate can help delineate biliary anatomy [26-28]. T2-weighted imaging of the biliary tree (Magnetic resonance cholangiopancreatography (MRCP) images) must be completed before contrast is excreted into bile ducts because gadolinium within the enhanced bile will can shorten the T2 and result in the biliary tree not being visible not be visible on MRCP images. This can be prevented by obtaining MRCP images before or within 5 minutes after administration of gadoxetate or within several minutes after administering gadobenate dimeglumine. T2-weighted and diffusion-weighted images can be obtained after injection of gadoxetate disodium to improve time efficiency, and diffusion-weighted imagining (DWI) sequences may be delayed more than 5 minutes after HBP agents.

In-phase and out-of-phase chemical shift gradient-recalled echo T1-weighted imaging should be included for lesion characterization and is a sensitive technique for confirmation of hepatic steatosis and iron overload; these sequences should be obtained prior to the administration of IV contrast material [27]. Out-of-phase images can be helpful to assess for signal loss from fat in fat-containing lesions, such as hepatic adenomas and HCC. Every effort should be made to ensure that the out-of-phase TE is shorter than the in-phase TE. A potential pitfall is Note that in livers with simultaneous iron overload and steatosis, a potential pitfall exists in which in-phase and out-of-phase imaging may show no comparative signal loss (ie, signal loss due to steatosis on the out-of-phase image may be counterbalanced by signal loss due to iron overload on the in-phase image). Another pitfall may occur when is that some scanners use a sequence design where in-phase images have a shorter TE than out-of-phase images. In these instances, signal loss on the out-of-phase echo could be from either iron overload, or steatosis, or a combination of both. Every effort should be made to ensure that the out-of-phase TE is shorter than the in-phase TE. In addition, the TEs for the in-phase and out-of-phase images at 3T are half that at 1.5T, which needs to be accounted for when assessing for fat or iron. A number of techniques have been developed, tested, and validated for quantitative measurement of liver iron and fat content [28-32]. These methods have been commercialized by many MR vendors and are available clinically for quantitative measure of liver iron and fat. The current gold standard for fat quantification with MRI is proton density fat fraction (PDFF). PDFF
is the proportion of mobile protons in liver tissue attributable to fat and thus is a noninvasive MR-based biomarker of liver triglyceride concentration.

In recent years, 3T imaging systems are more have become widely more available. Potential advantages of 3T systems include an increased signal-to-noise ratio (SNR) [33] and an increased conspicuity of enhancement after administration of a gadolinium chelate contrast agent [34]. Potential disadvantages include decreased image contrast on T1-weighted images, increased predisposition to susceptibility artifact, increased chemical shift artifact, increased specific absorption rate, and signal inhomogeneity [35]. The latter can be partially compensated for by the use of radiofrequency (RF) cushions [36] and/or parallel transmit technology. In short, 3T imaging can offer substantial improvements in SNR and spatial resolution and/or decreases in imaging times, but sequence modifications are often required to maintain desired image contrast and reduce artifacts [37,38]. However, in patients with obesity or those with cirrhosis, 1.5T MRI may be considered because of the standing wave and dielectric artifacts seen on 3T MRI.

DWI has become commonly used recently been investigated for abdominal protocols application [39-44]. The most common technique uses single-shot echo-planar imaging (SS-EPI). Breath-held, free breathing multiple-averaging, and respiratory-gated SS-EPI techniques can be used have been described [45,46]. Parallel imaging can be used to decrease imaging time and has been shown to result in accurate apparent diffusion coefficient (ADC) values [47]. DWI has shown promising results in detection and characterization of focal liver lesions, and in detection and staging of liver fibrosis, and appears to be at least a value-added adjunct sequence capable of revealing additional sites of disease in the abdomen [48,49]. The ability to depict areas of high cellularity can be helpful in hepatic lesion detection and in characterization in a noninvasive manner. DWI does not rely on IV gadolinium; therefore, its use is particularly attractive in patients who are unable to receive IV contrast agents with poor renal function who cannot receive contrast because of the potential risk of nephrogenic systemic fibrosis. ADC maps can be generated to help differentiate between restricted diffusion and T2 shine-through. At least 2 b-values are obtained, including b = 20–50 s/mm² and b = 400 to 1,000 s/mm². However, overlap exists between ADC values of solid benign hepatocellular lesions, such as focal nodular hyperplasia (FNH) or hepatocellular adenoma (HCA), and those of malignant lesions [40,43,50-56]. Thus, information provided by DWI needs to be interpreted in conjunction with lesion morphology and signal characteristics on other sequences. Moreover, ADC values are technique and scanner dependent; hence, diagnostic cutoff values reported in the literature may not be applicable to other scanners. Techniques such as simultaneous multislice (SMS) technique may allow DWI to be performed in under one minute [57].

MR elastography (MRE) is a technique that enables measurement of liver stiffness. Published data over the last 5 years show that this method has high accuracy in discriminating different stages of liver fibrosis [58-62].

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [63].

In patients with cirrhosis or those at high risk for HCC, please refer to the Liver Imaging Reporting and Data System (LI-RADS) (http://www.acr.org/Quality-Safety/Resources/LIRADS) for additional guidance on reporting of MRI in this population.

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 MRI examination of the patient as well as to others in the immediate area [64-73]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [64-73].
VI. 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 [74].

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 magnetic field strength (dB/dt), maximum RF power deposition (specific absorption rate), and maximum acoustic noise levels.

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, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [1], the ACR Guidance Document on MR Safe Practices: 2003 [2], and the ACR Manual on Contrast Media [10].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [4-13]

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 Body Imaging (Abdominal) of the Commission on Body Imaging and by the Committee on Practice Parameters – Pediatric Radiology of the Commission on Pediatric Radiology, in collaboration with the Society of Abdominal Radiology (SAR) and the Society for Pediatric Radiology (SPR).

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OLD REFERENCES


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

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NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 28

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Soft-Tissue Components of the Pelvis

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 4)*

ACR–SAR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE SOFT-TISSUE COMPONENTS OF THE PELVIS

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.

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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.
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.

ABOUT THIS DOCUMENT

This collaborative practice parameter has undergone extensive revision and has been divided into sections with links as indicated below:

Section 1. Detection, Staging, and Recurrence Assessment of Gynecologic Malignancies: Uterus, Cervix, Ovaries, Vulva, and Vagina

Section 2. Evaluation of Pelvic Mass or Acute or Chronic Pelvic Pain, Including Detection of Adenomyosis, Ovarian Cysts, Torsion, Tubo-Ovarian Abscesses, Benign Solid Adnexal Masses, Obstructed Fallopian Tubes, Deep Pelvic Endometriosis, Endometriomas, and Fibroids

Section 3. Assessment of Pelvic Floor Defects Associated with Urinary or Fecal Incontinence

Section 4. Determination of Fibroid Number, Location, Size, and Type Prior to Intervention

Section 5. A. Detection, Staging, and Recurrence Assessment of Urologic Malignancy: Bladder

Section 5. B. Detection, Staging, and Recurrence Assessment of Urologic Malignancy: Prostate

Section 5. C. Detection, Staging, and Recurrence Assessment of Urologic Malignancy: Scrotum and Penis

Section 6. Evaluation of Complications Following Pelvic Surgery, Including Abscess, Urinoma, Lymphocele, Radiation Enteritis, and Fistula Formation

Section 7. Identification of Source of Lower Abdominal Pain in Pregnant Women: Appendicitis, Ovarian and Uterine Masses, and Urological Conditions

Section 8. Identification and Classification of Perianal Fistulas

Section 9. Identification and Characterization of Congenital Anomalies of the Female and Male Pelvis, Including the Anatomic Evaluation of Ambiguous Genitalia and Disorders of Sexual Development (DSD)

I. INTRODUCTION

Magnetic resonance imaging (MRI) of the pelvis is a proven and useful tool for the evaluation, assessment of severity, and follow-up of diseases of the male and female pelvic organs. It should be performed only for a valid medical reason.

MRI of the pelvis is the imaging modality of choice for many clinical situations involving pelvic pathology. This technique has superb soft-tissue contrast and has the advantage of providing multiplanar and 3-D depiction of anatomy and pathology. Additional benefits include absence of ionizing radiation and exposure to iodinated contrast material. Careful attention to patient comfort prior to beginning the MR examination will result in improved diagnostic quality. MRI for the detection, staging, and recurrence of rectal cancer is not considered in this parameter.

II. INDICATIONS

Indications for MRI of the pelvis include, but are not limited to, the following:

1. Detection and staging of gynecologic malignancies, including those originating in the vulva, cervix, uterus, ovaries, and fallopian tubes (see Section 1).
2. Evaluation of acute or chronic pelvic pain or pelvic mass, including detection of adenomyosis, ovarian cysts, torsion, tubo-ovarian abscesses, benign solid adnexal masses, obstructed fallopian tubes, endometriomas, and uterine fibroids (see Section 2).
3. Assessment of pelvic floor defects associated with urinary or fecal incontinence (see Section 3).
4. Determination of number, location, size, and type (nondegenerating or degenerating) of fibroids for treatment selection and planning (see Section 4).
5. Planning and guidance for minimally invasive surgical and brachytherapy (see Sections 1 and 5b).
6. Assessment for recurrence of tumors of the bladder, prostate, or gynecologic organs following surgical resection or exenteration (see Sections 1, 5b, 5a, and 5c).
7. Detection and staging of malignancies of the prostate, bladder, penis, testis, and scrotum (see Sections 5b, 5a, and 5c).
8. Evaluation of complications following pelvic surgery, including abscess, urinoma, lymphocele, radiation enteritis, and fistula formation (see Section 6).
9. Identification of the source of lower abdominal pain in pregnant women, including appendicitis, ovarian condition or adnexal torsion, or uterine mass (see Section 7).
10. Identification and classification of perianal fistulas (see Section 8).
11. Identification and characterization of congenital anomalies of the male and female pelvic viscera, including the anatomic evaluation of ambiguous genitalia and disorders of sexual development (see Section 9).

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [1].

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [1], the ACR Guidance Document on MR Safe Practices: 2013 [2], and the ACR Manual on Contrast Media [3].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [4,5].

V. GENERAL SPECIFICATIONS OF THE EXAMINATION (additional specifications will be discussed in the relevant section)

The supervising physician should have a complete understanding of the indications, risks, and benefits of the examination as well as of alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. 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 MRI of the soft-tissue pelvis 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.
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.

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 utilization (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [6] and the ACR Manual on Contrast Media [3]).

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate sedation may be needed to achieve a successful examination. If conscious sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [7].

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. General Technique (additional technical advances will be discussed in the relevant section)

Whenever possible, a multicoil array should be used to allow for smaller fields of view (FOV) and higher spatial resolution. Fasting for 6 hours prior to the examination will diminish bowel peristalsis and improve quality. Alternatively, glucagon could be administered subcutaneously or intramuscularly to diminish artifacts from bowel peristalsis, unless contraindicated.

The majority of information is obtained using T2-weighted (T2-W) images. Fast spin-echo (FSE), turbo spin-echo, or their equivalents are recommended in the orthogonal planes (see relevant section) to clearly demonstrate the relevant anatomy. Ultrafast T2-W pulse sequences, such as single-shot FSE (SSFSE) or half-acquisition turbo spin-echo may be substituted, yielding a significant time savings at the cost of mildly diminished spatial resolution and with less T2-W imaging than comparable spin-echo technique. Anterior saturation bands over the anterior subcutaneous fat help minimize phase-encoding artifacts.

Contrast enhancement is often critical for detecting tumor extent. Rapid T1-weighted (T1-W) gradient-echo images should be obtained pre- and postdynamic intravenous IV bolus administration of a gadolinium chelate contrast material to highlight sites of disease. Images obtained during the arterial and venous phase of enhancement may be useful in determining the vascular supply and enhancement pattern of a pelvic mass. A 3-D sequence, particularly on high field strength platforms magnets (>1.0 T), yields superb thin-section contrast-enhanced images. Additional pulse sequences, for example diffusion-weighted imaging (DWI) with apparent diffusion coefficient (ADC) map, may be used as required for diagnosis and evaluation of extent of disease. In the case of advanced disease, MRI of the abdomen should be considered to search for distant metastases. Endoluminal coils (eg, endorectal) may be used for some indications.
1. MRI of the pelvis may be performed for pregnant patients in the second and third trimester. For pregnant patients in the first trimester, MRI of the pelvis is only recommended if the benefits outweigh any potential risks and then only as an adjunct to initial evaluation with ultrasound (US). See the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [8] and the ACR Manual on Contrast Media [3]. A multicoil array should be used with the patient fasting as tolerated to diminish fetal motion and bowel peristalsis. Diagnostic information can almost always be obtained using breath-hold (T1-W and T2-W) images. The patient may be imaged in the supine or left lateral decubitus position using a large FOV (38-44 cm).

D. Examination Technique (specific examination techniques will be discussed in the relevant section)

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [9]. For detection and staging of prostate malignancy, the report should follow the guidelines for terminology, including descriptions of lesion features and location, as published in the Prostate Imaging Reporting and Data System (PI-RADS) v2.1 [10].

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 MRI examination of the patient as well as to others in the immediate area should be provided [4,5,11-16]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [4,13].

VII. EQUIPMENT SPECIFICATIONS

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.

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance (MR) Imaging Equipment [17].

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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Collaborative Committee

(Members represent their societies in the initial and final revision of this parameter.)

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REFERENCES


Section 1. Detection, Staging, and Recurrence Assessment of Gynecologic Malignancies: Uterus, Cervix, Ovaries, Vulva, and Vagina

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

Diffusion-weighted MRI and dynamic contrast-enhanced (DCE) MRI are have become useful adjuncts to standard anatomic MR sequences [18]. High-field (3T) MRI has been more widely implemented for body-imaging applications, providing improved signal-to-noise ratio (SNR), spatial resolution, and anatomic detail as well as faster scanning techniques but with specific limitations due to magnetic susceptibility and motion artifacts and concerns about radiofrequency power deposition. Parallel imaging techniques increase SNR with reasonable specific absorption rates while markedly speeding up acquisition at 3T body imaging [19].

D. Examination Technique:

1. Detection and Staging

MRI is most valuable for extent of disease evaluation and staging in patients with known or clinically suspected gynecologic malignancy. It is used in treatment planning to guide surgery and/or radiation therapy, to monitor treatment response, and to detect local and regional recurrence [20,21]. For ovarian neoplasms and masses, MRI is typically used for problem solving after inconclusive pelvic US and is not routinely performed for staging (see Section 2).

Suggested sequences include the following:

i. Axial T1-W
ii. Orthogonal high-resolution T2-W FSE (relative to the uterus or cervix)
iii. Long- or short-axis precontrast and dynamic postcontrast 2-D T1-W or 3-D T1-W acquisition (with fat suppression)
iv. Axial T2-W of the pelvis to include the perineum (vaginal and vulvar cancers)
v. DWI with ADC map
vi. Optional: Vaginal gel for vaginal cancer or cervical cancer with clinical suspicion of vaginal invasion

Endoluminal coils (endovaginal or endorectal) for localization of cervical cancers and evaluation of parametrial extension have been reported to achieve high-resolution imaging images focally, but with a but are limited by the small FOV. These have not been widely adopted because of patient discomfort and limitations in imaging large tumors, extension to pelvic organs surrounding the primary site, and lymphadenopathy [22].

In staging for gynecologic malignancy, large FOV T1-W images are used to evaluate the abdomen and pelvis for lymphadenopathy, hydroureteronephrosis hydronephroureterectasis, and bone-osseous lesions. High-resolution long- and short-axis T2-W imaging of the uterine body is used for localization of endometrial cancer and for determining the depth of myometrial invasion and clearly demonstrates shows zonal anatomy to advantage [23]. Long- and short-axis imaging of the cervix is performed to show the local extent of the cervical cancer to identify search for parametrial invasion and to assess candidacy for trachelectomy (a fertility-sparing procedure) [24].

Precontrast- and postcontrast-enhanced dynamic multiplanar multiphase imaging using either 2-D long- and short-axis or volumetric T1-W gradient-echo sequences have shown myometrial invasion from endometrial carcinoma to advantage [25]. In patients with biopsy-proven adenocarcinoma involving both the lower uterine segment and cervix, DCE scans are useful in differentiating correct primary site of origin [26].
DWI with both low and high b-values (800-1,000 s/mm²) respectively, combined with use of ADC maps and correlated with anatomic imaging can demonstrate restricted diffusion in malignancy [18]. DWI assists in lesion detection and extent of disease evaluation, including metastases to the peritoneum or adnexa [27], myometrial invasion in endometrial cancer [28], and tissue characterization of ovarian masses [29]. Limitations of this technique include false-positive results from inflammatory conditions and other benign processes, such as benign masses with high cellularity [22]. Use of DWI for detection of pelvic lymphadenopathy is controversial [19].

For evaluation of vulvar and vaginal cancers, MRI is excellent, especially with multiplanar T2-W images, and MRI is better than physical examination for determining tumor size, extent, and perivaginal spread [30]. Installation of vaginal gel to separate the walls of the vaginal canal can improve visualization of a vaginal mass but is not required [31]. Axial T1-W FSE images with a large FOV are performed for detection of abdominopelvic lymphadenopathy and bone marrow abnormalities. Detection of regional lymphadenopathy is the most important prognostic factor that is correlated with depth of tumor invasion. Presence or absence of adenopathy guides decision making about the need for radical vulvectomy and inguinal lymphadenectomy, both of which are associated with significant morbidity but improved survival if inguinal nodes are involved [32].

High-resolution orthogonal T2-W FSE images in the axial and coronal planes are used for evaluation of the primary tumor. DCE sagittal T1-W images with fat suppression and small FOV high-resolution axial T2-W images should be obtained to include the entire perineum, including the vulva. DCE scans with fat suppression are useful to detect small lesions and show involvement of the urethra and anus by vulvar cancer [33].

2. Postsurgical Recurrence of Gynecologic Malignancy

Preoperative MRI is accurate in assessing tumor extent before pelvic exenteration for recurrent gynecological cancers and can guide the type of pelvic exenteration. In particular, MRI accurately assesses bladder and rectal wall invasion before major surgery [34] and aids in differentiating posttreatment changes from active tumor [35]. Eligibility for pelvic exenteration requires exclusion of metastatic disease, which is best achieved by PET/CT [36]. The MRI examination technique has not been standardized. Suggested sequences include the following:

i. Two-plane orthogonal T2-W FSE

ii. Precontrast and postcontrast fat-suppressed 3-D T1-W gradient echo

iii. DWI with ADC map

Conventional imaging serves as a surgical roadmap of recurrent disease. DWI is useful for detecting tumor recurrence, both in the pelvis and in areas of disseminated disease in the peritoneum [37].

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Section 2. Evaluation of Pelvic Mass or Acute or Chronic Pelvic Pain, Including Detection of Adenomyosis, Ovarian Cysts, Torsion, Tubo-Ovarian Abscesses, Benign Solid Adnexal Masses, Obstructed Fallopian Tubes, Deep Pelvic Endometriosis, Endometriomas, and Fibroids

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

Perfusion and DWI MRI sequences increase the diagnostic accuracy of conventional MRI with the overall accuracy for MRI greater than 90% for adnexal mass characterization [29]. If DCE-MRI using postprocessing subtraction techniques shows early enhancement in solid elements, then the mass is much more likely to be malignant. The absence of enhancing solid elements is more likely benign [38]. Susceptibility-weighted imaging shows hemosiderin deposition in extraovarian endometriosis and adenomyosis with increased sensitivity compared with conventional MRI [39]. ADC measurements on DWI may show quantitative differences between fibroids and adenomyosis [40]. 3-D T2-W MRI allows volumetric acquisition, providing submillimeter sections with multiplanar reformatting capability. There is a tradeoff between volume imaged, with both acquisition time and T2-weighting characteristics [41].

D. Examination Technique:

1. Detection and Characterization

The workup of adnexal masses is particularly challenging because the prevalence of ovarian malignancy is low compared with that of benign adnexal masses, and benign conditions frequently have an acute presentation. Because pelvic US is the initial study of choice for workup, MRI of the pelvis for adnexal mass or pelvic pain is useful after indeterminate pelvic US for problem solving. US is limited by its small FOV, obscuration of organs by overlying bowel gas, operator dependence, and limitations in patients with large body habitus. MR outperforms US with higher specificity due to its multiplanar imaging capabilities and excellent soft-tissue contrast for tissue characterization [42]. Adenomyosis is diagnosed when the junctional zone is thickened on T2-W images; however, less commonly, a myometrial contraction can mimic adenomyosis. Performing an additional sagittal T2-W sequence at the conclusion of the study can differentiate contraction from adenomyosis as the thickening will resolve with a contraction but will persist with adenomyosis [43]. The differential diagnosis of adnexal masses on MRI is based upon a systematic evaluation of their anatomic location, morphology (solid, cystic, or both), signal intensity (SI) characteristics, enhancement, and appearance on DWI. Deep pelvic endometriosis may present as an implant in the posterior, middle, and/or anterior pelvic compartments. MRI with vaginal and/or rectal gel may aid in detection of these implants but is considered optional [44]. Fasting 4 to 6 hours prior to imaging decreases artifacts from bowel peristalsis; alternatively, subcutaneous (SQ) or intramuscular (IM) glucagon may be administered if not contraindicated.

Suggested sequences include:

i. Orthogonal high-resolution T2-W FSE or a 3-D T2-W volumetric acquisition

ii. Axial in-phase, opposed-phase, and/or fat-suppressed T1-W gradient echo

iii. Pre- and dynamic postcontrast fat-suppressed 3-D T1-W gradient echo

iv. Optional: DWI with ADC map

v. Optional: T2-W with vaginal gel

vi. Optional: T2-W with rectal gel
Fluid, fat, blood, and fibrous tissues can be differentiated based upon MR signal characteristics that are often indeterminate on US. When differentiating between hemorrhagic ovarian cyst and endometrioma, the T2 dark spot sign has high specificity for endometrioma compared with T2 shading but a lower sensitivity [45]. For solid adnexal masses, low T2 SI is usually correlated with benignity [42]. Most cystic ovarian masses are benign. Guidelines have been established for evaluation of adnexal cysts based on patient menstrual status and symptoms [46,47]. Incidental functional ovarian cysts found on initial MRI do not require further workup if they are <3 cm in size in women of childbearing age, or ≤1 cm if postmenopausal [46]. In women of childbearing age with simple cysts >3 cm and ≤5 cm, cysts should be described and yearly US follow-up performed to ensure stability [46,47]. In postmenopausal women, simple cysts >1 cm and ≤7 cm can be described and yearly US follow-up performed to ensure stability. For simple cysts >7 cm in premenopausal or postmenopausal patients detected by initial pelvic US, pelvic MR may be performed to search for occult enhancing elements, or surgery may be considered [47].

Serous cystadenomas (the most common benign epithelial ovarian neoplasm) have fluid signal and thin walls [48]. Mucinous neoplasms are multilocular with varying MR SIs (“stained glass appearance”) [49]. The presence of papillary projections, wall thickening, and/or enhancement is worrisome for malignancy [50]. Restricted diffusion may be seen in malignancy, but there are many causes of false-positive findings [37].

Other fluid-containing extraovarian benign lesions have characteristic morphologies that suggest the correct diagnosis, such as the tubular shape and incomplete folds of a hydrosalpinx, the identification of a normal ovary or normal fallopian tube contiguous with a paraovarian or paratubal cyst, respectively, or the normal ovary embedded into the wall of peritoneal inclusion cyst [50].

In patients with acute pelvic pain from tubo-ovarian abscess, the diagnosis is usually evident clinically (cervical motion tenderness, discharge, leukocytosis). Further imaging is reserved for nonspecific clinical presentations or for patients who are refractory to medical therapy. CT is usually performed after equivocal pelvic US. However, MRI may be performed in nonspecific cases or in young females when decreasing radiation exposure is a priority. MR may show inflammation on contrast-enhanced scans and edema on fat-suppressed T2-W images [51].

Solid or mixed cystic and solid lesions are also characterized based upon morphology and tissue signal characteristics. Fat-suppressed and/or chemical shift MR techniques can be used to differentiate between bright signal from fat within mature cystic teratomas and blood within hemorrhagic cysts or endometriosis. Fat signal in mature cystic teratomas manifested by and/or chemical shift artifact at the fat-fluid interface (or within the teratoma in cases of intracellular fat) confirms the diagnosis [52]. T2 shading (bright T1 and dark T2 signal) in endometriosis is typical and results from chronic bleeding containing high protein and iron concentrations and protein cross-linking, all of which decrease both T1 and T2 relaxation time [53,54]. Ovarian fibromas have low T1 and T2 signal, similar to skeletal muscle due to fibroblasts and collagen. Fibromas may enhance [55].

Because acute ovarian torsion is a gynecologic emergency that is usually first evaluated with pelvic US, MR is not generally utilized in the acute setting. The use of MR generally has been limited to imaging subacute or chronic torsion. MR findings are those of an enlarged ovary with central stromal edema and/or hemorrhage, ipsilateral deviation of the uterus, fallopian tube thickening, and enlarged congested vessels with twisting of the vascular pedicle (beak sign) [51,56].

When a uterine fibroid resides in the broad ligament, it projects laterally from the uterine contour. This can be difficult to distinguish from a solid ovarian neoplasm both clinically and by pelvic US. MRI is valuable for further characterization, especially when the typical low SI of fibroids becomes complex because of degeneration. Identification of separate normal ovaries, continuity of the mass with uterine myometrium, and enhancing bridging vessels arising from the uterus supplying the mass [57] are key features that make the diagnosis of pedunculated fibroid or broad ligament fibroid.
In patients with dysmenorrhea and menorrhagia from adenomyosis, MRI shows the characteristic low-signal lenticular-shaped junctional zone thickening >12 mm diffusely or focally that distinguishes this condition from fibroids on T2-W images. Sometimes the two may coexist. Small hemorrhagic foci seen to best advantage on susceptibility-weighted images are helpful to identify adenomyosis and endometriosis [39]. MR can localize any associated macroscopic pelvic endometriosis. Deep pelvic endometriosis can affect the anterior, middle, or posterior pelvic compartments. Most common sites are retrocervical region, vagina, ovaries, bladder dome, rectosigmoid colon, and round ligaments. Less common sites in the pelvis include the abdominal wall in a Caesarean section scar, inguinal region, and pelvic nerves [58]. Cystic adenomyosis and subserosal polypoid adenomyomas can mimic an adnexal mass but typically are contiguous with myometrium forming a “beak sign,” indicating uterine origin [39].

REFERENCES


Section 3. Assessment of Pelvic Floor Defects Associated with Urinary or Fecal Incontinence

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

D. Examination Technique

MRI of pelvic floor dysfunction allows noninvasive, dynamic evaluation of all the pelvic organs in multiple planes with high soft-tissue and temporal resolution. Imaging consists of a 2-step process that combines high-resolution anatomic imaging and functional evaluation. MRI is most helpful in patients with multicompartiment physical examination findings or symptoms, posterior compartment abnormalities, severe prolapse, or recurrent pelvic floor symptoms after surgical repair [59-61].

Prior to beginning the examination, it is important to reassure patients about privacy and coach them appropriately regarding the maneuvers to ensure full patient cooperation. Patients are asked to empty their bladder and rectum within 1 hour prior to the examination, and rectal enema is optional prior to the examination. Although a recent study has shown superiority of the physiologic sitting position for the evaluation of defecography [62], such equipment is not readily available, and most patients are imaged in the supine position using conventional closed or wide-bore platforms with equal outcomes reported for both sitting and supine positions [63].

The patient is placed on a water-resistant pad on the MRI table, and approximately 100–120 cc of warmed US gel is instilled into the rectum. A measure of 10–20 cc of gel may also be used to opacify the vaginal canal. The patient is then positioned in the supine position and loosely wrapped in a waterproof incontinence pad. A multielement coil is necessary to achieve high-resolution imaging and optimal SNR and should be centered low enough to visualize prolapsed organs.

Suggested sequences include the following:

i. Axial and coronal T2-W FSE

ii. Sagittal T2-W SSFSE

iii. Sagittal midline rest, and straining, and defecography cine balanced steady-state free precession T2-W SSFSE

iv. Optional: axial or coronal rest and straining cine balanced steady-state free precession T2-W SSFSE

v. Optional: sagittal midline squeezing cine balanced steady-state free precession

Axial and coronal small FOV T2-W FSE is performed at rest to evaluate pelvic floor support structures. Following surgical repair, the superior aspect of the axial T2-W FSE image should begin at the level of the sacral promontory for patients who have undergone sacrocolpopexy. Sagittal half-Fourier SSFSE of the entire pelvis, from sidewall to sidewall, is then obtained to determine resting organ positions. Continuous imaging during straining and defecography has shown greater degrees of prolapse with a balanced acquisition with steady-state precession than with a SSFSE sequence given the improved temporal resolution [64]. Functional evaluation is performed by acquiring a single midsection sagittal SSFSE balanced steady-state free precession sequence with the anorectum at rest. The image should include the symphysis, bladder neck/urethra, vagina, anus/rectum, and coccyx.

Thereafter, serial (cine) imaging is repeated during the straining phase and repeated 2 to 3 times with increasing straining to achieve maximal Valsalva maneuver. Straining exercises can also be performed in the axial or coronal plane sequence to evaluate prolapse and its effect on the supporting structures [59,65]. Cine evaluation is then performed in the defecography phase until complete evacuation of rectal contrast is achieved. However, continuous imaging during defecography has shown greater degrees of prolapse with a balanced acquisition with steady-state precession than with a SSFSE sequence given the improved temporal resolution [64]. Knee flexion supported by a pillow and slight hip abduction can maximize strain maneuvers and complete defecation. Imaging can also be acquired during the “squeeze maneuver” (ie, squeezing the buttocks as if trying to prevent the escape of urine) to
evaluate puborectalis muscle contraction. Throughout this process, the technologist must continuously interact with the patient to optimize the functional evaluation.

REFERENCES


Section 4. Determination of Fibroid Number, Location, Size, and Type Prior to Intervention

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

3-D T2-W MRI allows volumetric acquisition of the uterus, providing submillimeter sections with multiplanar reformatting capability. There is a tradeoff between volume imaged, acquisition time, and T2 characteristics [41].

DWI reflects water mobility and tissue cellularity. ADCs can be calculated from images with different b-values [66]. This technique can be useful when attempting to differentiate typical fibroids from uterine sarcomas [67]. ADC values may also show quantitative differences between fibroids and adenomyosis [40].

MR elastography (MRE) measures a tissue’s stiffness. MRE of uterine fibroids can be correlated with T2-W imaging. Less-stiff fibroids appear more T2 hyperintense and more-stiff fibroids appear more T2 hypointense [68].

D. Examination Technique:

Although US remains the initial imaging modality in the workup of patients with suspected symptomatic fibroids, MRI is the most accurate imaging technique for fibroid detection and localization [69]. It is increasingly performed in symptomatic patients being evaluated for minimally invasive uterine-sparing therapies, such as uterine fibroid embolization (UFE) [70] and more recently MR-guided focused US (MRgFUS) [71]. For UFE candidates, MRI provides additional information compared with US and affects clinical management in a significant number of patients [72]. Single-institution and multicenter randomized controlled trials report significant decrease in symptoms and improved health-related quality of life following UFE [73,74]. MRI following UFE and MRgFUS has also been used to monitor outcome and diagnose complications.

Imaging is performed with a pelvic phased array coil. Fasting 4–6 hours prior to imaging decreases artifacts from bowel peristalsis; alternatively, SQ or IM glucagon may be administered if not contraindicated. Patients are asked to void before the examination. A moderately distended, half-full urinary bladder may be optimal for the examination.

Suggested sequences include the following:

i. Orthogonal T2-W FSE (at least one plane should be a high-resolution sequence and/or a 3-D T2-W volumetric acquisition)

ii. Axial T1-W with and without fat suppression

iii. Precontrast and dynamic postcontrast 3-D T1-W fat-suppressed gradient-echo images

iv. Optional: DWI with ADC maps

v. Optional: large FOV upper abdomen T2-W to assess kidneys for hydronephrosis and metastases in suspected malignancy

Before treatment, orthogonal T2-W images allow fibroid detection, localization (submucosal, intramural, or subserosal), measurement of size, and characterization. Other uterine pathology, if present (eg, adenomyosis), is also diagnosed on T2-W images. The T1-W images provide information on the relationship of the fibroid to the uterus and adnexa as well as identify blood and fat in fibroids and/or concurrent uterine or adnexal disease.

The majority of nondegenerated fibroids are well-circumscribed round or ovoid masses with homogeneous low SI on T2-W images compared with myometrium. These imaging features reflect whorls of smooth-muscle cells with...
various amounts of intervening collagen. Nondegenerated cellular fibroids exhibit different imaging features—high T2-W SI compared with myometrium—a function of compact smooth-muscle cells with a paucity of intervening collagen. On T1-W images, nondegenerated fibroids are low or isointense in SI to myometrium. Following contrast, nondegenerated fibroids enhance homogenously.

Degenerated fibroids have variable appearance on T1-W, T2-W, and postcontrast T1-W images. Types of fibroid degeneration include hyaline, calcific, myxoid, cystic, necrosis (hyaline or coagulative), and red. Although a combination of imaging features may suggest a specific type of degeneration, overlap in imaging features exists. This is also true for distinguishing a degenerated fibroid from a uterine sarcoma. Imaging features that have been reported in sarcomas include, but are not limited to, irregular margins, extensive hemorrhage, and necrosis [75-77]. DWI and ADC values may also add complementary information [78,79].

MRI features pertinent to the outcome of UFE include location, size, viability, ovarian arterial collateral supply to the uterus, and comorbid conditions [70].

Following successful UFE, fibroids undergo hemorrhagic infarction. Imaging features of an infarcted fibroid postembolization include hyperintense T1-W SI, increasing hyperintense T2-W SI over time, and no enhancement following intravenous contrast administration [80]. Small amounts of gas within an infarcted fibroid may be normal. Although follow-up imaging may not be necessary in patients who become asymptomatic following UFE, MRI can be employed to diagnose complications such as fibroid passage or pyomyoma. Surveillance MRI can also be used to assess for residual fibroid enhancement in patients with continued symptoms [81].

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368.
Section 5. Detection, Staging, and Recurrence Assessment of Urologic Malignancy

A. Bladder

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

DWI, which reflects the degree of tissue cellularity, is can be complementary to conventional imaging. Additionally, MR cystography relies on 3-D T2-W data sets amenable to postprocessing to simulate conventional cystography.

D. Examination Technique:

1. Detection and Staging

MRI is usually used for T staging once the cancer has been diagnosed and is considered superior to contrast-enhanced CT in demonstrating extent of bladder wall invasion (nonmuscle invasive from muscle-invasive bladder cancer). The study of the bladder requires high spatial resolution with a multielement surface coil, thin section, and large matrix. Moderate bladder distention is necessary, and patients are asked to void approximately 1-2 hours prior to imaging or to drink 500-1,000 mL of water in the 30 minutes prior to the examination [82]. Administration of an antiperistaltic agent can reduce bowel peristalsis for assessment for extravesical disease [83].

Suggested sequences include the following:

i. Three-plane orthogonal T2-W FSE or 3-D T2-W volumetric acquisition

ii. 3-D fat-suppressed gradient-echo T1-W perpendicular to the tumor

iii. Precontrast fat-suppressed 3-D T1-W gradient echo and DCE T1-W

iv. Optional: Whole-body or small FOV DWI with ADC maps

v. Optional: 3-D MR cystography

Non-fat-saturated small FOV high spatial resolution (slice thickness of 3–4 mm) FSE T2-W imaging is performed in 3 orthogonal planes to evaluate the detrusor muscle for tumor depth, extravesical disease, and invasion of surrounding organs. Anterior saturation bands should be applied for the axial and sagittal planes to minimize phase-encoding artifacts. SSFSE imaging may replace T2-W FSE sequences to decrease motion artifacts, although increased image blur and reduced intravoxel resolution and SNR can impair staging are slightly reduced. Recent advances have made 3-D T2-W imaging feasible with the introduction of shorter acquisition times, volumetric acquisition, and improved SNR.

Multiphase dynamic 3-D fat-suppressed gradient-echo T1-W imaging is obtained prior to and following contrast material administration. The plane of imaging should be perpendicular to the implantation base of the tumor. The majority of bladder tumors enhance briskly in the early phase (≤20 seconds) following contrast injection with the detrusor muscle enhancing late (60 seconds), thus allowing detection of small tumors and differentiation of superficial from muscle-invasive tumors [84,85]. Preliminary studies using DCE-MRI for quantitative analysis have shown correlation with T stage, tumor angiogenesis, and prediction of tumor response to neoadjuvant therapy [84,86-88].

Several recent studies have reported high b-value DWI to complement T2-W and gadolinium-enhanced imaging in improving the diagnosis of organ-confined muscle-invasive disease, extravesical extension, and prediction of tumor grade [88-95]. ADC values for bladder tumors are less than those for surrounding normal tissues. Given significant variation in ADC measurements, changes in SI in DWI must also be taken into consideration.
Trace high b-value DWI often depicts tumor better than ADC maps as there is more contrast between tumor and surrounding structures, and there is significant signal variation in ADC measurements [96,97]. Reduced FOV DWI has been shown to improve image quality, reduce artifacts, and yield high spatial resolution compared with whole-body DWI [98].

There has been interest in 3-D rendering techniques with MR data sets (including multiplanar reconstructions and creation of cystoscopy-like images) as a replacement for traditional cystoscopy and to assist in staging, where traditional cystoscopy may be contraindicated (urethral stricture) or suboptimal (narrow-necked bladder diverticula) [99].

2. Therapy Response and Pelvic Recurrence

MRI technique is similar to that described for preoperative staging evaluation regardless of whether the patient has undergone radical cystectomy, transurethral resection, or neoadjuvant chemotherapy. In particular, MRI can evaluate therapeutic response to induction chemoradiotherapy in patients with muscle-invasive bladder cancer; identify complete response; and optimize patient selection for bladder-sparing protocols as well as monitor recurrence [100]. Recent Some studies report DWI to be superior to contrast-enhanced MRI and T2-W imaging for differentiation between tumor recurrence from postoperative fibrosis and inflammation [101,102].

REFERENCES


Section 5. Detection, Staging, and Recurrence Assessment of Urologic Malignancy

B. Prostate

V. SPECIFICATIONS OF THE EXAMINATION

The recommended use of MRI in prostate cancer detection, localization, staging, characterization, and risk stratification consists of multiparametric MRI (mp-MRI) [103]. Mp-MRI refers to the use of T2-W imaging in combination with functional imaging techniques: DWI, DCE-MRI, and MRSI [103,104]. The optimal combination of anatomic and functional sequences has yet to be established. However, the more functional sequences are utilized, the better the accuracy seems to be [105,106].

Imaging should be performed at either 1.5T or 3T. The fundamental advantage of 3T over 1.5T is increased SNR, which improves the spatial, temporal, and spectral resolution. However, certain situations warrant imaging at 1.5T, eg, implantable devices deemed incompatible at 3T, or the location of a device would compromise image quality at 3T. Several groups have reported comparable performance between multichannel phased array coil MRI of the prostate at 3T and endorectal phased array coil MRI at 1.5T [107-110]. At 3T, most of the benefits of MRI can be achieved with multichannel phased array coil (at least 8-16 channels), although use of an endorectal coil or endorectal phased array coil combination can incrementally improve detection and staging [111,112]. However, the use of an endorectal coil deforms the shape of the gland. Use of the endorectal coil may add both imaging time and cost and may diminish patient acceptance, which would need to be considered by the supervising radiologist. The supervising radiologist must strive to optimize MRI protocols to obtain the best and most consistent image quality.

To minimize the artifacts introduced from biopsy-related hemorrhage, which can interfere with lesion detection and staging, imaging can be delayed between 8 and 12 weeks after the biopsy procedure [101]. However, detection of clinically significant cancer at a site of postbiopsy hemorrhage without a corresponding abnormality on mp-MRI is low, and a recent study has shown the presence of extensive hemorrhage and short delay after biopsy did not negatively impact accuracy for tumor detection using mp-MRI [113]. So if the primary purpose of the examination is to detect and characterize clinically significant cancer after a negative transrectal US-guided biopsy, a delay in mp-MRI may not be necessary [114]. Conversely, postbiopsy hemorrhage may adversely affect image interpretation for staging in some instances, and an interval between biopsy and MRI is appropriate and should be considered [115]. An antiperistaltic agent should be administered prior to imaging to reduce motion from bowel peristalsis; however, incremental cost and potential for adverse drug reactions should be taken into consideration.

Suggested sequences (regardless of coil) include the following:

i. Three-plane orthogonal high-resolution T2-W FSE of the prostate
   ii. Whole-body or small FOV DWI with ADC map
   iii. Precontrast fat-suppressed 3-D T1-W gradient echo and DCE T1-W
   iv. Large FOV axial T1-W and T2-W of the pelvis
v. Optional MRSI

High spatial resolution T2-W FSE imaging is used for detection, localization, and staging of prostate cancer and should be obtained in 3 planes. The axial T2-W imaging should cover the prostate gland and seminal vesicles, and locations should be the same as those used for DWI and DCE-MRI. Phase-encoding direction should be right to left to minimize motion and pulsation artifact overlapping the prostate gland. Recommended slice thickness is ≤3 mm and no gap. 3-D T2-W acquisition with a slice thickness <1.5 mm may be used as an adjunct to orthogonal T2-W FSE sequences, although soft-tissue contrast is not identical [116].

DWI improves the diagnostic performance for cancer detection when combined with T2-W images and provides information about tumor aggressiveness [117-121]. DWI should be acquired in the axial plane with motion-probing gradients applied in 3 orthogonal planes. Diffusion kurtosis effect occurs at b-values > 1,000 s/mm²; therefore, ADC maps should be calculated with b-values that are ≤1,000 s/mm² [122]. Although the optimal b-values have not been determined for calculation of ADC map, it is agreed that at least two b-values are required and b-values (s/mm²) should include low (0-100 s/mm² and preferably 50-100 s/mm²) and intermediate medium (400-500) and high (800-1,000 s/mm²) b values [10]. A meta-analysis has shown mixed results with higher b-values (≥1000) to suppress normal prostate tissue background signal [120]; however, in recent studies, acquired High b-values between 1,400–2,000 s/mm² can have added value for tumor localization, although field strength and coil selection, technical parameters—including SNR—and analysis of trace DWI and/or ADC maps will impact the utility of these higher b-values [120,123-131]. A high b-value DWI (≥1,400 s/mm²) should be acquired separately or calculated from the low and intermediate b-value images [10]. Alternatively, calculated high b-values from the acquired lower b-values can be used to create the ADC map to create images of high diagnostic value without added imaging time [122]. An ADC map is recommended, but b=0 value, if possible, should be excluded from the calculation. Axial slice thickness should be ≤4 mm with no gap, and the location should ideally match the axial T2-W and DCE-MRI images without sacrificing SNR.

The added value of DCE-MRI over the combination of T2-W and DWI is not certain and may be secondary with only modest improvement in tumor detection, localization, and local staging. DCE-MRI should always be used in combination with T2-W FSE imaging and at least one other functional parameter (DWI or MRSI) given the decreased specificity for central gland tumors, or in the setting of prostatectasis and postbiopsy hemorrhage [103,132,133]. Serial imaging of the gland should be performed prior to and following IV gadolinium administration (injection rate 2-4 cc/s), and a rapid T1-W 3-D gradient-echo sequence with fat suppression is the preferred acquisition [103,132]. Pharmacokinetic features require a high temporal resolution (<150 seconds per phase) with an observation period of at least 5 minutes to evaluate for washout [134,135]. Unenhanced T1-W images from this sequence can be used to detect postbiopsy hemorrhage. Axial slice thickness should be ≤3 mmno gap, and the location should match axial T2 and DWI axial images. Images can be evaluated qualitatively, semiquantitatively, or quantitatively.

MRSI has been shown to improve lesion detection and provide valuable information about lesion aggressiveness but requires expertise, use of an endorectal coil at 1.5T endorectal W imaging [138]. The volume of interest (VOI) is aligned with the axial T2-W images to maximize coverage of the whole gland while minimizing surrounding tissue contamination. A multivoxel 3-D chemical shift imaging technique is preferred with a voxel size <0.5 cc.

Finally, a T1-W or T2-W imaging of the pelvis with a pelvic phased array coil is performed to assess for nodal or osseous metastasis, albeit limited given the morphologic limitations of MRI for lymph node assessment.

2. Local Recurrence after Radiation Therapy and Radical Prostatectomy

MRI can accurately detect local recurrence after radiation therapy and radical prostatectomy, allowing salvage radiotherapy as potential treatment option [139-141]. DCE-MRI in combination with T2-W imaging is...
particularly accurate in detecting recurrence after radiation therapy and radical prostatectomy. DWI, in combination with T2-W imaging, has been shown to be sensitive for detection of local recurrence in patients following radiation therapy but is inconsistent following interstitial brachytherapy or prostatectomy given the susceptibility artifacts from seeds and surgical clips, respectively [142-144]. However, studies evaluating DCE-MRI, DWI, and T2-W imaging following external-beam radiation therapy have shown no added benefit if DCE-MRI is added to DWI and T2-W imaging for recurrence [143,145]. The role of MRSI is controversial, especially given the metabolic changes that occur in the normal gland following radiation therapy and the theoretical undetectable citrate levels following prostatectomy, which complicates the metabolic criteria used for diagnosis. MRSI is also limited by spatial resolution and is sensitive to field inhomogeneity [139].

The multiparametric MRI technique can be tailored to the type of therapy with appropriate selection of functional parameters.

3. Ablative Therapy for Prostate Cancer

Ablative therapy techniques include cryotherapy, high-intensity modulated focused US, laser ablation therapy, radiofrequency ablation, and photodynamic therapy. Imaging criteria for focal therapy differ from imaging criteria for whole-gland treatment, as the objective of imaging is accurate localization and contouring of the index lesions [146]. Although research evidence for MRI in focal therapy is limited, mp-MRI may be the optimum approach needed to achieve the objectives for focal therapy.

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Section 5. Detection, Staging, and Recurrence Assessment of Urologic Malignancy

C. Scrotum and Penis

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

D. Examination Technique:

1. Scrotum

Although sonography remains the primary modality in the diagnosis of scrotal pathology, MRI provides valuable information in the detection and localization of scrotal masses (intratesticular versus paratesticular), morphology, and tissue characterization, especially when sonography is inconclusive [147-150]. MRI is also recommended for local staging of testicular germ cell tumors [150].

Patients are prepared by placing a towel under the scrotum to elevate both testes to a horizontal plane, and the penis is draped over the anterior abdominal wall. Either a small-diameter multipurpose or multielement pelvic coil is centered over the scrotum. MRI sequences of the scrotum should be performed with small FOV and high spatial resolution (slice thickness ≤4 mm and no gap).

Suggested sequences include the following:

i. Axial T1-W without and with fat suppression

ii. Axial T1-W, in-phase and opposed-phase

iii. Three-plane orthogonal T2-W FSE

iv. Optional DCE fat-suppressed T1-W 2-D SE or 3-D gradient-echo or fat-suppressed T1-W 2-D SE

v. Optional: Axial DWI with ADC maps

Axial T1-W spin-echo sequences with and without fat suppression, followed by axial, coronal, and sagittal T2-W FSE imaging, are optimal for lesion detection, characterization, and localization. T2-W sequence is best obtained with echo time (TE) of 100-140 ms to optimize contrast [150]. Differentiates tumor from normal structures. In-phase and opposed-phase imaging of the scrotum can identify the fat-water interface and can help depict hemorrhage due to the T2* effects of hemosiderin. DCE-MRI using 3-D gradient-echo T1-W imaging in 2 orthogonal planes has been shown to improve characterization of scrotal lesions [151,152]. Alternatively, postcontrast conventional 2-D spin-echo in 2 planes can be substituted [150]. Intravenous gadolinium can be administered when indeterminate pathologies are found using fat-suppressed 2-D spin-echo or 3-D gradient-echo T1-W imaging in 2 orthogonal projections.

Preliminary investigations report improvement in characterization of intratesticular lesions with ADC of carcinomas being lower than that of normal testes and some benign intratesticular lesions [153,154]. Axial DWI is recommended (slice thickness of 3-5 mm) with b-values including 0-100, 400-500, and 800-1,000 s/mm².

Staging is typically performed with CT for assessment of retroperitoneal nodes. However, MRI is an appropriate substitute with performance of either T1 or T2-W imaging to the level of the renal hila [155].

2. Penis

MRI is the most sensitive imaging modality for the local staging of penile carcinomas because of its high soft-tissue contrast and multiplanar capability. It is important for the penis to be placed in a position of comfort, not bent or rotated, and to remain fixed in position throughout the examination, which is typically achieved with
the penis draped and taped to the anterior abdominal wall. However, artifacts from excessive abdominal wall
motion during breathing can degrade image quality, and the penis may need to be positioned inferiorly [156].
A small surface coil placed on the penis is optimal for high spatial resolution images (FOV: 14–16 cm), although
a multielement pelvic coil can be used and enables a larger FOV to assess for inguinal and pelvic
lymphadenopathy [156,157]. Suggested sequences include the following:

i. Three-plane orthogonal high-resolution T2-W FSE (optional fat suppression in one plane)

ii. Axial T1-W

High spatial resolution T2-W sequence (3-4 mm) provides excellent contrast resolution between the
hypointense tunica albuginea and hyperintense corpora and urethra, and is most useful for local staging. Fat
suppression may be used in one plane to increase the dynamic range. The use of IV gadolinium has not been
shown to improve detection or local staging or to be advantageous to standard T2-W sequences [156,158-160].
Artificial erection by intra cavernous injection of prostaglandins or combinations has been shown to increase
diagnostic accuracy for invasion of the tunica albuginea and corpora but is rarely applied in practice given the
risk of priapism [158,161]. Osseous structures can be assessed with a T1-W sequence and inguinal lymph node
evaluation with either a T1-W or T2-W acquisition.

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Section 6. Evaluation of Complications Following Pelvic Surgery, Including Abscess, Urinoma, Lymphocele, Radiation Enteritis, and Fistula Formation (for parameter on performance of MRI for perianal fistulas, refer to the section Identification and Classification of Perianal Fistulas)

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

Fat-suppressed T2-W images are sensitive to edema, inflammation, and abscess formation [162]. The use of negative or biphasic endoluminal bowel-contrast agents (such as ferumoxsil oral suspensions or dilute barium suspensions) reduce the SI in the bowel lumen on T2-W images, thereby increasing the conspicuity of high signal inflammation and abscess on T2-W images [163]. DWI may assist in the differentiation between cystic lesions and abscesses [164,165].

D. Examination Technique:

CT is usually the first study performed in the search for an abscess, especially in the setting of postoperative complications or for nonspecific symptoms and signs of infection. Because MR has better soft-tissue contrast and lacks ionizing radiation, it sometimes has been used as an alternative to CT in patients of child-bearing age and children [166].

MRI is performed with a pelvic phased array coil.

Suggested sequences include the following:

i. Orthogonal planes (axial and coronal) or 3-D T2-W fat-suppressed FSE or short tau inversion recovery (STIR) to highlight inflammation and/or edema

ii. Axial T1-W

iii. Precontrast and dynamic postcontrast fat-suppressed 3-D T1-W gradient echo

iv. Optional: DWI with ADC maps

v. Optional: MR enterography (see below)

Abscesses may be caused by postoperative complications or infectious or inflammatory bowel conditions (such as Crohn’s disease, appendicitis, diverticulitis, radiation enteritis, and pelvic inflammatory disease). On both CT and MR, an abscess is a collection of purulent fluid, pus, usually often with peripheral rim enhancement, that may contain gas from gas-forming organisms [167]. Gas may cause blooming artifact on dual-echo gradient-echo in-phase images (longer TE images) [168]. MR shows inflammation as enhancement on T1-W contrast-enhanced scans (especially if subtraction is performed following a 3-D acquisition) and edema as fluid signal on fat-suppressed T2-W images [51]. In the acute setting, DWI may show high signal on the high b-value image and restricted diffusion on the ADC map in an abscess [169]. Abscesses may be treated by percutaneous drainage; however, imaging guidance is usually accomplished using US or CT.

Pelvic hematomas can be caused by trauma, surgery, and/or coagulopathy. Although seromas and lymphoceles have the appearance of simple fluid on all MR sequences without and do not enhancement, the MR appearance of hematoma varies with the age of the blood but is commonly hyperintense on T1-W images [170,171].

Urinomas can usually result from obstructive uropathy, but may also occur after trauma, or surgery, or may occur iatrogenically after instrumentation [170]. MRI does not play a role in acute urinary tract injuries [172], but resultant findings may be seen in MRI scans that were requested for other reasons. Urinomas have fluid signal on MR, with
low signal on T1-W and high signal on T2-W images. Extravasation of urine can be directly demonstrated in the excretory phase after IV contrast administration from the genitourinary system. Management of urinomas differs from that of other postoperative collections in that it usually involves treatment of the primary cause of urine extravasation—such as stent or nephrostomy tube placement, or operative repair of tears or damage—in addition to percutaneous drainage of the collection.

Lymphoceles, usually a complication of lymphadenectomy, are managed differently than other postoperative fluid collections if refractory to medical therapy, as the former may undergo may be managed by catheter drainage with or without sclerotherapy [169]. Uncomplicated lymphoceles are unilocular with fluid signal on all MR sequences and are located in the distribution of previous lymph node dissection [173]. DWI and ADC maps may help identify active disease.

Acute radiation enteritis occurs within days to weeks of exposure and is manifested by mucosal hyperenhancement and bowel wall thickening of bowel wall, usually affecting the small bowel as it is more sensitive to injury. Chronic radiation enteropathy usually presents with bowel obstruction due to stricture formation. MR also shows wall thickening, scarring, tethering, and abnormal or absence of peristalsis. T2-W sequences and contrast enhancement are used to differentiate active inflammation (bright signal) from fibrosis with stenotic disease (dark signal with luminal narrowing). Fistulas may form secondary to radiation injury with tissue breakdown [174].

MR enterography using ultrafast or turbo spin-echo sequences to reduce artifacts from peristalsis with IV contrast enhancement can demonstrate radiation changes, such as bowel-wall thickening and dilation, submucosal edema, fatty stranding in the adjacent mesentery, and an abrupt transition point from adhesions. These studies involve administration of IV or IM glucagon to reduce peristalsis and ingestion of up to 1.5 L of biphasic negative endoluminal contrast agents. Balanced gradient-echo sequences (such as FIESTA or true FISP) in axial and coronal planes with breath-holding best show mural abnormalities and findings surrounding the bowel loops. 3-D spoiled gradient-echo fat-saturated T1-W sequences are acquired before and serially after IV contrast administration in the coronal and axial planes [175]. For more information, see the ACR–SAR–SPR Practice Parameter for the Performance of Magnetic Resonance (MR) Enterography [176].

Imaging along with physical examination can identify the site of a fistula and map its course and extent. Fistulas may be caused by surgery, radiation, trauma, childbirth, infection, inflammatory bowel disease, and malignancies. In patients with a malignancy, fistulas may occur as a result of a primary or recurrent tumor or as a consequence of surgery or radiation therapy. On T2-W images, fistulas typically have high signal due to fluid. Short inversion time inversion-recovery (STIR) images may show a fistulous tract to advantage. Air-filled tracts produce low SI on all MR pulse sequences [177]. On DCE T1-W imaging, the fistulous tract often enhances.

The sagittal plane usually best delineates vaginal fistulas. For vesicovaginal fistulas, CT or MR with excretory phase imaging shows contrast material outlining the fistulous communication between the bladder and the vagina, and vaginal gas—air—fluid levels. In patients with contraindications to iodinated IV contrast material, MR is preferred to noncontrast CT [177].

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Section 7. Identification of Source of Lower Abdominal Pain in Pregnant Women: Appendicitis, Ovarian and Uterine Masses, and Urologic Conditions

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

DWI reflects water mobility and tissue cellularity. ADCs can be calculated from images with different b-values.

D. Examination Technique: (Please also refer to the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging [1]).

The etiology of acute pelvic pain in pregnant patients falls into one of 3 categories: gastrointestinal disease, gynecologic disease, or urologic disease. The most common cause is acute appendicitis [178]. Other common pelvic etiologies include degenerating fibroid and significant hydronephrosis [179].

The goal of imaging a pregnant patient with pelvic pain is to promptly identify the source of the pain. This information guides surgical and medical management. US remains the initial imaging modality for evaluating pelvic pain. However, the advent of widespread motion-insensitive MR sequences, coupled with the absence of ionizing radiation, has led to an increase of MR examinations in pregnant patients, especially when US is equivocal or limited [3,180-187].

Patients should fast between 4–6 hours prior to imaging to decrease bowel peristalsis. A 1.5T magnet strength (or lower) is suggested in pregnant patients to decrease specific absorption rates. Patients can be imaged in the supine or left lateral decubitus position using a multicoil array and a large FOV (38-44 cm).

Suggested imaging sequences include the following:

i. Three-plane orthogonal T2-W SSFSE images
ii. Axial fat-suppressed T2-W SSFSE images or STIR
iii. Axial T1-W in-phase and out-of-phase gradient-echo images
iv. Optional: Coronal T1-W
v. Optional: 2-D time-of-flight (TOF)
vi. Optional: Orthogonal T2-W fast imaging with steady-state free precession images
vii. Optional: DWI with ADC maps
viii. Optional: 2-D or 3-D balanced-steady-state-free-precession (b-SSFP) noncontrast MRA/MRV

(See the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [8]).

1. Gastrointestinal Disease

The MRI features of acute appendicitis parallel those of CT: a fluid-filled, dilated appendix > 6 mm with a thickened wall and periappendiceal inflammation and fluid. A diameter between 6 and 9 mm without secondary finding is indeterminate [187]. It is important to have an adequate imaging FOV to ensure identification of the entire appendix, which is displaced superiorly and medially by the enlarging uterus [182]. 2-D TOF imaging can help distinguish the appendix from adjacent engorged gonadal vessels.

Bowel-wall edema is common to many gastrointestinal diseases: inflammatory bowel disease, enteritis, colitis, enteropathies, and ischemia [188]. On T2-W and DWI, edema manifests images as high SI [189]. Noting the
segment of bowel affected and any ancillary imaging features (eg, fibrofatty proliferation) aids in arriving at the correct differential diagnosis.

2. Gynecologic Disease

Fibroids may be a source of acute pain during pregnancy owing to rapid growth, torsion, and/or hemorrhagic infarction. Of these, hemorrhagic infarction may have characteristic imaging features: diffuse or peripheral high SI on T1-W images, central high SI on T2-W images, and restricted diffusion [182,188].

Pelvic mass origin and characterization can be challenging in pregnant patients, and MRI can be used as a problem-solving tool. MR can be used to delineate whether a mass is uterine or adnexal or to differentiate conditions such as mature cystic teratomas, dermoid, and endometriomas with confidence. Acute torsion may occur in pregnancy as the ovaries are lifted out of the true pelvis by the enlarging uterus. The enlargement and edema that accompanies torsion is readily apparent on fat-suppressed T2-W images and include afollicular stroma with peripherally displaced follicles [56]. Hemorrhage within the stroma is a later finding, and T1-W and T2-W SI reflects the age of the blood products [182]. A twisted pedicle, though specific, is not commonly identified.

3. Urologic Disease

Cystitis has bladder wall thickening with or without air and/or filling defects. Nondependent signal voids in the urinary tract in the absence of instrumentation suggest air, whereas dependent filling defects may be blood clots, and/or calculi, and/or fungus balls. Pelviocaliectasis and ureterectasis are common in late pregnancy and are differentiated from obstruction by noting ureteral tapering to the point where there is extrinsic compression by the gravid uterus anteriorly and the sacral promontory posteriorly. Ureteral calculi, in contrast, result in abrupt caliber change of the ureter and may have associated high SI on T2-W images due to inflammatory changes [182]. Pyelonephritis results in lower ADC values compared with normal renal cortex [190].

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PRACTICE PARAMETER 34  MRI Soft Tissue Pelvis
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**Section 8. Identification and Classification of Perianal Fistulas** (For parameters on performance of MRI for abscess, please refer to the section Evaluation of Complications Following Pelvic Surgery, Including Abscess, Urinoma, Lymphocele, Radiation Enteritis, and Fistula Formation)

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

Digital subtraction MR-fistulography and high-resolution precontrast and postcontrast fat-suppressed 3-D $T_1$-$W$ gradient-echo sequence with subtraction postprocessing have been reported to be an important complement to surgical exploration [191]. DCE 2-D $T_1$-W images with time-SI curves provide information on fistula activity [192].

This technique may be useful to identify a subgroup of patients with perianal Crohn’s disease at increased risk for complications. These patients may benefit from more frequent monitoring. DWI reflects water mobility and tissue cellularity and can improve diagnostic confidence.

D. Examination Technique:

Imaging with a pelvic phased array coil is standard practice that results in high accuracy for detecting perianal fistulas [193-196]. This is especially true for patients with Crohn’s disease who are prone to distant fistulous extensions and abscesses. Some centers rely on an have utilized an endoluminal coil alone or in combination with an external coil and report good imaging results, but endoluminal coils are not routinely used [197].

Suggested sequences include [198] the following:

i. Sagittal $T_2$-W SSFSE (localizer) to prescribe true axial and coronal images of the anal canal (oblique axial and oblique coronal)

ii. Oblique axial $T_2$-W FSE

iii. **Oblique coronal $T_2$-W FSE**

iv. Oblique axial fat-suppressed $T_2$-W FSE

v. Oblique axial fat-suppressed $T_1$-W fat

vi. Oblique axial and oblique coronal postcontrast fat-suppressed 3-D $T_1$-W gradient echo

vii. Optional: oblique coronal fat-suppressed $T_2$-W FSE

viii. Optional: STIR images

ix. Optional: DWI with ADC maps

x. Optional: digital subtraction MR-fistulography

xi. Optional: DCE 2-D $T_1$-W images with time-SI curves

The majority of perianal fistulas are not associated with an underlying condition. They result from impaired drainage of the anal glands, leading to abscesses that subsequently fistulize. However, perianal fistulas frequently complicate Crohn’s disease and can be seen in up to a quarter of patients with longstanding (20 years) disease [199,200].

MRI is superior to digital rectal examination and anal endosonography in classifying fistulous tracts and identifying their internal opening [201,202]. The objectives in performing and interpreting MRI for perianal fistulas are 3-fold:

1) to determine the relationship of the fistula to the sphincter complex; 2) to identify any secondary fistulae and/or abscesses; and 3) to monitor medical therapy for perianal fistulizing Crohn’s disease [203,204]. The most accepted MRI fistula classification system is the St. James University Hospital classification [205], which is a modification of the Parks classification [206].
There are 5 grades:

i. Grade 1: Simple linear intersphincteric fistula

ii. Grade 2: Intersphincteric fistula with intersphincteric abscess or secondary fistulous tract

iii. Grade 3: Transsphincteric fistula

iv. Grade 4: Transsphincteric fistula with abscess or secondary tract within the ischioanal or ischiorectal fossa

v. Grade 5: Supralevator and translevator disease

On unenhanced T1-W images, fistulous tracts, inflammation, and abscesses have low to intermediate SI and may be difficult to distinguish from sphincters and normal muscles. On T2-W and STIR images, linear fistulas and their complications (secondary tracts and/or abscesses) have high in SI compared to surrounding structures. The use of contrast increases the conspicuity of the fistulous tracts and abscess cavity walls. Contrast-enhanced T1-W images can also help distinguish fluid from inflammatory tissue, common in Crohn’s disease patients. Time-SI curves following dynamic contrast administration provide information about disease activity. Additionally, DWI improves diagnostic confidence and may be especially helpful as an adjunct to T2-W images in patients with a contraindication to IV contrast [207].

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Section 9. Identification and Characterization of Congenital Anomalies of the Female and Male Pelvis, Including the Anatomic Evaluation of Ambiguous Genitalia and Disorders of Sexual Development (DSD)

V. SPECIFICATIONS OF THE EXAMINATION (general specifications were discussed earlier in the document)

C. Technical Advances:

3-D T2-W MRI allows volumetric acquisition of the male and female pelvis, providing submillimeter sections with multiplanar reformating capability. There is a tradeoff between volume imaged, acquisition time, and T2 characteristics [41]. When evaluating nonpalpable undescended testes, DWI is complementary to conventional imaging [208]. High-resolution images of the seminal vesicles can be obtained with endorectal MR and/or by acquiring images on a 3T system.

D. Examination Technique:

1. Müllerian Duct Anomalies

The workup of suspected Müllerian duct anomaly (MDA) is often undertaken in the setting of infertility, obstetric complications, primary amenorrhea, and/or endometriosis. Although US, especially 3-D US, is often the initial imaging examination and performs well in experienced hands [209,210], MRI is the most accurate modality to characterize and classify MDAs [211]. In young females who are not sexually active, MRI may be performed rather than transvaginal US [212]. Hysterosalpingography and hysterosalpingo contrast sonography are best suited to evaluate synechiae and fallopian tube patency.

The original 1979 Buttram and Gibbons classification of MDAs [213] was modified in 1988 by the American Society of Reproductive Medicine [214]. Accurate classification is critical as treatments vary by subtype, thus underscoring the role of diagnostic imaging. A comprehensive MRI examination evaluates the uterine corpus, uterine cervix, vagina, and adnexa [215]. Vaginal gel insertion may aid in evaluating cervical and/or vaginal involvement, such as by a vaginal septum [216]. The kidneys must also be assessed because there is a 30–50% prevalence of associated renal anomalies. Imaging is performed with a pelvic phased array coil. Fasting 4–6 hours prior to imaging decreases artifacts from bowel peristalsis; alternatively, SQ or IM glucagon may be administered if not contraindicated. Patients are asked to void before the examination.

Suggested sequences include the following:

i. Orthogonal high-resolution (long and short axis) T2-W FSE of the uterus and upper vagina. This should include a T2-W FSE coronal oblique view, oriented parallel to the long axis of the uterus, in order to assess the uterine fundal contour. Alternatively, and/or a 3-D volumetric T2-W acquisition may be obtained

ii. Axial T1-W with and without fat suppression

iii. Coronal large FOV T2-W SSFSE that includes the renal fossae

iv. If a patient is unable to cooperate, orthogonal T2-W SSFSE of the uterine corpus, uterine cervix, and vagina may be performed, recognizing the more limited spatial resolution

v. Optional: T2-W FSE with vaginal gel to define the vaginal canal and/or cervix

vi. Optional: T2-W FSE that includes the abdomen in patients with disorders of sex development for presurgical planning of prophylactic gonadectomy or surveillance in those who choose gonad preservation

vii. Optional: DWI can help identify and characterize the gonads in patients with disorders of sexual development
IV contrast is not indicated.

During organogenesis, the paired Müllerian ducts undergo a 3-stage process: 1) development (elongation and descent); 2) fusion; and 3) reabsorption of the uterovaginal septum. The goal of high-resolution T2-W imaging is to identify abnormalities that may occur from the time the paired Müllerian ducts descend, elongate, and fuse to the time of reabsorption of the intervening tissue, the uterovaginal septum. The short-axis T2-W images provide information on the number of endometrial, endocervical, and/or endovaginal cavities, whereas the long-axis T2-W images provide information on the true fundal contour of the uterus. T2-W sequences also provide information on whether or not any 2 cavities communicate. T1-W images allow diagnosis of concomitant hematomata and/or endometriosis that may accompany certain MDAs. Finally, a large FOV coronal image assesses renal abnormalities that often accompany MDAs.

2. Male: **Congenital Pelvis Anomalies** Seminal Vesicle Anomalies

Congenital anomalies of the male pelvis includes a variety of cystic lesions such as ejaculatory duct cysts, Cowper gland duct cysts and syringoceles, prostatic utricle, and Müllerian duct cysts and seminal vesicle cysts [217]. Other anomalies include abnormalities of the seminal vesicle, cryptorchidism, and congenital absence of the vas deferens. US is often the initial imaging modality for evaluating the seminal vesicles, prostate gland, and/or cryptorchidism. CT and MRI are typically reserved for problem solving (eg, investigation of intra-abdominal undescended testes).

The seminal vesicles are extraperitoneal secretory glands that lie posterior to the bladder and cephalad to the prostate. They originate from the lower mesonephric ducts. Congenital anomalies include agenesis, hypoplasia, and cysts. Seminal vesicle agenesis and hypoplasia may be associated with cryptorchidism. Likewise, seminal vesicle cysts may be associated with renal anomalies, ectopic insertion of ureters, and/or agenesis of the vas deferens. Multiplanar MRI allows comprehensive evaluation of the seminal vesicles and their surrounding structures.

Suggested sequences include [218] the following:

i. Orthogonal T2-W

ii. Axial T1-W

iii. Contrast-enhanced T1-W images may be performed in complicated cases (eg, proteinaceous cyst)

iv. Optional coronal large FOV T2-W SSFSE that includes renal fossae

3. Male: Cryptorchidism

Imaging may help identify a nonpalpable testis by serving as a surgical roadmap in an effort to preserve testicular function and/or detect early malignant tumors [219]. US is often the initial modality in the workup of a nonpalpable testis and has moderate success [220]; however, a meta-analysis found that US rarely impacts treatment while at the same time increases health care costs [221]. MRI is usually reserved for patients with nondiagnostic US.

Sequences include the following:

i. Axial and coronal T1-W images

ii. Axial and coronal T2-W fat-suppressed images to include the abdomen.

iii. Optional: Orthogonal contrast-enhanced T1-W images may increase conspicuity of the nonpalpable testis

iv. Optional: Axial high b-value single-shot spin-echo echoplanar images with chemical shift selective fat suppression
The nonpalpable testis is typically hypointense to muscle on T1-W images, hyperintense to muscle on T2-W, and enhances following IV contrast. Although conventional imaging performs well in locating a nonpalpable testis, a high b-value DWI can increase the preoperative sensitivity and accuracy of detection of nonpalpable testes. A nonpalpable testis is markedly hyperintense to muscle on high b-value DWI.

REFERENCES


ALL REFERENCES


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PRACTICE PARAMETER 47 MRI Soft Tissue Pelvis 2020 Resolution No. 28
PRACTICE PARAMETER


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Development Chronology for this Practice Parameter

2005 (Resolution 4)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 15)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 4)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–NASCI–SPR Practice Parameter for the Performance of Body Magnetic Resonance Angiography (MRA)

Sponsored By: ACR Council Steering Committee

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Revised 2015 (Resolution 8) *

ACR–NASCI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF BODY MAGNETIC RESONANCE RESONANCE ANGIOGRAPHY (MRA)

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, 813 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.

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PRACTICE PARAMETER 1

Body MRA

2020 Resolution No. 29
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), the North American Society for Cardiovascular Imaging (NASCI), and the Society for Pediatric Radiology (SPR).

Magnetic resonance angiography (MRA) is a proven and useful tool for the evaluation, assessment of severity, and follow-up of diseases of the vascular system. Contrast-enhanced MRA (CE-MRA) has been shown to be equivalent to conventional angiography in the evaluation of diseases of many portions of the vascular system and for pretreatment planning [1-5]. In addition, as compared with conventional angiography, MRA is less expensive, less invasive, and lacks ionizing radiation exposure. Despite its proven efficacy, MRA remains an evolving amalgam of different techniques. Consequently, only general recommendations can be made regarding imaging protocols. Detailed protocols have been omitted to avoid promoting obsolete methodology. This document pertains to the assessment of vessels below the thoracic inlet, which are referred to as body MRA. For information on assessment of vessels of the head and neck or assessment of the heart, see the ACR–ASN–SNIS–SPR Practice Parameter for the Performance of Cervicocerebral Magnetic Resonance Angiography (MRA) [6] and the ACR–NASCI–SPR Practice Parameter for the Performance and Interpretation of Cardiac Magnetic Resonance Imaging (MRI) [7].

Body MRA should be performed only for a valid medical reason. Most MRI systems have available specialized sequences that have been optimized for performing MRA. Although it is not possible to detect all vascular abnormalities by using MRA, adherence to the following practice parameters will enhance the probability of their detection.

MRA has important attributes that make it valuable in assessing vascular disease. Compared with radiographic catheter-based invasive angiography, it is considerably less invasive with no significant risk of vascular injury. Although MRA techniques are free of adverse effects from iodinated contrast media, some gadolinium-based contrast agents have been linked to the development of nephrogenic systemic fibrosis (NSF) in patients with severe renal insufficiency (see the ACR Manual on Contrast Media) [8-12]. More recently, Ferumoxytol, an ultra-small superparamagnetic iron oxide (USPIO) contrast agent and not a gadolinium-based contrast agent, has been reported as a suitable alternative to gadolinium-based contrast agents and as capable of yielding high-quality CE-MRA [13-18]; however, this is an off-label indication. However, unenhanced Noncontrast MRA techniques are also available for assessing the vasculature in patients who cannot or should not receive gadolinium-based contrast agents [19-22]. Compared with vascular ultrasound, MRA is less operator dependent, yields images of the vascular system in a format familiar to most referring physicians, is less limited by body habitus and overlying bowel gas, and has greater 3-D capability. Contrast-enhanced CT angiography (CTA) can also provide excellent vascular illustration but is associated with increased patient concerns related to exposure to ionizing radiation and the use of iodinated contrast media—concerns not borne by utilization of MRA. MRA has the ability also to provide time-resolved vascular imaging without the additional ionizing radiation exposure concerns related to multiphase CTA. In addition, CTA does not provide quantitative information about blood flow, which is
possible with phase contrast MRA (PC-MRA), and CTA does not assess oxygen saturation, which is possible with susceptibility-weighted MRA. MRA has also shown promising results for atherosclerotic plaque characterization, notably for detection of high-risk features (eg, intraplaque hemorrhage, lipid-rich necrotic core, or fibrous cap thinning/rupture) of carotid atherosclerotic plaque [23-25].

MRA is also useful in diagnosing vascular disease in children and is more advantageous for this patient population given the lack of radiation exposure and ability to include time-resolved scans. Pediatric MRA may require specialized imaging approaches to accommodate the different spectrum of disease, physiology, smaller vessel caliber, typically faster blood flow, larger motion concerns, and varying body size as compared with adults and may require sedation or general anesthesia.

Application of this practice parameter should be in accordance with the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [26] and the ACR–SIR Practice Parameter for Sedation/Analgesia [27].

(For pediatric considerations, see sections II.B.4 and IV.C.)

II. INDICATIONS

A. General Considerations

Adult indications for body MRA include, but are not limited to, the definition and evaluation of the following:

1. Presence and extent of vascular stenosis or occlusion due to atherosclerosis, vasculitis, or thromboembolic phenomena
2. Etiology of thoracic, abdominal, or pelvic hemorrhage
3. Mapping vascular anatomy for preprocedural planning and postprocedural surveillance of treatment
4. Presence, location, and anatomy of aneurysms and vascular malformations
5. Presence, nature, and extent of injury to vessels, including dissection
6. Vascular supply to, or involvement by, tumors
7. Presence and extent of venous disease, including occlusion, thrombosis, and tumor invasion
8. Venous anatomy, including congenital abnormalities, extrinsic compression, or causes of intrinsic stenosis or obstruction
9. Presurgical assessment of vascularity that may be involved by or affected by disorders in proximity
10. Nature and extent of other congenital or acquired vascular abnormality
11. Quantitative measurements of blood flow

B. Specific Considerations

1. Thoracic vasculature

MRA is useful for assessing the aorta, and its branch vessels, and can be used to assess the pulmonary vasculature. Indications for thoracic MRA include, but are not limited to, the definition and evaluation of the following:

a. Thoracic aorta
   i. Aneurysm and/or atherosclerosis of the thoracic aorta and branch vessels
   ii. Posttraumatic pseudoaneurysm
   iii. Acute aortic syndrome evaluation
       a) Dissection
       b) Intramural hematoma
       c) Penetrating atherosclerotic ulcer
iv. Atheroembolic disease—identification of aortic thrombi
v. Vasculitis
vi. Neoplasia, both primary and secondary
vii. Postoperative evaluations
   a) Perianastomotic leaks
   b) Infection
   c) Pseudoaneurysm
viii. Endovascular stent graft, including endoleaks
ix. Congenital disorders, including vascular malformations, arch anomalies, and aortic coarctation
b. Coronary arteries
   i. Abnormal arterial anatomy
   ii. Atherosclerotic narrowing
   iii. Vasculitis
   iv. Aneurysmal disease (including Kawasaki disease)
v. Coronary artery bypass graft

c. Pulmonary veins
   i. Venous mapping prior to and following radiofrequency ablation for atrial fibrillation
   ii. Pulmonary vein anomalies, including anomalous return and stenosis
d. Pulmonary arteries
   i. Thromboembolism
   ii. Pulmonary artery hypertension
   iii. Stenosis
   iv. Vascular malformations
      a) Pulmonary sequestration
      b) Pulmonary arteriovenous malformations
   v. Neoplastic disease
   vi. Preoperative and postoperative assessment of lung transplantation
e. Internal mammary and intercostal vessel evaluations
f. Bronchial arteries and aortopulmonary collateral vessels
g. Congenital or acquired thoracic venous disorders
h. Assessment of preoperative and postoperative status, including known or suspected complications following repair or palliation of congenital cardiovascular disorders in adults and children

2. Extremity evaluations
   a. Arteries
      i. Atherosclerotic occlusive disease
         a) Intermittent claudication
         b) Acute and chronic critical limb ischemia
         c) Patients with previous interventions (postoperative)
            i. Stent grafts
            ii. Bypass grafts
         d) Atheroembolism
      ii. Congenital anomalies, including vascular malformations
      iii. Vasculitide
      iv. Arterial fibrodysplasia
      v. Postinterventional intimal hyperplasia
      vi. Arterial entrapment syndromes
      vii. Adventitial cystic disease
      viii. Vascular malformations and fistulae
      ix. Aneurysmal disease
      x. Assessment of complications of arterial bypass grafts
x. Assessment of surgically created dialysis fistulas and grafts with unenhanced MRA
xi. Preoperative mapping of vascular anatomy for plastic surgery graft procedures
b. Assessment for vascular involvement with musculoskeletal tumors
c. Venous evaluations
   i. Thrombus
      a) Central
      b) Peripheral
      c) Effort thrombosis of the upper extremity
      d) Venous compression
   ii. Venous malformations
   iii. Varicose veins/venous mapping
   iv. Assessment for vascular involvement with musculoskeletal tumors
   v. Assessment of causes of peripheral edema
      a) Thrombus
      b) Venous compression
      c) Assessment of strictures from indwelling catheters
   vi. Assessment of patent vessels for venous access and mapping for surgical creation of native dialysis fistulas and grafts with unenhanced MRA
   vii. Assessment of vein suitability as bypass conduits

3. Abdominal and pelvic vasculature MRA
   a. Diagnosis and/or assessment of the following vascular abnormalities:
      i. Aneurysm of the aorta and major branch vessels
      ii. Stenosis or occlusion of the aorta and major branch vessels resulting from atherosclerotic disease, thromboembolic disease, or large-vessel vasculitis
      iii. Dissection of the aorta
      iv. Vascular malformation and arteriovenous fistula
      v. Portal, mesenteric, or splenic vein thrombosis
      vi. Inferior vena cava (IVC), pelvic vein, gonadal vein, renal vein, or hepatic vein thrombosis
   b. Vascular evaluation in one of the following clinical scenarios:
      i. Lower-extremity claudication
      ii. Known or suspected renovascular hypertension
      iii. Known or suspected chronic mesenteric ischemia
      iv. Hemorrhagic hereditary telangiectasia
      v. Known or suspected Budd-Chiari syndrome
      vi. Portal hypertension
      vii. Known or suspected gonadal vein reflux
   c. Preprocedure assessment for the following:
      i. Vascular mapping prior to living organ donation
         a) Liver
         b) Kidney
         c) Pancreas
         d) Combined organ transplant
      ii. Assessment of renal vein and IVC patency in the setting of renal malignancy or neoplasm
      iii. Vascular mapping prior to placement of or surgery on a transjugular intrahepatic portosystemic shunt (TIPS).
      iv. Vascular mapping prior to resection of abdominal and pelvic neoplasms
      v. Vascular mapping prior to uterine fibroid embolization
      vi. Vascular mapping prior to hepatic bland embolization, chemoembolization, and radioembolization procedures
      vii. Vascular mapping prior to tissue grafting
d. Postprocedure assessment for the following:
   i. Evaluation of organ transplant vascular anastomoses (hepatic, renal, and pancreatic)
   ii. Detection of suspected leak following aortic aneurysm surgery or MR-compatible aortic stent graft placement
   iii. Evaluation of ovarian artery collateral flow following uterine fibroid embolization

4. Pediatric indications for body MRA
MRA is particularly applicable in children because of the risk (albeit low) related to catheter-based angiographic procedures, including the small potential risk of exposure to ionizing radiation [28]. The need and potential risk of sedation should be considered. Various studies of children have shown MRA to be useful for assessing vascular abnormalities of the chest, abdomen, and extremities [1,29-31].

Indications for body MRA for children include, but are not limited to, the definition and evaluation of the following:
a. Congenital anomalies of the aorta, coronary arteries, pulmonary vasculature, and associated branch vessels
b. Aortic, pulmonary arterial, and branch vessel vasculopathies in the setting of a known or suspected syndrome (eg, Marfan syndrome and other connective tissue disorders, midaortic syndrome, neurofibromatosis type 1, and William syndrome)
c. Vasculitis
d. Arterial dissection
e. Aneurysmal disease
f. Renovascular hypertension
g. Vascular malformations of the trunk and extremities
h. Central and peripheral venous occlusive disease
i. Congenital venous/portovenous anomalies
j. Presence of thrombosis, including caval, portal, mesenteric, or splenic vein
k. Blood supply to vascular neoplasms for operative planning
l. Vascular anastomoses and complications of organ transplants
m. Postoperative anatomy following vascular surgery
n. Evaluation of surgically created dialysis fistulas and grafts with unenhanced MRA
o. Evaluation of extremity peripheral vasculature in congenital anomalies (eg, Klippel-Trenaunay syndrome)
p. Portal hypertension
q. Thoracic Arterial and venous thoracic outlet syndrome

Detailed discussion for additional imaging of the coronary arteries can be found in the ACR–NASCI–SPR Practice Parameter for the Performance and Interpretation of Cardiac Magnetic Resonance Imaging (MRI) [7].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The physician responsible for performing body MRA must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of thoracic, abdominal, and extremity anatomy (including congenital or developmental variants and common collateral pathways) as well as the indications, pertinent vascular considerations, and complications associated with common vascular procedures and surgeries.
IV. SPECIFICATIONS OF THE EXAMINATION

The supervising physician must have complete understanding of the indications, risks, and benefits of the examination as well as the alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. 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 Body 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 practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

The supervising physician should have an adequate good understanding of both the clinical indications for body MRA as well as 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 and Preparation

The physician responsible for the examination should supervise patient selection and preparation, protocol the examination, and be available in person or by phone for consultation. Patients should be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment or, in the case of CE-MRA, by exposure to gadolinium-based contrast media (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [32]).

When intravenous (IV) gadolinium-based contrast media are required for successful performance of MRA, IV contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution’s policy on IV contrast utilization (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [32]).

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate sedation may be needed to achieve a successful examination. General anesthesia may be required for certain patients, particularly young children. If moderate sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [27]. Although in some age groups (generally less than 6 years) some form of sedation may be needed, the need for sedation may be mitigated with the use of an alternative [33,34], such as use of an audiovisual systems during MRI [35] or the “feed-and-sleep” technique in neonates and infants [36].

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
C. Examination Technique

MRA is a general term that refers to a diverse group of MR pulse sequences. Different mechanisms can be used to generate signal from flowing blood without gadolinium [19-22, 38-40]. Time of flight (TOF) technique relies on inflow enhancement to generate images of blood flow [10]. [41][41][41][41][40][39][38][37][37][38][38]Flow images and quantitative measurements of flow velocity can be obtained using phase contrast (PC) MRA methods in which the image contrast is generated by velocity-induced phase shifts [42,43]. A third method relies on a steady-state free precession (SSFP) sequence that captures the intrinsic T1 and T2 features of blood as bright signal [44-46]. A fourth technique requires some form of cardiac gating and exploits the different signal intensities of blood using a T2-weighted echo train spin-echo sequence between systole, at which time flow void predominates, and diastole, at which time the relatively static blood has high signal intensity [47]. With this technique, angiographic images can be obtained by subtracting the systolic dataset from the diastolic dataset. The use of contrast media for CE-MRA has the benefit of speed of acquisition and reliable vascular signal for detection of intraluminal defects, such as an intimal tear, as well as the ability to provide time-resolved MRA (TR-MRA). CE-MRA relies on enhancement of the blood signal by an intravascular paramagnetic contrast agents, typically gadolinium-based, and uses a rapid, 3-D T1-weighted gradient-echo acquisition [48-50]. Individuals using MRA must understand these concerns as well as those related to the artifacts and limitations of the various MRA techniques available at their sites. There are also benefits and technical concerns for MRA based on the field strength of the MR scanner. MRA performed on a high-field MR scanner (eg, 3T), for instance, offers the advantages of speed and higher vascular signal-to-noise relative to that performed on a low-field 0.5T MR scanner [51-53]. However, MRA performed on a high-field MR scanner presents concerns related to higher absorption rate (specific absorption rate [SAR]) and artifacts related to metallic susceptibility.

1. Noncontrast MRA

Time-of-flight (TOF) technique relies on inflow enhancement to generate images of blood flow [10]. The most commonly used inflow techniques are 2-D TOF and 3-D TOF. In 2-D TOF acquisitions, multiple contiguous thin slices are obtained and combined to form a 3-D data set. The 3-D technique inherently acquires a volume of data. The region of coverage of a 3-D TOF sequence is limited by radiofrequency saturation within the acquisition volume. When using a 2-D TOF technique to image the aorta and arteries of the lower extremities, cardiac or peripheral gating can minimize artifacts related to vascular pulsation and improve image quality at the expense of a greatly lengthened examination [54,55]. Blood flow in a particular direction can be selectively imaged through the use of saturation bands. With a 2-D acquisition, these saturation bands can be prescribed to travel with the imaging slice, ensuring adequate elimination of undesired signal along the entire course of the vessels of interest.

Quiescent inflow slice-selective (QISS) MRA is a variant of TOF that relies on radiofrequency saturation of stationary in-plane spins followed by a delay time to allow for inflow enhancement [56-59]. Initial experience with this technique for the noncontrast evaluation of the lower-extremity peripheral arteries shows promising results.

Flow images and quantitative measurements of flow velocity can be obtained using PC-MRA methods in which the image contrast is generated by velocity-induced phase shifts [42,43]. As with TOF, PC-MRA can be obtained as either a 2-D or 3-D data set (ie, 4-D flow MRI). IV contrast enhancement may also be used to increase the signal obtained from the blood. PC techniques are based on the physical properties of moving spins. 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 of the TOF technique, although direction of flow can also be indicated without the need for saturation bands. PC-MRA can be obtained without or with electrocardiogram (ECG) triggering. The application of ECG triggering will typically lengthen the acquisition time. It is essential to trigger the PC acquisition to the cardiac cycle if measurements of flow velocity or flow volume are desired. Therefore, peripheral or cardiac gating should be available.

A third method relies on a steady state free-precession (SSFP) sequence that captures the intrinsic T1 and T2 features of blood as bright signal [44-46]. Because of balanced SSFP’s (bSSFP) reliance on T2/T1 signal, intraluminal thrombus may be masked on bSSFP MRA (Nota bene, use of PC-MRA, a flow-based technique, is often helpful to confirm luminal patency in these cases). Two-dimensional and 3-D SSFP MRA techniques use a type of unspoiled gradient-echo sequence in which the gradients are balanced and the signal is a composite signal from free-induction decay and stimulated echoes. The typical bSSFP sequence does not depend on flow and, therefore, does not distinguish flow direction or velocity. Flow-related artifacts are also dramatically reduced with this type of sequence, but it is sensitive to artifacts from static magnetic field inhomogeneity (off-resonance artifacts). The abdominal aorta and visceral (eg, renal) arterial branches can be selectively imaged, however, through the use of an asymmetrically applied inversion prepulse that can effectively null the signal from venous blood [19].

A fourth technique requires some form of cardiac gating and exploits the different signal intensities of blood using a T2-weighted echo train spin-echo sequence between systole, at which time flow void predominates, and diastole, at which time the relatively static blood has high signal intensity. A form of echo train spin-echo MRA exists that depends on the different signal intensities between rapidly flowing blood during systole and relatively static blood during diastole. During systole, intravascular signal is reduced because of the flow-related signal void using a T2-weighted echo train spin-echo or bSSFP sequence. During diastole, the blood behaves as a relatively immobile fluid and demonstrates relatively high signal intensity. By timing the acquisition of data sets to the cardiac cycle, systolic and diastolic data sets can be acquired and subtracted, eliminating background signal. The remaining intravascular signal can be displayed in a similar manner to other MRA techniques. This technique is best suited for imaging vessels that exhibit pulsatile flow and therefore may be limited in evaluation of distal extremity circulation when severe inflow disease diminishes distal pulsatility.

A fifth technique is the two-point Dixon water-fat separation technique noncontrast MRA of the whole heart and vasculature that has shown promising results on 1.5T and 3T scanners compared with spectral presaturation inversion recovery (SPIR) fat-suppressed balanced fast field echo (BFFE) coronary MRA in coronary imaging and vascular studies [60,61]. A novel 3-D respiratory-triggered gradient-recalled echo Dixon-based MRA/MR venography (MRV) technique that provides high-resolution anatomical imaging of the vasculature of the neck, body, and extremities without the need for IV contrast material or breath-holding has also recently been described [62].

2. CE-MRA
3-D CE-MRA combines a fast T1-weighted gradient-echo acquisition with an intravenously administered paramagnetic contrast agent. There are now a variety of contrast agents available for performance of CE-MRA that may differ in terms of relaxivity, gadolinium concentration, biodistribution, elimination, and various safety concerns (see the ACR Manual on Contrast Media) [12,38,63-67]. For example, higher-relaxivity gadolinium-chelate extracellular contrast agents can provide improved vascular signal-to-noise and contrast-to-noise ratios for an equimolar dose of a lower-relaxivity gadolinium-chelate extracellular contrast agent. Such agents reduce T1 relaxation time of blood and nearly eliminate the loss of signal related to saturation effects and flow-related artifacts due to intravoxel dephasing, thus leading to a more accurate assessment of stenosis [68,69]. CE-MRA has documented efficacy in assessing the arterial and venous
systems in the thorax, abdomen, pelvis, and extremities [2,5,39,48,68,70-82]. In most cases, CE-MRA does not require cardiac gating and is, therefore, easily applicable in patients with irregular cardiac rhythms. The coronary arteries and aortic root, however, move quite significantly during each cardiac cycle, and CE-MRA of these vessels typically benefits from proper cardiac gating [83,84]. Using breath-holding during MRA often minimizes imaging artifacts related to motion artifacts, and artifacts due to complex flow are minimized. Respiratory-gated MRA using navigator echoes that synchronize image acquisition with the respiratory cycle in real time can often achieve higher-resolution 3-D MRA, notably in patients with limited breath-holding ability. These advantages make CE-MRA extremely useful for imaging of the vasculature in the thorax, abdomen, pelvis, and extremities. CE-MRA techniques can be combined with a moving table to allow large areas of coverage [85-87]. Novel Contemporary k-space filling and parallel imaging techniques allow for high-temporal-resolution (time-resolved) imaging of vascular territories, [38,53,88-91], potentially eliminating the need for precise acquisition timing. Alternatively, accurate timing of acquisition can be enhanced through the use of a timing bolus, “fluoroscopic triggering,” or automatic bolus detection techniques [92-94]. It is important for non-TR-MRA that the contrast bolus duration matches the image acquisition duration in order to avoid either edge enhancement or blurring secondary to the changing contrast concentration in the vessels of interest throughout the scan. This can be done by adjusting the injection rate. CE-MRA is typically performed during the first pass of the bolus but often includes equilibrium phase acquisitions, which provide time-resolved vascular information. Postcontrast imaging using SSFP MRA [95] and PC-MRA [93] can often provide supplemental vascular information to CE-MRA even when performed well after the first pass of the bolus.

More recently, Ferumoxytol, an USPIO contrast agent, has been reported to successfully yield high-quality CE-MRA [13-18]; however, this is an off-label indication. Ferumoxytol is not a gadolinium-based contrast agent, and unlike gadolinium-based contrast agents, it does not pose a risk of NSF. Although recent studies suggest an excellent safety profile, careful consideration to relative risk and benefit is nonetheless required, given that the agent has a “black box” warning from the FDA and anaphylactic reactions resulting in death have been reported. Ferumoxytol has a prolonged intravascular half-life of several hours, which is much longer than that of traditional extracellular gadolinium-based contrast agents, which provides a prolonged window of opportunity for MRA.

3. Special Considerations
   a. MRV
      Venous illustration can be achieved using both noncontrast and CE-MRA methods. Indications for MRV are listed above. Contrast-enhanced MRV (CE-MRV) is implemented in much the same way as CE-MRA, whereby an IV gadolinium-based contrast agent injection is combined with the acquisition of a 3-D T1-weighted spoiled gradient-echo data set [96]. Digital subtraction of a precontrast mask from a postcontrast acquisition may improve depiction of venous structures, but this is not considered essential. Exact timing of the contrast bolus is less critical for venous imaging. Selection of an empiric delay time of 40–60 seconds following the contrast injection, which allows time for the contrast agent to fully equilibrate in the venous system, is usually adequate. The use of a blood pool contrast agent is particularly advantageous when imaging venous structures because it remains within the circulation for several hours after the initial injection [97]. Blood pool contrast agents ensure prolonged increase in vascular signal for high spatial resolution steady state CE-MRV. Respiratory gating can be used for equilibrium phase imaging in the thorax to allow free-breathing image acquisition. Ferumoxytol, which has a prolonged vascular half-life and does not have the same patient safety concerns (eg, NSF) as gadolinium-based contrast agents, may be particularly appropriate for MRV.

Noncontrast MRV is another option for MRV desirable in patients with renal dysfunction, pregnancy, gadolinium-based contrast agent allergy, and in children [62]. Noncontrast MRV is best achieved with SSFP or turbo spin-echo [98] imaging approaches. ECG or respiratory gating can be employed in the
chest to offset motion artifact, and inversion recovery may be utilized to improve contrast and background suppression. TOF imaging, which depends on the generation of signal from flowing blood, may also be used for imaging the venous system and is best suited to the portal and intracranial circulations.

There are some specific clinical disorders of the venous system where additional maneuvers or techniques may be helpful for further disease characterization. Venous imaging using TR-MRA, which allows direct visualization of the physiologic blood flow dynamics, is helpful for the diagnosis of pelvic congestion syndrome because of its ability to determine temporal filling and whether anterograde or retrograde flow is present in the ovarian vein [99]. Provocative positioning of the patient may be required in some instances for final diagnosis. In Paget-Schroetter syndrome (ie, effort-induced thrombosis), for example, MRV, either during first pass or steady state, may need to be performed during both arm adduction and arm abduction to demonstrate dynamic compression of the subclavian vein between clavicle and rib.

b. Pediatric Patients

In infancy and childhood, MRA can provide valuable information about the vascular system, particularly for assessing various types of vascular malformations and syndromes, congenital lesions, such as coarctation of the aorta, or anomalous pulmonary venous return. However, technical and safety issues are more complex in pediatric patients. The smaller size of vasculature increases the demand for higher spatial resolution, and more rapid circulation time requires higher temporal resolution. In addition, sedation and/or general anesthesia may be necessary to successfully complete the examination, depending on the age of the child or possibly the complexity of the clinical questions being answered. Many of these concerns have been discussed earlier in this document by suggesting noncontrast, free-breathing high-resolution MRA imaging or using the “feed-and-sleep” method without need for sedation. Regarding the safety of using gadolinium-based contrast agents in neonates, readers are referred to the ACR-SPR Practice Parameter for the Use of Intravascular Contrast Media [32]. Infants and young children, special attention must be paid to the appropriate dose of contrast media taking into account the immature renal function, especially in infancy. Given the small body size of some pediatric patients, certain clinical applications of CE-MRA may necessitate dilution of contrast media to increase the volume of the administered contrast.

c. MRA Interpretation

The supervising physician should review all MRA 2-D source images to reduce possible confusion of high-signal material (eg, fat or thrombus) with flow signal. Review of the source images also aids diagnosis by eliminating overlapping structures and determining whether artifacts are the cause of spurious signal or signal loss.

MRA data are routinely postprocessed using a multiplanar reformation (MPR), maximum intensity projection (MIP) reconstruction, and volume-rendering techniques. Rotating displays of 3-D data sets allow separation of vessels that are superimposed on a single projection. Additionally, multiple views are needed to fully depict altered vascular anatomy. Targeted MIP renderings can be made to clarify areas of tortuosity and vessel overlap. The supervising physician must be familiar with MPR, MIP, and volume-rendering techniques and with the limitations and strengths of each method. The type and frequency of artifacts will vary with the display technique; thus, the supervising physician must understand the potential errors associated with each display method [69,100-105]. Optimized pulse sequences and quantitative postprocessing tools for evaluating blood vessel caliber, flow velocity, volume, and direction should be used when indicated clinically.
V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [106].

In addition to examining the vascular structures of interest, the MR 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.

In addition, if contrast agents are used for MRA, the dose, method of injection, and type of contrast agent administered must be documented in the report.

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 [107-109]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [110].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [107-109].

For additional safety considerations, see the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [26], the ACR Guidance Document on MR Safe Practices: 2013 [107], and the ACR Manual on Contrast Media [12].

VI. EQUIPMENT SPECIFICATIONS

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.

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [111].

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, Safety, Infection Control and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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RESOLUTION NO. 30

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–SPR–SSR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of Bone and Soft Tissue Tumors

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 5) *

ACR–SPR–SSR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF MAGNETIC RESONANCE IMAGING (MRI) OF BONE AND SOFT-TISSUE TUMORS

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 parameter was developed and written collaboratively by the American College of Radiology (ACR), the Society for Pediatric Radiology (SPR), and the Society of Skeletal Radiology (SSR).

Magnetic resonance imaging (MRI) is a proven and well-established imaging modality in the detection, evaluation, assessment, staging, and follow-up of tumors of the musculoskeletal system. Properly performed and interpreted, MRI not only contributes to initial diagnosis and identification of local recurrence but is also useful to serve as an important guide to biopsy, and inform treatment planning, as well as and assess response to therapy. However, MRI of a tumor or suspected mass should be performed only for a valid medical reason and after careful consideration of alternative imaging modalities. An analysis of the strengths of MRI and other modalities should be weighed against their suitability for particular patients and particular clinical conditions. Radiographs should be the initial imaging study obtained for clinical suspicion of bone tumors used for the initial diagnosis of primary bone tumors. In addition, radiographs are usually the first imaging test performed for most suspected soft-tissue masses and are particularly valuable for identifying showing the presence and character of calcification, fat, or other radiopaque material. For superficial palpable soft-tissue masses, ultrasound may be useful to characterize lesion location, detect internal vascularity, and differentiate solid from cystic lesions [1-3].

Technetium-99m–labeled diphosphonates Radionuclide bone scintigraphy scanning and single-photon emission computed tomography (SPECT), with or without CT co-registration, is often used when occult bone disease is suspected or and to screen the entire skeleton for polyostotic disease conditions such as metastasis metastastasis. Other nuclear medicine examinations have a role for specific clinical scenarios (eg, Indium-111 oxine, a labeled white blood cell (WBC) scan study for suspected osteomyelitis). CT shows detailed bone anatomy and aids in identifying osteoid and chondroid matrix. CT can also be useful to demonstrate the presence of fat within both bone and soft-tissue lesions. Sonography may aid in examination of soft-tissue masses (eg, cystic versus solid; assessment of vascularity) [1,2]. Conventional, MR, or CT angiography remains useful for evaluating tumor vascularity, identifying the relationship of the lesion to adjacent major blood vessels, planning resection and reconstruction, and providing a road map access for presurgical embolization [4]. Positron emission tomography (PET) with or without CT or MR co-registration can help stage and grade tumors [5-10], assess response to therapy [11-14], and detect tumor recurrence [8,15], but it may not reliably discriminate between benign and malignant tumors [6,16].

Although MRI is one of the most sensitive, noninvasive diagnostic tests for detecting anatomic abnormalities of the musculoskeletal system, findings may be misleading if not closely correlated with radiographs, clinical history, clinical physical examination, and physiologic tests [17,18]. Adherence to the following guidelines will enhance the probability of detecting such abnormalities.

II. INDICATIONS

Indications for MRI of soft-tissue and bone tumors include, but are not limited to, the following:
1. Initial characterization, detection, or exclusion of tumors [19-34]
2. Local staging of tumors [35-39]
3. Evaluation of tumors prior to biopsy, surgery, chemotherapy, and/or radiotherapy [27,35,40-44]
4. Evaluation of the response of tumors to treatment, including neoadjuvant chemotherapy, postresection chemotherapy, and radiotherapy [45-56]
5. Detection and evaluation of complications related to tumors or their treatment, including hemorrhage, infection, and neurologic and vascular conditions [27,52,55-65]
6. Posttreatment and long-term surveillance and characterization of local, regional, and distant tumor recurrences [53,54]

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [66].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for MRI of bone and soft-tissue tumors 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’s 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 must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. The physician should be familiar with relevant prior ancillary studies that the patient may have undergone. The physician performing MRI interpretation must have a clear understanding and knowledge of the relevant 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 should be available in person or by phone for consultation by direct communication. Patients must be screened and interviewed prior to the examination to exclude individuals who may have contraindications to MRI, in which the risks may outweigh the benefits at risk by exposure to the MR environment.

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
utilization (See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [67] and the ACR Manual on Contrast Media [68]).

Pediatric patients or patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate sedation or general anesthesia may be needed to achieve a successful examination particularly in young children. If minimal or moderate sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [69]. Young children may require sedation or general anesthesia in order to prevent patient motion during the MR examination. Strategies should be employed to mitigate the use of sedation whenever possible and should include motion-insensitive imaging acquisitions and the use of a child life specialist support [70].

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

Diagnostic-quality MRI of suspected bone and soft-tissue masses can be performed using a variety of magnetic designs (closed-bore whole body, open whole body) and a variety of field strengths [21,23,26,29]. Regardless of system design, efforts should be made to maximize signal-to-noise ratios (SNR). Field of view (FOV) should be tailored to the size of the patient and the size of the suspected mass [23,63,71,72]. For example, a 48-cm FOV would be appropriate for an extremely large tumor of the pelvis or thigh, whereas a 12-cm FOV may be appropriate for a small mass in the foot. At times, additional sequences with a larger FOV will be necessary to evaluate proximal or distal spread of disease. It is important to obtain as many transverse, sagittal, or coronal images through the lesion as is reasonable. Slice thicknesses will also vary depending on the size of the lesion [23]. For example, a 1-cm mass might require 3-mm-thick slices, whereas a tumor greater than 30 cm in size may be appropriately imaged with 1-cm slice thickness [23]. An interslice gap may be chosen to decrease signal loss due to cross talk [71] but in general should be no more than one-half of the slice width and should not impair complete visualization of the mass. The imaging matrix should balance the intravoxel SNR with desired in-plane spatial resolution.

The size and location of the lesion will often dictate the most appropriate coil to use for imaging. Small lesions or lesions located in the extremities will often be best imaged using a local surface coil, a cylindrical coil, or a dedicated joint coil. For extremely large lesions or lesions involving the torso, the body or torso coil may be a more appropriate choice [23,39,43]. Every attempt should be made to include The entire soft-tissue or bone tumor and associated marrow signal abnormality edema in association with the possible tumor should be captured within the imaged volume. Additionally, For some tumors, two separate but overlapping volumes might be necessary. High-grade sarcomas of bone, The entire bone, including the adjacent joints, should be imaged to evaluate for skip lesions and regional metastases. The use of a multiple-channel receiver coil unit may allow the use of parallel imaging and compressed sensing imaging techniques to reduce overall scan time or improve SNR and may be useful in reducing motion-related artifacts [73-75].

For patients with more than one suspected bone or soft-tissue mass, it may be necessary to perform separate MR examinations. For example, a patient with a mass involving both the pelvis and leg may require two separate studies.

When imaging bone and soft-tissue tumors at an MR imager of field strengths less than 1.5T, it is used to image bone and soft-tissue tumors, then other imaging parameters, such as the receiver bandwidth and number of acquisitions, will require modification to ensure adequate spatial and contrast resolution for confident diagnosis. This is often at the expense of longer examination times [63,76]. It may also be more difficult to achieve uniform
fat suppression on low-field systems using spectrally selective radiofrequency (RF) presaturation pulses, potentially
necessitating the use of Dixon or short tau inversion recovery (STIR) techniques [77-80]. Other systems may be
more prone to imaging artifacts (eg, chemical shift artifact on high-field magnets), again necessitating modification
of imaging parameters, such as receiver bandwidth, to ensure that these artifacts do not detract from the diagnostic
quality of the resultant images. Some MRI systems may not be appropriate for specific indications. For example,
high-resolution evaluation of a small mass may not be feasible with a low-field, open magnet, regardless of the
chosen imaging parameters [81].

MRI of bone and soft-tissue tumors usually includes images in at least two orthogonal planes (transverse, sagittal,
and coronal) [21,23,24,30,63]. The long axis images may be oriented orthogonal to the magnetic bore or may be
angled to better identify specific anatomic structures. Coverage of the tumor must ideally should include all of the
anterior, posterior, medial, lateral, superior, and inferior margins of the mass, unless clinically/radiographically
impractical [21,23,44].

MRI of suspected bone and soft-tissue tumors can be performed with a variety of pulse sequences. The choice of
sequences can be tailored to optimize the examination for specific clinical questions and according to local
preferences. An imaging protocol would usually be composed of at least one T1-weighted pulse sequence image
and one fluid-sensitive T2-weighted sequence with or without fat suppression.

Short echo time (TE) images with a relatively short repetition time (TR) (T1-weighted) are commonly used to
evaluate tumors [21,23,71,76]. Because of the Properly optimized, most institutions use fast spin-echo
sequences for T1-weighted imaging. If image blurring inherent in a with fast spin-echo imaging occurs image
made with a short effective TE, conventional spin-echo imaging can may be utilized preferred [21,23,71,76].
Properly optimized, however, some investigators have used fast spin-echo imaging for T1 weighted images. To
demonstrate pathologic tissues, T2-weighted (fluid-sensitive) imaging using conventional spin-echo or fast spin-
echo sequences are most commonly used [77-80,82]. T1-weighted spoiled gradient-echo chemical shift imaging
(i.e., water-fat in-phase/opposed-phase imaging) can be used to demonstrate the presence of lipid components in
tissues and may help discriminate benign from malignant disease processes, such as in evaluation of fractures and
bone marrow infiltration [83,84]. Gradient-recalled sequences may also be valuable, in particular in evaluating for
internal areas of hemorrhage, gas, ossification, or calcification. Diffusion-weighted imaging (DWI) may also be
useful to quantitatively and qualitatively assess bone and soft-tissue masses [85-87]. DWI uses the variability
of Brownian motion of water to characterize lesions as having restricted or unrestricted motion of water,
which correlates with lesion cellularity [88].

T1-weighted sequences are routinely done without fat suppression to depict anatomic relationships; however, the
addition of fat suppression may be helpful to detect hemorrhage or fat within a mass and enhancement when IV
contrast is given [89]. Fluid-sensitive images, obtained with long TR using conventional or fast spin-echo
sequences, can be used to characterize bone and soft-tissue tumors, providing complementary information to the
T1-weighted images. Therefore, a combination of both T1-weighted and T2-weighted images is typically performed
in each imaging plane [21,78-80,82]. Lesion conspicuity may be increased with the addition of fat suppression to
fluid-sensitive images; however, fat-suppressed imaging decreases the variation in tumor signal intensities that may
be useful in tissue characterization. T2-weighted sequences can be performed with or without fat suppression, or
Short-Tau Inversion Recovery (STIR) sequences can be used [78,79,82]. A combination of techniques may prove
advantageous. For example, the transverse images may be obtained without fat suppression and the long axis planes
(sagittal and/or coronal images) performed with fat suppression or STIR sequences. The exact TR, TE, and flip
angle chosen will depend on the field strength of the magnet and the relative contrast weighting desired [90-92].

Various techniques may be used to minimize the MR artifacts that can reduce imaging quality. Wraparound artifact,
including that originating from signal received from other parts of the body, can be reduced by phase using
oversampling, by switching the phase and frequency readout directions, by presaturation pulses, or by using RF
shielding. Truncation (Gibbs) artifacts may obscure or mimic intralvesional detail and can be reduced by changing
the phase-encoding direction. Involuntary patient motion is best controlled by ensuring patient comfort combined
with gentle immobilization or sedation when necessary and often requires sedation or general anesthesia for young
children [63,93]. Desensitizing “practice runs” orchestrated by a child life specialist may also be effective for
children [70] as well as the use of MR video goggles. Use of MR systems and coils that provide a high SNR, such
as high-field (3T) MR systems and multichannel coils, with or without parallel imaging and/or compressed
sensing, can reduce overall scan duration and individual sequence scan times and may help reduce bulk motion
artifacts and patient discomfort [73,74]. Motion artifact can also be reduced by sampling k-space in a rotating
fashion, utilizing radially directed imaging planes [94]. Flowing blood can produce ghosting artifacts, which can
be reduced with presaturation pulses or the use of gradient moment nulling [63,93].

In many cases, it may be advantageous to administer a gadolinium-based IV contrast agent [95-101]. IV contrast
may be helpful to differentiate cysts from solid masses and may provide additional details of the imaging features
of bone and soft-tissue masses [82,96,97]. Subtracting the precontrast images from the postcontrast images may be
beneficial to show subtle areas of enhancement and to distinguish enhancement from adjacent fat or hemorrhage
[102]. Fast, multiphase dynamic contrast-enhanced imaging can provide analysis of tumor perfusion kinetics,
including parametric perfusion data, that may help to distinguish malignant from benign tumors [103-105], to stage
tumors and response to therapy [49,106-108], to determine an optimal site for biopsy [108] improve tumor detection,
or evaluate potential extension of tumor cells along related fascial planes [109]. The decision to use IV contrast
should be based on medical appropriateness.

Follow-up MR imaging of musculoskeletal tumors is generally performed using sequences similar to those used
for initial diagnosis, including T1-weighted and T2-weighted images [53,54]. Because local recurrence may often
appear similar to the original tumor, MRI following treatment or surgery should ideally be interpreted with
comparison to prior MRI examinations, including the preoperative or pretreatment MRI, if available.
Follow-up MR examinations of patients with previously treated soft-tissue tumors often benefit from the addition
of IV contrast agents gadolinium chelates [52,53]. Protocols for follow-up and interpretation of MRI findings vary
depending on the type of tumor, the therapeutic methods used, and the aggressiveness of the tumor (see the ACR
Appropriateness Criteria®, Follow-up of Malignant or Aggressive Musculoskeletal Tumors [110]).

MR spectroscopy may be useful in gauging therapy response and tumor staging [111-116]. It may also be used to
detect certain metabolites in tumors to help in lesion characterization [113,117-122], but caution should be used in
interpretation because some metabolites that were thought to be specific may not be (eg, choline for malignant
tumors [123]). Newer imaging sequences employing isotropic or near-isotropic 3-D sequences (eg, IDEAL,
SPACE, CUBE, etc) can produce images with shorter scan duration but have not been thoroughly evaluated for
imaging of musculoskeletal tumors at this time. Whole-body MR screening examinations can be useful both for
staging of disseminated or hematologic tumors, such as multiple myeloma, and to limit radiation dose to pediatric
and pregnant patients [124-129].

For interpretation, the images are most commonly viewed electronically on a workstation but may also be printed
on hard copy or viewed on a workstation. If hard copy viewing is used, some practices may film the images with
magnified or narrowed window settings, but this can be left to local preferences. MR examinations in patients with
suspected tumors should be read cautiously and preferably in conjunction with available radiographs. Since local
recurrence may often appear similar to the original tumor, MR imaging following treatment or surgery should
ideally be interpreted with comparison to prior MRI exams, including the preoperative or pretreatment MRI, if
available. There are many pitfalls and artifacts that can suggest that a nonneoplastic mass is an aggressive tumor or
that a malignant tumor appears to be a benign lesion based on the MR appearance alone [82,130,131]. Furthermore,
imaging artifacts can also contribute to incorrect staging of tumors [82,130,131].
V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [132].

The report should address the presence or absence of a mass, the size of the lesion and description of anatomic extent, its composition (hemorrhage, necrosis, etc), signal intensity, and enhancement characteristics. When imaging is sufficiently characteristic, a diagnosis or differential diagnosis should be provided. A description of the anatomic location of a tumor, including its intracompartmental and extracompartmental extent, as well as its relationships to adjacent major muscles, vessels, and nerves, will contribute to the tumor's grading and staging. The presence or absence of fascial extension of tumor should be described, which will contribute to the surgical resection planning. The presence or absence of any regional lymphadenopathy or skip lesions should be noted.

VI. 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 [133].

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 and/or MR safety officer. Guidelines should be provided that deal with potential hazards associated with MRI examination to the patient as well as to others in the immediate area [134-136]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [134-137].

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 RF power deposition (specific absorption rate), and maximum acoustic noise levels.

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, Safety, Infection Control and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [66], the ACR Guidance Document on MR Safe Practices: 2013 [138], and the ACR Manual on Contrast Media [68].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [135,136].
## 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 Committee on Body Imaging (Musculoskeletal) of the Commission on Body Imaging and by the Committee on Practice Parameters – Pediatric Radiology of the Commission on Pediatric Radiology, in collaboration with the SPR and the SSR.

### Collaborative Committee

Members represent their societies in the initial and final revision of this parameter.

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REFERENCES


70. Edwards AD, Arthurs OJ. Paediatric MRI under sedation: is it necessary? What is the evidence for the alternatives? Pediatric radiology 2011;41:1353-64.


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

Development Chronology for this Parameter

2005 (Resolution 8)

Amended 2006 (Resolution 35)

Revised 2010 (Resolution 18)

Amended 2014 (Resolution 39)

Revised 2015 (Resolution 5)
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RESOLUTION NO. 31

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SPR–SSR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Knee

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 6) *

ACR–SPR–SSR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF MAGNETIC RESONANCE IMAGING (MRI) OF THE KNEE

PREAMBLE

These practice parameters are 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 cautions 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, 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 the practice parameters 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 the practice parameters. However, a practitioner who employs an approach

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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.
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substantially different from these practice parameters 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 these practice parameters 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 these practice parameters is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was developed and written collaboratively by the American College of Radiology (ACR), the Society of Pediatric Radiology (SPR), and the Society of Skeletal Radiology (SSR).

Magnetic resonance imaging (MRI) is a proven imaging modality for the detection, evaluation, assessment, staging, and follow-up of disorders of the knee. Properly performed and interpreted, MRI not only contributes to diagnosis but also serves as an important guide to treatment planning and prognostication. However, it should be performed only for a valid medical reason and after careful consideration of alternative imaging modalities. Radiographs will be the first imaging test performed for most suspected suspicious bone and soft-tissue abnormalities of the knee and will often suffice to diagnose or exclude an abnormality or direct further imaging workup. Computed Tomography (CT) provides better details of bone trabeculae, cortex, and periosteal new bone formation compared to the radiographs. With multiplanar reformatting, capabilities, CT can be helpful to demonstrate radiographically occult fracture or osseous loose body within the joint [1]. Ultrasound can evaluate the extraarticular soft tissues around the knee, including tendons and bursae, assess for joint effusion, and document synovitis [1]. In children, who often have an abundance of unossified epiphyseal cartilage and periartricular soft tissues that can limit the clinical assessment, ultrasound is particularly helpful to confirm or exclude a clinically suspected joint effusion. Bone scintigraphy is often used when radiographically occult bone disease is suspected or to screen the entire skeleton for conditions such as metastases. Other nuclear medicine (NM) examinations have a role for specific clinical scenarios (eg, a labeled white blood cell study or Positron Emission Tomography (PET)/CT for suspected osteomyelitis). Dual-energy CT techniques have also been used in evaluation of crystalline arthropathy, such as gout [2]. Computed tomography can show detailed bone trabecular and cortical anatomy, whereas sonography may be appropriate to examine superficial soft tissue structures around the knee, such as tendons, bursae, and joint effusion. Lastly, arthroscopy provides a detailed examination of the internal structures of the knee joint, allowing the surgeon to treat as well as to diagnose many internal derangements.

Although MRI is a sensitive, noninvasive diagnostic test for detecting anatomic abnormalities of the knee, its findings may be misleading if not closely correlated with radiographs, clinical history, symptomatology, physical examination, and radiographs physiologic tests. Adherence to the following practice parameters will enhance the probability of detecting such abnormalities.

II. INDICATIONS

A. Primary indications for MRI of the knee include, but are not limited to, the diagnosis, exclusion, and grading of suspected:

   1. Meniscal disorders: nondisplaced and displaced tears, discoid menisci, parameniscal cysts; complications of meniscal surgery † [3-11]
2. Ligament abnormalities: cruciate and collateral sprains and tears; complications following ligament repair or reconstruction † [12-17]
3. Extensor mechanism abnormalities: quadriceps and patellar tendon degeneration, partial and complete tears; patellar fractures and sleeve avulsions; and retinacular sprains and tears [18-22]
4. Osteochondral abnormalities: osteochondral fractures, osteochondritis dissecans, and treated osteochondral defects † [23-25]
5. Articular cartilage abnormalities: degeneration, chondromalacia, chondral fissures, fractures, flaps, and separations; complications following chondral surgery † [26-33]
6. Loose bodies and impinging structures: Hoffa syndrome, patellar and quadriceps impingement [34]
7. Evaluation of prefemoral fat pad in appropriate clinical scenarios [35]
8. Synovial-based disorders: synovitis, bursitis, symptomatic plicae†, and popliteal cysts* [36-39]
9. Osseous abnormalities: osteonecrosis, marrow edema syndromes, stress fractures, radiographically occult fractures, physeal and transphyseal injuries, and transphyseal bar evaluation, osseous and nonosseous and tethering mapping for growth disturbance and limb-length discrepancy* [40-43]
10. Muscle and tendon disorders: strains, partial and complete tears, tendonitis, tendinopathy, inflammation, and ischemia [44,45]
11. Iliotibial band friction syndrome [46,47]
12. Neoplasms of bone, joint, or soft tissue* [48,49]
13. Infections of bone, joint, or soft tissue* [50,51]
14. Congenital and developmental conditions: Blount disease, dysplasia, normal variants* [52,53]
15. Vascular conditions: popliteal artery entrapment, aneurysm, stenosis, occlusion, cystic adventitial disease* [54-56]
16. Neurologic conditions: common peroneal or tibial nerve traumatic injury, entrapment, compression injury, denervation, and peripheral neuropathy* [57]

B. MRI of the knee may be indicated to further clarify and stage conditions diagnosed clinically and/or suggested by other imaging modalities, including, but not limited to, the following:

1. Arthritis: inflammatory, infectious, neuropathic, degenerative, crystal-induced, posttraumatic* [58-62]
2. Primary and secondary bone and soft-tissue tumors* [48,49]
3. Fractures and dislocations [63-65]

C. MRI of the knee may be useful to evaluate specific clinical scenarios, including, but not limited to, the following:

1. Prolonged, refractory, or unexplained knee pain [66]
2. Acute knee trauma [67]
3. Mechanical knee symptoms: catching, locking, differentiating a stiff versus a locked knee (fixed extension block), limited or painful range of motion, snapping, crepitus† [68,69]
4. Tibiofemoral and/or patellofemoral instability: chronic, recurrent, subacute, acute dislocation, and subluxation† [64,65,70-72]
5. Tibiofemoral malalignment and/or patellofemoral malalignment or maltracking [73-75]
6. Swelling, enlargement, mass, or atrophy*
7. Patients for whom diagnostic or therapeutic arthroscopy is planned † [66,76-81]
8. Patients with recurrent, residual, or new symptoms following knee surgery† [10,13,14,27,82-86]
9. Patients with selected complications following knee arthroplasty [87,88] using appropriate metal artifact reduction strategies [89]

* Conditions in which intravenous contrast may be useful.
† Conditions in which intra-articular contrast (performed by direct intra-articular injection or indirect joint opacification following intravenous administration) may be useful.
III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [90].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for MRI of the knee 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 must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing the 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 by qualified personnel prior to the examination to exclude individuals who may be at risk by exposure to the MR environment.

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 utilization (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [91]).

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of 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 [92].

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

Diagnostic-quality knee MRI is possible using a variety of magnet designs (closed-bore whole-body, open whole-body, dedicated extremity) and field strengths [5,7,93,94]. Regardless of magnet design, a local coil is mandatory to maximize signal-to-noise ratio (SNR). Typically, a cylindrical coil (often called an “extremity” or “knee” coil) surrounds the knee. Newer multichannel knee coils or flexible surface coils containing 8 or more coil elements will further increase SNRs and are required when using techniques like parallel imaging, which can be used to increase spatial resolution and/or decrease the time of the scan [95]. Occasionally, a very large extremity may require a slightly larger coil (a posterior neck coil, for example), but every attempt should be made to ensure that the size of the coil closely matches that of the knee circumference [96]. In children with smaller knee joints, a multichannel flexible surface coil may provide superior SNR than a one-size-fits-all dedicated knee coil. The coil’s placement should allow imaging of the major structures in and around the knee; at times, repositioning the coil and/or extremity will be necessary to demonstrate additional pertinent anatomy.

Certain MR systems (eg, those using low-field-strength magnets) have inherently lower SNRs than others. When using such a system to perform knee MRI, other imaging parameters, such as the receiver bandwidth and number of acquisitions, will require modification to ensure adequate spatial and contrast resolution for confident diagnosis, often at the expense of longer examination times [97-99]. It may also be more difficult to achieve uniform chemical fat suppression on low-field-strength systems, necessitating the use of Dixon [100] or short tau inversion recovery (STIR) techniques. Other systems may be more prone to imaging artifacts (eg, chemical shift artifact on high-field magnets), again necessitating that imaging parameters, such as readout bandwidth, be modified to ensure that these artifacts do not detract from the diagnostic quality of the resultant images [5]. For some indications, like high-resolution imaging of articular cartilage, images obtained with a low-field system will be of lower quality compared with those acquired on a high-field system [94,100-104]. Detection of other conditions, such as cruciate ligament tears, is less dependent on magnet strength and design.

Typically, the patient is positioned supine with the affected knee completely or nearly completely extended in the coil. Mild external rotation of the leg is often comfortable for the patient. Gentle immobilization of the extremity and use of comfort measures for the entire body will help to reduce involuntary patient motion and resultant artifacts.

Knee MRI examinations usually include images acquired in appropriate transverse (axial), sagittal, and coronal imaging planes [105,106]. Multiplanar images can be acquired directly or reconstructed electronically from volumetric data acquired in one imaging plane. Some practices obtain standard sagittal and coronal images orthogonal to the anatomic planes of the knee, whereas others may angle the planes to better identify specific anatomic structures, such as the posterolateral corner ligaments [107,108]. The coverage should include all the anterior, posterior, medial, and lateral supporting structures of the knee, though not all structures need to be included in every imaging plane. Superiorly, the distal aspects of the quadriceps tendon and suprapatellar joint recess should be included. The distal insertions of the patellar tendon and pes anserinus tendons should be included inferiorly [109].

The field of view (FOV) should be tailored to the size of the knee and the structures being examined, but for the standard sequences, the FOV should be 16 cm or smaller. Occasionally, additional sequences with a larger FOV will be appropriate to completely evaluate a detected or suspected abnormality completely, for example, in the extensor mechanism or bone marrow. Slice thickness in the sagittal and coronal planes of 4 mm or less is necessary to demonstrate subtle meniscal pathology, but even thinner sections may be advantageous for detailed analysis of other structures, such as the articular cartilage. An interslice gap can decrease signal loss due to cross talk [110] but should typically be no more than 33% to 50% of the slice width and should not impair complete visualization of the intra-articular structures. In younger children, the imaged structures are often smaller in size; thus, smaller
FOV (<14 cm), thinner slice thickness (2.5-3.5 mm), and lower interslice gap (<20%) are often preferred. The imaging matrix should balance intravoxel SNR with desired in-plane spatial resolution and reduction of truncation artifacts but should be at least 192x196 steps in the phase direction and 256 steps in the frequency direction for 2-D imaging. Three-dimensional sequences with near isotropic voxels allow for multiplanar reconstructions from a single acquisition [111-113].

Knee MRI uses a wide variety of pulse sequences [96]. Many practices tailor the specifics of each study to optimize the examination for specific clinical questions. The choice of sequences will vary because of local preferences and/or available equipment or software limitations. Spin-echo, fast (turbo) spin-echo (FSE), and gradient-recalled sequences each may have a role for knee MRI. A typical imaging protocol will be composed of one or more of these pulse sequence types. The exact repetition time (TR), echo time (TE), and flip angle chosen will depend on the field strength of the magnet and the relative contrast weighting desired.

Fast (turbo) spin-echo images with a relatively short effective TE are most frequently used to examine the menisci. A short-echo train short-interecho spacing, and/or tailored radiofrequency pulses can reduce potential blurring. The literature supports that, for FSE and meniscal tears, a short effective TE, short echo train length, and narrow echo spacing reduces blurring and is “equivalent” to conventional spin echo (CSE). Two-dimensional and 3-D gradient-recalled images can also demonstrate meniscal disorders [109,111,113]. To show ligament pathology, water-sensitive images obtained using conventional or FSE long-TE sequences [114,115] or T2*-weighted gradient-recalled sequences [113] may be used. Including at least one plane of T1-weighted sequences is useful for characterizing narrow abnormalities [116], various stages of hemorrhage [117], and muscle pathology [44,45]. Additionally, T1-weighted images (often with fat suppression) are used after IV administration of gadolinium-based contrast agents to show tissue enhancement [118].

Imaging of articular cartilage disorders can be accomplished with a variety of pulse sequences [27,29], including FSE proton density-weighted, intermediate-weighted, T2-weighted sequences with or without fat suppression [26-28,119,120], or 3-D gradient-recalled sequences, or 3-D FSE sequences [113,121-123]. Newer sequences that may be advantageous to assess articular cartilage include modified steady-state free precession or spoiled gradient-recalled sequences that create separate water and lipid images [124-126] that selectively excite water protons [127,128] or that average 2 separate echoes to increase T2 weighting [129,130]. In contrast to these traditional pulse sequences that are optimized to detect sites of morphologic change, quantitative cartilage imaging tools such as T1-rho or T2 relaxation time mapping can detect microstructural changes within the cartilage matrix, which occur prior to irreversible damage [32,33].

In skeletally immature children with a history of knee trauma with that involved the transphyseal physis, development of physeal bar is a complication that can lead to growth disturbances, angular deformities, and limb length discrepancies. Extension resulting ingrowth disturbance and limb-length discrepancy. The resulting deformity depends on several factors: the nature and severity of the initial insult, residual growth potential, location and extent of physeal involvement. The latter can be “mapped” and better quantified using a 3-D fat-suppressed spoiled gradient-recalled echo sequence. Physeal bar evaluation and mapping can be performed by using 3-D fat-suppressed spoiled gradient-recalled echo sequence [42,43]. Additional specialty sequences have been advocated for cartilage imaging and may require product licenses and postprocessing specialized equipment and software. In addition, MR arthrography may be useful for evaluating articular surfaces in the knee [87], especially following articular cartilage transplantation [128], or on low-field systems where many of the newer sequences are not available [131]. IV contrast-enhanced MRI administration is typically recommended for the diagnosis of cartilage involvement in infants and young children because infection manifests differently than in older children. In infants and young children, skeletal infection particularly (S. aureus) has a propensity for involvement of the unossified cartilage, which may be occult on unenhanced MRI sequences.[123].

Suppressing the signal from fat may enhance the diagnostic yield of some pulse sequences [96]. Fat suppression techniques include spectral suppression of water protons, a phase-dependent method, such as the Dixon method or
STIR [100,132-136]. The latter 2 techniques may be necessary on low-field systems. Methods also exist for generating separate water and lipid images [124-126] or for selectively exciting water protons, which essentially nulls the contribution of fat in the final images [127,128]. Fat suppression is useful for identifying marrow abnormalities [132,133] and may be a useful adjunct when performing MR arthrography [14,84] or when FSE sequences are used to examine the menisci, ligaments, and articular surfaces of the knee [26,119,135].

It may be possible to shorten the time required for a knee MR examination without compromising diagnostic yield when using high-field-strength systems and multichannel surface coils [137]. Reduced sampling of k-space using parallel imaging, multichannel local coils allow the use of parallel imaging compressed sensing, and machine-learning acceleration techniques can which decrease acquisition times for individual pulse sequences [95,112,125,138,139]. Additionally, high-resolution 3-D near-isotropic imaging with near-isotropic voxels is possible using with newer gradient-recalled and FSE sequences on the latest generation MR systems [111,112,126]. Using these methods, a single volumetric acquisition obtained and reconstructed into multiple imaging planes will decrease can eliminate the need to obtain multiplanar 2-D sequences and thereby decrease the total number of pulse sequences needed. Synthetic MRI of the knee may allow a single sequence to provide T1-, proton density–, and T2-weighted images to also shorten the overall scan times [140].

Additional imaging techniques may have a role for specific knee disorders. Direct and indirect MR arthrography may be beneficial for various internal knee derangements and for imaging postoperative conditions [14,24,34,83,84,87,141]. In cases in which the etiology of a focal marrow lesion is uncertain, comparing the lesion signal intensity on a pair of gradient-recalled images with TE values chosen so that fat and water protons are in phase and out of phase, respectively, may help show fat within the lesion, thus supporting benignity [142].

Various techniques are useful to reduce artifacts that can degrade imaging quality. Wraparound artifact, including that originating from signal received from the contralateral knee, can be reduced by phase oversampling, by swapping the phase and frequency orientations, or by using radiofrequency shielding between the knees [143,144]. Truncation (Gibbs) artifacts may obscure or mimic meniscal tears; changing the phase-encoding direction or increasing the imaging matrix will reduce this artifact [143,145]. Ensuring patient comfort combined with gentle immobilization when necessary may reduce involuntary patient motion [96]. Presaturation pulses or the use of gradient moment nulling will reduce ghosting artifacts from flowing blood [143,146]. Chemical shift artifact is more severe at higher field strengths and may necessitate an increase in the receiver bandwidth [5,147]. Susceptibility artifacts, which originate from local field heterogeneity, are also more severe at higher field strengths and when using gradient-recalled pulse sequences. Avoiding gradient-echo imaging and reducing the voxel size by increasing the imaging matrix and/or decreasing the slice thickness and FOV will help reduce the magnitude of susceptibility artifacts [143].

In knees containing large metallic implants, a combination of longer echo trains, increased receiver bandwidth, decreased FOV, increased matrix size in the frequency-encoding direction, and control of the phase and frequency encoding directions will reduce, but typically not completely eliminate, metal artifacts [83,88]. 

**Vendor specific pulse sequences have been developed which can further reduce metal artifacts** [148-150]. The term “metal artifact reduction sequences” (MARS) has been applied to such strategies. **Lower magnet strength (1.5T rather than 3T) and use of nonfat-suppressed pulse sequences is preferred. In the presence of metal hardware, STIR imaging is often preferred over spectral fat suppression techniques, and gradient echo (GRE) techniques should be avoided** [151,152].

It is the responsibility of the supervising physician to determine whether additional or unconventional pulse sequences or imaging techniques would confer added benefit for the diagnosis and management of the patient. Examinations that use techniques not approved by the Food and Drug Administration (FDA), such as the intra-articular injection of gadolinium chelates (direct MR arthrography) [153-155], can be considered when they are judged to be medically appropriate.
V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [156].

The report should address the condition of the menisci, major ligaments, articular cartilage, osseous structures, and extensor mechanism. In selected cases, a description of findings in the neurovascular structures, muscles and tendons, synovium, and cortical bone would be appropriate.

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 [157-160]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [157-160].

VI. EQUIPMENT SPECIFICATIONS

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.

Equipment monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [139].

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, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [90], the ACR Guidance Document on MR Safe Practices: 2003 [161], and the ACR Manual on Contrast Media [162].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [158,159].

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Members represent their societies in the initial and final revision of this practice parameter.

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PRACTICE PARAMETER 13 MRI Knee

2020 Resolution No. 31


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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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RESOLUTION NO. 32

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–SPR–SSR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Shoulder

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 7) *

ACR–SPR–SSR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF MAGNETIC RESONANCE IMAGING (MRI) OF THE SHOULDER

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.

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 developed and written collaboratively by the American College of Radiology (ACR), the Society of Pediatric Radiology (SPR), and the Society of Skeletal Radiology (SSR).

Magnetic resonance imaging (MRI) is an established and proven imaging modality for the detection, evaluation, assessment, staging, and follow-up of disorders of the shoulder. Properly performed and interpreted, MRI contributes not only to diagnosis but also to treatment planning and prognostication. However, it should be performed only for a valid medical reason and after careful consideration of alternative diagnostic modalities. MRI of the shoulder may be performed without contrast, following intra-articular contrast injection (“direct” MR arthrography) to increase conspicuity of intra-articular abnormalities, or with intravenous (IV) contrast to identify hyperemic lesions or to create “indirect” arthrographic images by enhancing synovial-lined structures and their contents.

An analysis of the strengths and potential risks of MRI and other diagnostic modalities should be weighed against their suitability for specific patients and particular clinical conditions. Computed tomography (CT) is used to evaluate the bone integrity of the glenoid fossa and humerus and the alignment and congruence of the glenohumeral joint [1]. When combined with arthrography, CT can also be used for evaluating the labrum, articular cartilage, and loose bodies [2]. Sonography can be used to evaluate the rotator cuff and biceps tendon and has the advantage of imaging during physiologic motion [3-7]. Radiographs are usually the first imaging test performed for most suspected abnormalities in the shoulder and will often suffice to diagnose or exclude an abnormality or to direct further imaging evaluation. Radionuclide bone scanning can screen the entire skeleton in addition to the shoulder for radiographically occult bone disease, such as metastases. Other nuclear medicine examinations have a role for specific clinical scenarios (eg, a labeled white blood cell study for suspected osteomyelitis). Conventional single-contrast or double-contrast arthrography can accurately depict most articular-surface and full-thickness tears of the rotator cuff [8,9]. Sonography can be used to evaluate the rotator cuff and biceps tendon and has the advantage of imaging during physiologic motion [3-7]. Ultrasound and fluoroscopy can be used to guide arthrographic injection [10,11]. Computed tomography (CT) is used to evaluate the bone integrity of the glenoid fossa and humerus and the alignment and congruence of the glenohumeral joint [1]. When combined with arthrography, CT can also be used for evaluating the labrum, articular cartilage, and loose bodies [2]. Lastly, arthroscopy provides a detailed examination of the internal structures of the shoulder, allowing the surgeon to treat as well as diagnose many internal derangements.

Although MRI is one of the most sensitive diagnostic tests for detecting anatomic abnormalities of the extremities, findings may be misleading if not closely correlated with other imaging studies, clinical history, clinical examination, and physiologic tests. Adherence to the following practice parameter will enhance the probability of accurately diagnosing such abnormalities.
II. INDICATIONS

A. Primary indications for MRI of the shoulder include, but are not limited to, diagnosis, exclusion, and grading of suspected:

1. Rotator cuff tendon abnormalities: massive, full-thickness, partial-thickness, and recurrent (postoperative) tears, tendinopathy, calcific tendinitis, and cuff tear arthropathy† [12-22]

2. Disorders of the long head of the biceps brachii: full-thickness, partial-thickness, and recurrent (postoperative) tears, tendinopathy, calcific tendinitis, subluxation, and dislocation† [10,11,20,23-25]

3. Conditions affecting the supraspinatus outlet: acromial shape, os acromiale, subacromial spurs, acromioclavicular joint disorders, coracoacromial ligament integrity, subacromial bursitis† [15,26-29]

4. Labral abnormalities: tears, cysts, and degeneration, and tears, including superior labrum anterior posterior (SLAP) lesions, Bankart lesions and their variants, and recurrent (postoperative) labral tears† [2,20,30-44]

5. Abnormalities of the rotator interval and biceps pulley† [23,45,46]

6. Muscle disorders affecting the shoulder girdle: atrophy, hypertrophy, denervation, masses, and injuries [18,22,47-53]

7. Glenohumeral chondral and osteochondral abnormalities: osteochondral fractures and osteochondritis dissecans, articular cartilage degeneration, fissures, fractures, flaps, and separations† [54-56]

8. Intra-articular bodies†

9. Synovial-based disorders: synovitis, bursitis, metaplasia, and neoplasia*2 [57,58]

10. Marrow abnormalities: osteonecrosis, marrow replacement and edema syndromes, and osseous contusion and stress fractures* [59]

11. Neoplasms, masses, and cysts of bone, joint, or soft tissue* [29,39,60]

12. Infections of bone, joint, or soft tissue* [61-63]

13. Congenital and developmental conditions, including dysplasia and normal variants* [64-67]

14. Vascular conditions: entrapment, aneurysm, stenosis, and occlusion* [68]

15. Neurologic conditions: entrapment, compression, masses, and peripheral neuritis* [37,42,69]

16. Pathology in the shoulder following arthroplasty [70]

B. MRI of the shoulder may be indicated to further clarify and stage conditions diagnosed clinically and/or suggested by other imaging modalities including, but not limited to, the following:

1. Arthritides: inflammatory, infectious, neuropathic, degenerative, crystal-induced, posttraumatic* [29,71,72]

2. Frozen shoulder (adhesive capsulitis)† [45]

3. Primary and secondary bone and soft-tissue tumors* [60]

4. Fractures and dislocations [26,73,74]

C. MRI of the shoulder may be useful to evaluate specific clinical scenarios including, but not limited to, the following:

1. Prolonged, refractory, or unexplained shoulder pain*†3

2. Acute shoulder trauma [26,74]

3. Impingement syndromes: subacromial, subcoracoid, internal† [15,27,28,75-78]

4. Glenohumeral instability: chronic, recurrent, subacute, and acute dislocation and subluxation† [43,64,74,79-81]

5. Shoulder symptoms in the overhead motion or throwing-athlete† [82-84]

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2 * Conditions in which IV contrast may be useful.

3 †Conditions in which intra-articular contrast (performed by direct intra-articular injection or indirect joint opacification following IV administration) may be useful.
6. Mechanical shoulder symptoms: catching, locking, snapping, crepitus†
7. Limited or painful range of motion
8. Swelling, enlargement, mass, or atrophy* [39]
9. Patients for whom diagnostic or therapeutic arthroscopy is planned†
10. Patients with recurrent, residual, or new symptoms following shoulder surgery† [14,18,20,22,51,85,86]

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [87].

The interpreting physician needs a thorough knowledge and understanding of the anatomy of the shoulder, including the numerous normal variations in the glenohumeral capsular and labral configurations and their corresponding MRI appearances.

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for MRI of the shoulder 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 must be familiar with the potential hazards associated with MRI, including potential adverse reactions to contrast media. 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 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.

Certain indications require administration of IV contrast media. IV contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution’s policy on IV contrast utilization. (See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [88].)
Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of
moderate sedation may be needed to achieve a successful examination. If moderate sedation is necessary, refer to
the ACR–SIR Practice Parameter for Sedation/Analgesia [89].

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

Shoulder MRI can be performed using a variety of magnet designs (closed or open) and field strengths (low,
medium, or high) [16,38,90-94]. Because the inherent signal-to-noise ratio (SNR) is reduced with lower field
strength MR systems, imaging practice parameters may require modifications. With lower field strength systems,
for example, the number of acquisitions can be increased at the expense of longer imaging times and increased risk
of involuntary patient motion [90,92,95,96]. Alternatively, the voxel size can be increased (by a combination of
larger field of view (FOV), thicker slices, and/or decreased matrix) at the expense of spatial resolution [92,93,96,97].
Fat-suppression techniques that rely on the difference between fat and water frequencies (chemical shifts) are
unreliable at low field strength, and substituting short tau inversion recovery (STIR) images may be necessary
[90,93]. Even when the imaging protocol is optimized for shoulder imaging on a low-field open system, subjective
image quality will likely be inferior to that obtained with a high-field system [93,96]. Various investigators using
different equipment and scanning protocols have reached contradictory conclusions regarding the diagnostic
performance of low field strength MR scanners for shoulder disorders. Some studies have found that the accuracy
for complete and partial rotator cuff tears and for labral abnormalities is not significantly different for open, low-
field and closed, high-field systems, with careful attention to technique [91,93,94,98]. MR arthrography can further
enhance the diagnostic yield for shoulder MRI performed on low field strength systems [90,96]. Other investigators
have found lower accuracy for evaluating disorders like SLAP tears, capsular abnormalities, and small rotator cuff
tears with specific low-field systems compared with high-field ones [97-99].

Regardless of system design, a local coil is mandatory to maximize the SNR. Commercially available coils
appropriate for shoulder imaging include single-loop contoured or flat-surface coils [100,101], paired coils in a
Helmholtz configuration [36,102], circularly polarized flexible coils [97], solenoid coils [92], and phased array
designs [31,41].

Patients are positioned supine with the affected arm at the side. For evaluation of the rotator cuff and anterior
labrum, internal rotation of the arm should be avoided [81,101,103]. When MR arthrography is performed,
repositioning the affected arm into the abduction external rotation (ABER) position may increase sensitivity for
anterior inferior labral tears [2,32,104,105] and may increase accuracy for rotator cuff tears, especially partial-
thickness undersurface tears [106-108]. Images with the patient’s arm in this position are obtained parallel to the
humeral shaft prescribed from a coronal localizer image [32].

Shoulder MR examinations usually include images acquired in the transverse (axial), oblique sagittal, and oblique
coronal planes. The oblique sagittal and oblique coronal planes sections are prescribed orthogonal to each other
using either the glenoid fossa or the supraspinatus tendon as reference anatomic landmarks. Evaluation of the
rotator cuff is performed using both oblique coronal and oblique sagittal images [109]. Prescribing the oblique
sagittal images in the frontal plane so that they are perpendicular to the distal supraspinatus tendon may be useful
for identifying subtle partial-thickness rotator cuff tears [110]. The oblique coronal and oblique sagittal images can
be used to evaluate the labrum, biceps tendon, acromial anatomy, supraspinatus outlet, acromioclavicular joint, and
rotator interval [23,27,46]. The transverse images best display the subscapularis tendon, the long head of the biceps
transverse images may aid in detecting anterior rotator cuff tears. The use of multiple imaging planes increases the accuracy of detecting subscapularis tendon tears [111]. Radial imaging can be used to evaluate the rotator cuff, especially the subscapularis tendon, long head biceps tendon, rotator interval, and for the glenoid labrum has been reported [112-114], but it is not widely used.

FOV should be tailored to the size of the patient and the structures being examined, but for the standard sequences, the FOV should be 16 cm or smaller on medium-field and high-field units. Larger FOVs and smaller imaging matrices may be necessary on lower field systems but will result in lower spatial resolution, limiting the sensitivity of the examination [93,96]. Occasionally, additional sequences with a larger FOV will be appropriate to more fully evaluate a specific suspected or detected abnormality, for example, in the scapulothoracic bursitis articulation or in the anterior chest wall, i.e., the pectoralis major tear in the anterior chest wall muscle. Slice thickness in the oblique sagittal and oblique coronal planes of 4 mm or less is needed to demonstrate subtle tendon pathology, but thinner sections may be advantageous for detailed analysis of other structures, such as the labrum and articular cartilage. An interslice gap may be selected to decrease signal loss due to cross talk [115] but should be no more than 33% of the slice width. Two interleaved scans may allow imaging without gaps at the expense of an increase in scan time. The imaging matrix should balance intravoxel SNR with desired in-plane spatial resolution and reduction of truncation artifacts but should be at least 160 steps in the phase direction and 256 steps in the frequency direction for 2-D imaging, other than when imaging a large tumor. Some practices may use higher imaging matrices (up to 512 steps) to increase spatial resolution for diagnosing labral lesions, including SLAP tears [31,33].

Shoulder MRI can be performed with a wide variety of pulse sequences [116]. The choice of sequences can be tailored to optimize the examination for specific clinical questions and may vary because of local preferences. Conventional spin-echo, fast (turbo) spin-echo, and gradient-recalled sequences have all been used successfully for shoulder MRI. A typical imaging protocol will be composed of one or more of these pulse sequence types. The prescribed repetition time (TR), echo time (TE), and flip angle will depend on the field strength of the magnet and the relative contrast weighting desired.

Fluid-sensitive sequences, such as long-TR/moderate-to-long TE (proton-density weighted or T2-weighted) images with or without fat suppression or STIR images, are typically used for evaluating the rotator cuff, with either conventional spin-echo or fast (turbo) spin-echo technique [21,117-119]. T2*-weighted gradient-echo recalled sequences can also be used for diagnosing rotator cuff abnormalities but probably with lower accuracy compared with conventional spin-echo or fast spin-echo sequences [120,121]. To show labral abnormalities, long-TR (proton-density weighted or T2-weighted) spin-echo or fast spin-echo images or T2*-weighted gradient-recalled images are typically performed [33,36,122], although gradient-echo imaging may be less accurate when used in isolation for anterior labrum abnormalities compared with conventional spin-echo or fast spin-echo imaging [101]. Lesions of the superior labrum such as SLAP tears can be visualized on fast spin-echo, long-TR images [31,41,114], or with MR arthrography [30,34]. T1-weighted sequences (short TR/short TE) have a role in characterizing marrow abnormalities [73], various stages of hemorrhage [123,124], and muscle pathology [22,47,48,51,52]. T1-weighted sequences have been used to characterize the degree of rotator cuff muscle atrophy in patients with tendon tears, which can be used to predict patient outcomes after surgery [125-129]. Additional imaging methods, such as spectroscopic MRI, T2-mapping, and 3-D Volume-interpolated Breathhold Examination (VIBE) with 2-point Dixon, have been used to provide a more quantitative measure of muscle atrophy [130-135]. 3-D T1-weighted fast field-echo and 3-D MR reconstruction using axial Dixon 3-D–T1-weighted–Fast low angle shot (FLASH) sequences as well as 3-D VIBE MR arthrography have proven accurate in quantifying glenoid bone loss when compared with CT and surgical measurements [136-139]. T2 relaxation maps of glenoid articular cartilage are possible and provide quantitative measures that reflect early structural change in articular cartilage.

MR arthrography using direct intra-articular injection of saline [81] or dilute gadolinium-containing contrast [79] may improve diagnostic accuracy in unstable shoulders [44]. Additionally, MR arthrography may improve diagnostic performance for some rotator cuff tendon tears, particularly partial-thickness tears, postoperative...
recurrent tears, and subscapularis tears [14,19,104,106,140-142]. Contrast opacification of the glenohumeral joint can also be accomplished indirectly by allowing IV-injected contrast to diffuse across the synovial membrane; MRI in this circumstance is performed after a short delay (during which time the patient may be asked to move or exercise the shoulder) following IV injection of a gadolinium-containing agent [106,143]. T1-weighted images either without (valuable to assess presence and degree of muscle fatty infiltration and/or volume loss) [2,79,140] or with fat suppression [30,32,141] are most frequently used when direct or indirect MR arthrography is performed with gadolinium-containing contrast. At least one fluid-sensitive sequence with fat suppression is still necessary when performing MR arthrography to detect pathology that does not communicate with the joint as well as to identify altered bone marrow signal intensity.

Suppressing the signal from fat may enhance the diagnostic yield of some pulse sequences [116]. Fat suppression can be performed using spectrally selective radiofrequency (RF) pulses, selective water excitation, a STIR sequence, or a phase-dependent method (eg, the Dixon method) [90,93,144,145]. The latter two techniques may be necessary on low-field systems [93,108]. Fat suppression is useful for identifying marrow abnormalities and may be a useful adjunct when performing MR arthrography [146]. The addition of fat suppression may increase diagnostic accuracy for rotator cuff tendon tears [118,144], especially partial-thickness tears [21]. Fat suppression is a useful adjunct to T1-weighted images when MR arthrography is performed using gadolinium-containing contrast [30,32,141].

Recent advances have demonstrated the ability to shorten MRI shoulder acquisition time without decreasing diagnostic yield, using the combination of high field strength systems and parallel imaging [147].

Additional imaging techniques have specific roles for certain shoulder disorders. Both shoulders are imaged together for evaluation of glenohumeral dysplasia related to brachial plexus birth injury allowing evaluation of associated rotator cuff muscle atrophy, glenohumeral alignment, and glenoid version [148]. Applying axial traction to the affected arm via a weight attached to the wrist may aid in the visualization of SLAP lesions [149]. The ABER position may help with the MR arthrographic diagnosis of instability lesions and partial-thickness, articular-surface rotator cuff tears [2,32,104-108]. Flexion-adduction and internal rotation of the shoulder can increase conspicuity of posterior labral tears if they are suspected and not seen on routine positioning [150].

Various techniques are used to minimize artifacts that can reduce imaging quality. Wraparound artifact should be reduced by phase oversampling [151]. Involuntary patient motion is best controlled by ensuring patient comfort combined with gentle immobilization when necessary [116]. Securing the affected arm against the thigh may further reduce motion artifacts [81]. When available, software that compensates for motion by the use of navigator echoes can be useful [152]. Flowing blood and other periodic motions produce ghosting artifacts, which can be reduced with presaturation pulses or gradient moment nulling [151,153]. Chemical shift artifact is more severe at higher field strengths and may necessitate an increase in the receiver bandwidth [16,95,151]. Susceptibility artifacts, which originate from heterogeneity of the local field, are also more severe at higher field strengths and when using gradient-recalled pulse sequences. In clinical practice, patients with known metallic implants should be scheduled for MRI using 1.5T rather than 3T units. Avoiding gradient-echo imaging and reducing the voxel size will help reduce the magnitude of susceptibility artifacts [151,152]. Other techniques to reduce susceptibility artifact include the avoidance of spectral fat suppression and the use of a STIR sequence as well as the use of a fast spin-echo (FSE) technique rather than spin-echo (SE) imaging [154,155].

Newer techniques include the use of view angle tilting (VAT) to correct the in-plane distortions, slice encoding for metal artifact correction (SEMAC), and multiacquisition variable-resonance image combination (MAVRIC), which correct both the in-plane and through-slice distortions [156]. Vacuum phenomena in the shoulder joint can also result in artifact generation, especially when gradient-recalled pulse sequences are used [157]. Lastly, magic angle artifact can produce apparent increased signal intensity on short-TE images within the supraspinatus tendon as it curves over the humeral head, mimicking intratendinous pathology particularly on short-TE images [158,159]. This pitfall is best avoided by confirming abnormal signal intensity in the tendon on long-TR images and correlating apparent signal intensity abnormalities with changes in tendon thickness.
It is the responsibility of the supervising physician to determine whether additional pulse sequences or imaging techniques would confer added benefit for the diagnosis and management of the patient. Examinations that use techniques not approved by the Food and Drug Administration (FDA), such as the intra-articular injection of gadolinium chelates (direct MR arthrography) [160], can be considered when they are judged to be medically appropriate.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [161].

At a minimum, the report should address the condition of the rotator cuff muscles and tendons, supraspinatus outlet, biceps tendon, and labrum. In selected cases, a description of findings in the major ligaments and capsule, articular cartilage, bone marrow, synovium, and cortical bone would be appropriate. An effort should be made to adopt a standardized lexicon of terms, and the report should use precise anatomic descriptions of identified abnormalities whenever possible [162].

VI. EQUIPMENT SPECIFICATIONS

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 RF power deposition (specific absorption rate), and maximum acoustic noise levels.

Equipment monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [89].

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, 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 [163-165]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [163-166].

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [87], the ACR Guidance Document on MR Safe Practices 2003 [167], and the ACR Manual on Contrast Media [168].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [164,165].
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BE IT RESOLVED,
that the American College of Radiology adopt the ACR–STR Practice Parameter for the Performance of High-Resolution Computed Tomography (HRCT) of the Lungs 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.

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Revised 2015 (Resolution 17)*

ACR–STR PRACTICE PARAMETER FOR THE PERFORMANCE OF HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) OF THE LUNGS 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 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.

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.
NOT FOR PUBLICATION, QUOTATION, OR CITATION

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

High-resolution computed tomography (HRCT) imaging of the lungs is well established for diagnosing and managing many pulmonary diseases [1-7]. Optimal methods of acquisition and interpretation of HRCT images require knowledge of anatomy and pathophysiology [8] as well as familiarity with the basic physics and techniques of CT. This parameter outlines the principles for performing high-quality HRCT of the lungs.

The main objective of HRCT is to detect, characterize, and determine the extent of diseases that involve the lung parenchyma and airways.

HRCT is the use of thin-section CT images (0.625-mm to ≤1.5-mm slice thickness) with a high spatial frequency reconstruction algorithm to detect and characterize diseases that affect the pulmonary parenchyma and small airways [9]. Following the development and widespread availability of multidetector CT (MDCT) scanners capable of acquiring near-isotropic data throughout the entire thorax in a single breath-hold, **HRCT is generally performed using MDCT** [10-14]. Two general approaches are available for acquiring HRCT images. The first and more traditional method entails obtaining axial HRCT images spaced at 10-mm to 20-mm intervals throughout the lungs. The second method uses the ability of MDCT scanners to provide This permits the acquisition of volumetric single breath-hold data sets, allowing spaced, contiguous, and/or overlapping HRCT images to be reconstructed. With MDCT, the volumetric data enables multiplanar (MPR) thin-section HRCT reconstruction, which facilitating evaluation of the distribution of diffuse lung disease [12] **evaluation of coexisting focal lung disease** and the application of postprocessing techniques, such as maximum intensity projection (MIP), minimum intensity projection (minIP), and software that uses volumetric data for quantification of features in the lungs and airways [11]. Quantitative CT is emerging as an important technique for determining the extent of fibrotic and obstructive lung diseases and requires specific standardized protocols that will not be addressed here [15].

An older approach to HRCT used noncontiguous inspiratory thin-section images acquired at 10-20mm intervals through the lungs. Although this method substantially reduces the radiation dose, its diagnostic value is more limited; it may have a limited role in screening individuals at risk for diffuse lung disease.

Optimal performance of HRCT studies requires familiarity with the advantages and disadvantages of each HRCT method, with the choice between these approaches reflecting available equipment, clinical indication(s), and radiation dose considerations.

With both methods, image data HRCT images are routinely acquired at suspended full inspiration with patients in the supine position. Additional options, useful in many cases, include obtaining inspiratory prone images to differentiate posterior lung disease from dependent atelectasis and end-expiratory images to evaluate for air trapping [16].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

The indications for the use of HRCT of the lungs include, but are not limited to, the following [5,8,17-25]:

PRACTICE PARAMETER 2 HRCT Lungs 2020 Resolution No. 33
1. Evaluation of known or clinically suspected diffuse lung disease that is incompletely evaluated on standard chest (CT) or chest x-ray or that which is chest x-ray occult
2. Evaluation of suspected small airway disease
3. Visual estimation Quantification of the extent of diffuse lung disease for evaluating effectiveness of treatment
4. Guidance in selection of the most appropriate site for biopsy of diffuse lung disease

B. Contraindications

There are no absolute contraindications to HRCT of the lungs. As with any imaging procedure, the benefits and risks should be considered prior to thoracic CT performance.

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 [26].

For imaging of diffuse lung disease in the pediatric patient, please refer to the ACR–ASER–SCBT–MR-SPR Practice Parameter for the Performance of Pediatric Computed Tomography (CT) [27].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [28].

The physician is responsible for reviewing all indications for the examination, specifying the precise technical factors to be used for the HRCT study, generating a final report, and monitoring and maintaining the quality of images and interpretation.

The physician should be thoroughly acquainted with the many anatomic and physiologic manifestations of thoracic disease. Additionally, supervising physicians should have appropriate knowledge of alternative modalities for imaging of the thorax, including chest radiography and standard thoracic CT as well as angiography, ultrasonography, magnetic resonance imaging (MRI), and nuclear medicine studies.

The CT technologist must be familiar with optimal techniques for acquiring an HRCT examination, and in particular, need to communicate breathing instructions with the patient to ensure high-quality, motion-free inspiratory and expiratory images.

IV. SPECIFICATIONS AND PERFORMANCE OF THE EXAMINATION

A. Written Request for the Examination

The written or electronic request for HRCT of the Lungs 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 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)
B. Technical Parameters

Although many of the operations of a CT scanner are automated, a number of technical parameters remain operator dependent. Because these factors can significantly affect the diagnostic value of the HRCT examination [39-31], it is necessary for the supervising physician to be familiar with the following:

1. Radiation exposure factors (mAs, kVp)
2. Collimation
3. Display section thickness for multidetector systems
4. Table increment or pitch and gantry rotation time and table speed
5. Matrix size, scan field of view, and reconstruction field of view
6. Display section thickness for multidetector systems and iterative reconstruction techniques
7. Reconstruction algorithm, filter or (kernel) and iterative reconstruction techniques
8. Detector configuration for multidetector systems
9. Automatic exposure control (angular and longitudinal tube current modulation) and image quality reference parameter
10. Radiation dose report
11. Reformatted images (MPR, curvilinear, MIP, and minIP) and 3-D surface or volume rendered (VR) and image plane (axial, coronal, sagittal)
12. Reconstruction techniques such as filtered back projection or iterative reconstruction

C. Optimal HRCT Protocol

Optimization of the CT examination requires the supervising physician to develop an appropriate HRCT protocol based on careful review of relevant patient history and clinical indications as well as all prior available imaging studies that are relevant.

1. Protocols should be prepared according to the specific medical indication. Techniques that provide image quality consistent with the diagnostic needs of the examination at acceptably low radiation dose levels to the patient should be selected. When volumetric HRCT data are acquired, utilization of the MPR capabilities is encouraged to facilitate assessment of disease distribution and morphology. For each indication, the protocol should include at least the following:
   a. Tube potential and tube current appropriate to patient size. For the lowest dose to provide diagnostic quality, see the ACR–AAPM–SPR Practice Parameter for Diagnostic Reference Levels and Achievable Doses in Medical X-Ray Imaging [32]. Typically, this entails use of 120 (kVp) and approximately ≤240 mAs. Use of lower tube potentials (eg, 100 kVp) and tube current settings is encouraged, especially for younger patients or those who may need serial imaging. In this case, using similar technical parameters for each study facilitates direct comparison between studies and is of particular value if quantitative CT measurements are employed.
   b. Techniques available to minimize dose (eg, tube current modulation) should be utilized. Imaging using lower radiation settings is subject to image noise, which can be offset with iterative reconstruction techniques [33]. However, special caution should be taken when utilizing iterative techniques because high degrees of iterative reconstruction weighting may obscure subtle interstitial pulmonary findings and lead to an inaccurate characterization of the patient's underlying lung disease.
   c. Proper supine and/or prone patient positioning with optimal breathing instructions.
   d. State of respiration (inspiration and/or expiration) with appropriate breathing instructions; it is critical to obtain inspiratory scans on full inspiration. Expiratory images are typically acquired at end-systolic expiration.
   e. Table speed for volumetric HRCT to enable single breath-hold acquisition, when possible.
f. Axial (incremental HRCT) or helical (volumetric HRCT) modes of data acquisition. As mentioned above, helical, volumetric acquisition is generally recommended for the inspiratory acquisition. For expiratory and prone acquisitions, acquiring exploratory and/or prone sequence images in a helical fashion is discouraged. For those sequences, axial acquisition with nonirradiated increments of 10–20 mm or more is preferable to reduce radiation dose.

g. Gantry rotation: ≤1 s.

h. Reconstructed image thickness (≤1.5 mm for axial CT, ≤1.5-mm nominal slice thickness for helical CT).

i. Moderately high spatial-frequency reconstruction algorithm, such as a bone algorithm for lung images. Avoid use of an overly sharp reconstruction algorithm, which would create excessive image noise and high degrees of iterative reconstruction, which can decrease spatial resolution [33,34].

j. Proper patient positioning (positioning the patient at isocenter to minimize radiation dose and optimize image quality).

k. Superior and inferior extent of the region of interest to be imaged, typically from the lung apices to the costophrenic sulci. For additional series, such as prone or expiratory HRCT imaging, shorter z-axis coverage and/or greater increment between imaging locations is encouraged to decrease patient radiation exposure.

l. When possible, scan field of view should be selected appropriate to patient size at time of imaging.

m. Reconstructed field of view limited to the lungs, adjusted for small, medium, and large patients to optimizing spatial resolution for each patient.

n. Plane, thickness, and interval for reconstructions or reformats (eg, coronal, sagittal, oblique MPRs and MIPs) from volumetric HRCT data to be sent to the picture archiving and communications system (PACS) or reconstruction directly at the PACS workstation.

o. Retention of the radiation dose report in the radiological record, in alignment with the ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [35].

2. Attention should be directed toward the following:

a. Radiation dose to the degree indicated in the ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [35], considering factors influencing radiation dose, particularly for small adults, and techniques such as increasing pitch, lowering tube current or kV, and limiting the z-axis coverage to the region of clinical question. Other factors that can decrease radiation dose are the use of sequential acquisition and larger interscan gap, which can be employed when expiratory and prone HRCT imaging is performed to supplement an inspiratory examination. The necessity appropriateness of prone imaging should be considered determined in all patients, particularly on subsequent HRCT scans; omitting unnecessary sequences provides an opportunity to reduce dose. Alternatives to breast shielding need to be carefully considered and utilized. Please refer to the AAPM Position Statement on the Use of Bismuth Shielding for the Purpose of Dose Reduction in CT Scanning at (http://www.aapm.org/publicgeneral/BismuthShielding.pdf).

b. Producing motion-free images at the appropriate inspiratory and expiratory level

3. Use of Intravenous (IV) iodinated contrast should not be used when performing an HRCT to evaluate the lung parenchyma and small airways primarily because subtle pulmonary findings may be obscured by intrapulmonary contrast. In addition, IV contrast adds little value to the interpretation of diffuse lung disease yet exposes patients to the risks associated with the administration of iodinated contrast.

4. Periodic update and review of the HRCT protocol

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [36,37].
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 [38].

To achieve acceptable clinical HRCT scans of the lungs, a CT scanner should meet or exceed the following capabilities as specified in the ACR–SCBT–MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [35]:

1. Scan times: ≤1 s per image; a scan time of <1 s per image may apply to direct axial acquisition but may not apply to helical CT acquisition of HRCT images
2. Image thickness: ≤1.5 mm
3. Algorithm available: bone or moderately high spatial frequency
4. Axial mode available on CT scanner

Review capability of a PACS workstation should be available to the radiologist; authorized health care providers should be able to review images remotely. A method for digitally transmitting the image data should be available.

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)

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).

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 Body Imaging (Thoracic) of the Commission on Body Imaging and the Committee on Practice Parameters – General, Small and Rural Practice of the Commission on General, Small, and Rural Practice, in collaboration with the STR.

Collaborative Committee

Members represent their societies in the initial and final revision of this practice parameter.

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REFERENCES

22. Silva CI, Churg A, Muller NL. Hypersensitivity pneumonitis: spectrum of high-resolution CT and pathologic findings. AJR. American journal of roentgenology 2007;188:334-44.
NOT FOR PUBLICATION, QUOTATION, OR CITATION


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

2000 (Resolution 10)
Revised 2005 (Resolution 28)
Amended 2006 (Resolution 17, 35)
Revised 2010 (Resolution 43)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 17)
RESOLUTION NO. 34

Mandatory Early Radiology Education for Medical Students by Radiologists

WHEREAS, radiology is central to most medical specialties for diagnostic evaluation and patient management; and

WHEREAS, the importance of radiology is recognized by other medical specialties - as evidenced by the integration of radiology which may not be taught by radiologists into medical school curricula; and

WHEREAS, medical students may have pocket ultrasound tools to complement physical exam, their knowledge of other imaging resources and radiologists’ importance to timely diagnoses and patient care is lacking; and

WHEREAS, radiology is not a mandatory course in the core curriculum of many medical schools, and may not be available as an elective until the fourth year after students have chosen a specialty; and

WHEREAS, the ACR has developed the Radiology-TEACHES program: https://www.acr.org/Clinical-Resources/Radiology-TEACHES directed toward appropriateness criteria, and this program’s principal investigator received the Teaching Value Award in 2017 from the ABIM Foundation Creating Value Challenge for his team’s work; therefore,

BE IT RESOLVED, that the ACR form a taskforce to investigate avenues for introducing medical students to mandatory radiology clerkships taught by radiologists during their second or third years, and/or a longitudinal radiology curriculum, to allow medical students the opportunity to select radiology early enough as their career preference and be able to match successfully into a diagnostic radiology/interventional radiology residency program and to allow those seeking a career in other areas of medicine to have an appreciation of radiology's central role. The taskforce will report to the Council at its 2021 meeting.

Sponsored by: Illinois Radiological Society
Fiscal Note

Mandatory Early Radiology Education for Medical Students by Radiologists

To support the resolution for Mandatory Early Radiology Education for Medical Students by Radiologists, the ACR would incur the following estimated costs:

**Costs:**
- De minimis (< $10,000)
RESOLUTION NO. 35

RFS and YPS Standing to Submit ACR Resolutions

WHEREAS,

the American College of Radiology (ACR) has robust participation in its Resident and Fellow (RFS) and Young and Early Career Physician Sections (YPS), with both sections coordinating and participating in dedicated educational programming for the annual ACR meetings.

WHEREAS,

the American College of Radiology encourages chapter resident and fellow sections and will continue to assist in their formation; adopted 1985, amended 1995, 2005 (Res. 12). The chapters should provide residents and fellows the opportunity for membership and access to policy program development and implementation through the development of chapter resident and fellow sections; adopted 1984, 1994, amended 2004, 2014 (Res. 1-a ). [1]

WHEREAS,

the ACR encourages state chapters to facilitate greater involvement by young and early career professionals. The YPS shall work in coordination with the Commission on Membership and Communications to increase membership and volunteerism in the ACR by young and early career professionals, and ACR Commissions and Committees will be encouraged to have representation from this important and unique demographic group. [1]

WHEREAS,

the popularity of radiology, and more specifically, attendance and membership in the ACR has expanded beyond these sections, now welcoming and including medical students [2]

WHEREAS,

currently resolutions may only be submitted and/or sponsored by one of the following: a chapter, an individual councilor, the Council Steering Committee, or the Board of Chancellors. [3]

WHEREAS,

other organized medical societies allow the submission of resolutions to their societies, oftentimes first through their medical student/resident-fellow/young physician sections prior to consideration on the floor of major societal meetings. [4]
WHEREAS,

the submission of resolutions to the ACR meetings encourages participation and can be used to fulfill ACGME core competency requirements such as Systems Based Practice and Professionalism [5] ; therefore,

BE IT RESOLVED,

that the ACR Bylaws Committee draft a resolution for the ACR 2021 annual meeting to amend the bylaws to allow submission of resolutions by the RFS or YPS.

Sponsored by: Taj Kattapuram, MD, Councilor, Colorado Radiological Society
J.Paul Nielsen, MD, Councilor, Colorado Radiological Society
Andrew Moriarty, MD, Councilor, YPS
Fiscal Note

RFS and YPS Standing to Submit ACR Resolutions

To support the resolution for **RFS and YPS Standing to Submit ACR Resolutions**, the ACR would incur the following estimated costs:

**Costs:**
- De minimis (< $10,000)

REFERENCES

   https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2019.pdf
## REFERENCE COMMITTEE IV

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| 37. | ACR Practice Parameter for Communication of Diagnostic Imaging Findings  | REVISED PP    |
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|     | Urerethrography                                                           |               |
| 39. | ACR–SIR Practice Parameter for **Minimal and/or Moderate** Sedation/Analgesia | REVISED PP    |
| 40. | ACR–SIR Practice Parameter for the Performance of Angiography, Angioplasty, and | REVISED PP    |
|     | Stenting for the Diagnosis and Treatment of Renal Artery Stenosis in Adults |               |
| 41. | ACR–ACNM–ASNR–SNMMI Practice Parameter for Brain PET-CT Imaging in Dementia | REVISED PP    |
| 42. | ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of  | REVISED PP    |
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| 47. | Multispecialty-Generalist                                                 | NEW POLICY    |
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
To support the resolution for Ten Year Extension of Policy, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)
Res: 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. 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.

PRACTICE PARAMETER 1 Communication Diagnostic Imaging

2020 Resolution No. 37
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 ordering referring 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 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:
NOT FOR PUBLICATION, QUOTATION, OR CITATION

i. Date of dictation

ii. Date and time of transcription

iii. Patient’s date of birth or age

iv. Patient’s gender

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, 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.

B. Principles of Reporting (Final Report)

1. The final report is the definitive documentation of the results of an imaging examination or procedure.

2. The final report should be proofread. Use of abbreviations or acronyms should be limited to avoid ambiguity.
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 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/hospital’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 establish 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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Additional Resources Suggested Reading (Additional articles that are not cited in the document but that the committee recommends for further reading on this topic)
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:
2. Williams v Le, 662 S.E. 2d 73 (Va 2008)
9. Daly v. United States, 946 F.2d 1467 (9th Cir. 1991)
12. 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.

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Revised 2005 (Resolution 11)
Revised 2010 (Resolution 11)
Revised 2014 (Resolution 11)
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.

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 38) *

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, cistourethrography, voiding cistourethrography, 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 reformatations 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.

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

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 reformatations 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.
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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Revised 2000 (Resolution 38)
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Amended 2006 (Resolution 17, 35)
Revised 2010 (Resolution 41)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 31)
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.

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Revised 2015 (Resolution 23) *

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

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.

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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.
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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 (e.g., 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 preprocedure 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 immediately 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).

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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


APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification

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

APPENDIX B

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)
- Craniofacial 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

APPENDIX C

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

- Clear liquids† 2-h minimum fasting period*
- Breast milk 4-h minimum fasting period*
- Infant formula 6-h minimum fasting period*
- Nonhuman milk‡ 6-h minimum fasting period*
- Light meal§ 6-h minimum fasting period*
Fried foods, fatty foods, or meat Additional fasting time (eg, 8 h or more) may be needed

**Pharmacologic**

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

**Gastric acid secretion blockers**

**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

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.

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. With This can be in the form of end-organ damage frequently affecting the kidneys as well as the or involve 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 or 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 obturate 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) [16,39-41,43-45,59,60] 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 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 PTRA, 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 that 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].
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 [39,41,58,66,68,98,99], 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 1

<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>

PRACTICE PARAMETER 8

Renal Artery Stenosis

2020 Resolution No. 40
### Symptomatic renal artery dissection

| Symptomatic renal artery dissection | PTRAS may be of benefit [89] | Moderate | Strong |

### Chronic renal failure with ARAS

| Chronic renal failure with ARAS | Medical therapy is equivalent to PTRAS [16,39,45,72,73,79,120,121] | High | Strong |

### Acute renal failure with hemodynamically significant bilateral ARAS and low resistive index, or ARAS to a single functioning kidney

| Acute renal failure with hemodynamically significant bilateral ARAS and low resistive index, or ARAS to a single functioning kidney | PTRAS may be of benefit [66,97] | Low | Weak |

### Renal failure with prior intervention (in-stent stenosis, endograft, or open surgery)

| Renal failure with prior intervention (in-stent stenosis, endograft, or open surgery) | Repeat intervention may be beneficial [103] | Very-Low | Weak |

### Renal mass preservation with ARAS

| Renal mass preservation with ARAS | Medical therapy preferred (PTRAS not indicated) [16,39,45] | Moderate | Strong |

### Cardiac disturbance syndromes with ARAS

| Cardiac disturbance syndromes with ARAS | PTRAS may be beneficial in flash pulmonary edema [66,113,116-118] | Low | Weak |

### Prevention of cardiovascular mortality with ARAS

| Prevention of cardiovascular mortality with ARAS | Medical therapy is equivalent to PTRAS [16] | High | Strong |

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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 diluted 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 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 antiplatelet 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 A 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).

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).

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).

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.

   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):

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 (eg, 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\(^2\) 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\(^3\) 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

\(^2\) 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-m)

\(^3\) 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)

See the ACR-SPR Practice Parameter for the Use of Intravascular Contrast Media.
Renal Artery Stenosis

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:
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1. Equipment needed for the procedure
2. 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.
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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)

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
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.

<table>
<thead>
<tr>
<th>Specific Major Complications From Percutaneous Renal Revascularization</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</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>hospital stay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Worsening of CRF requiring</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>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) 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


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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...
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, % RAS = 100 x (1 – [the narrowed lumen diameter / 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.

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
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Amended 2007 (Resolution 12m, 38)
Revised 2009 (Resolution 26)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 22)
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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 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 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 flurbetaben) 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 pathologyamyloid 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 (5-12 mCi) IV. The recommended doses are 10 mCi, 5 mCi, and 8.1 mCi for florbetapir, flumetamol, and florbetaben, 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 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 (eg, 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 (e.g., by volume rendering or surface projections, such as 3-D stereotactic surface projection (SSP), can be helpful for detection of disease patterns.

8. 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

18F FDG refers to a positron-emitting radiopharmaceutical containing radioactive 2-deoxy-2-(18F) 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-(18F) fluoro-D-glucose, abbreviated 18F FDG, has a molecular formula of C6H1118FO5, with a molecular weight of 181.26 Da. 18F decays by positron (β+) 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.

18F FDG is taken up by cells and phosphorylated to 18F-FDG-6-phosphate (18F-FDG-6P) at a rate proportional to the rate of glucose utilization within a given tissue. 18F-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, 18F-FDG-6-phosphate may be dephosphorylated back to 18F-FDG via glucose-6-phosphatase. This pathway is relatively minor in brain, skeletal muscle, and cardiac muscle, which permits PET imaging of the accumulated 18F-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 Structure]

$^{18}$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 Structure]

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

![Florbetaben Structure]

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-[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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REFERENCES


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, i.e., 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 better 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. 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 (bowlhunter’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.
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

extrasations 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 thickness for this preliminary 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, are

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

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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

determined 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⁻¹ 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 (eg, 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 [90]. 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 [91].

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 [90,92-97].
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).
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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.

Development Chronology for this Practice Parameter
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NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 43

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ANSR–SNIS–SPR Practice Parameter for the Performance of Cervicocerebral Magnetic Resonance Angiography (MRA)

Sponsored By: ACR Council Steering Committee

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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.

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

PREAMBLE

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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 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 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 threedimensional (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 pathological conditions [15-22]. In some clinical instances, follow-up computed tomographic angiography (CTA) CT or catheter angiography may be necessary to fully characterize the abnormality.

Indications for cervicocerebral MRA in the pediatric population include, but are not limited to, the definition 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
7. Evaluation of etiology of intracranial/intraspinal hemorrhage hemorrhage and
8. Sickle cell vasculopathy
9. Vasculitis and collagen vascular disease
10. Moyamoya disease
11. Detection and evaluation of aneurysms, or pseudoaneurysms, and venous varices
12. Cerebral arteriovenous malformations (AVMs), arteriovenous fistulas, and venous vascular malformations
13. Vascular status following extracorporeal membrane oxygenation.
14. Blood supply to vascular neoplasms for operative planning
15. Acute ischemic stroke, vasospasm, and thromboembolism
16. Traumatic injury to cervicocerebral vessels, including dissection
17. Localization of arterial and venous structures for operative planning
18. Invasion, encasement, and constriction of blood vessels by neoplasm
19. Soft-tissue vascular anomalies in the head and neck region
20. Atherosclerotic steno-occlusive disease
21. Nonatherosclerotic, noninflammatory vasculopathy
22. Moyamoya disease
23. Detection and evaluation of aneurysms, or pseudoaneurysms, and venous varices
24. Cerebral arteriovenous malformations (AVMs), arteriovenous fistulas, and venous vascular malformations
25. Vascular supply to tumors and vessel encasement and narrowing by tumors
26. Nature and extent of other congenital or acquired AVM (soft tissue) vascular anomalies (eg, hemangioma, venous malformation, AVM, lymphatic malformation)
27. Extent of disease in vasculitis and vasculopathy
28. Operative planning for tumor resection
29. Differentiation of aneurysms and masses
30. Definition of the relationship of masses to nearby vascular structures
31. 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, 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 ages 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]. Individual Practitioners using MRA must understand the artifacts and limitations of each imaging technique. The most commonly used techniques are common MRA sequences utilize noncontrast 2-D and 3-D TOF, and CE 3-D PC, 3-D CE, and 4-D CE time-resolved techniques. Methods

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 each 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 of the image. 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 with undesirable venous enhancement which cannot be eliminated overcome 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, the physical properties of moving spins. 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 analogous to that obtained with the TOF technique although and 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 augment 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 nutrition for 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 differentiation 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-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 form 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 rates of 2 to 4 mL/sec generates a bolus profile with a 5 second to 7 seconds 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

- 2000 (Resolution 11)
- 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 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.

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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

CT Head Brain

2020 Resolution No. 44
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] [45,46]
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], 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 [55-64]

B. Secondary Indications (when MRI is unavailable or contraindicated, or if the supervising physician determines CT to be appropriate [54]) [28,80]

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]

9. Drug toxicity [33, 85-87]

10. Congenital morphologic brain abnormalities [88]

11. Brain death [74-76, 93-94]

12. 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].
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 ≤1 second and continuous cine imaging ≥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 nonnecessary 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].

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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]. [46,150,154]
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PRACTICE PARAMETER 8
CT Head Brain
2020 Resolution No. 44
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REFERENCES


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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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Revised 2015 (Resolution 20)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 45

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.

PRACTICE PARAMETER

Fetal MRI

Resolution No. 45
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 extrophy, 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 [61]
   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 x 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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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 – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the SPR.
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PRACTICE PARAMETER

Fetal MRI

2020 Resolution No. 45


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Development Chronology for this Practice Parameter

2010 (Resolution 13)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 11)
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.
To support the resolution for Multispecialty/General Radiologists, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (< $10,000)

REFERENCES