# REFERENCE COMMITTEE I

Paul A. Larson, MD, FACR, Chair  
Seth Hardy, MD, MBA, FACR  
Debra S. Dyer, MD, FACR  
Eric M. Rubin, MD  
Thomas Farquhar, MD  
Omar Khalilzadeh, MD

## COMMISSIONS, COMMITTEES & TASK FORCES:

- Audit Committee
- Ethics Committee
- Commission on Body Imaging
- Commission on Pediatric Radiology
- Awards & Honors Committee
- Intersociety Committee
- Commission for Women & General Diversity
- Commission on General, Small, Emergency and Rural Radiology

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## ACR STAFF:

- Director: Christine Waldrip  
- Assistant: Beth Meehan  
- Moderator: Lavonne Robbins  
- Attorney: Tom Hoffman  
- Recorder: Troy Williams  
- Observer: Jennifer Walter
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) A. GENERAL

8. ADVOCACY ON BEHALF OF RADIOLOGY
The Board of Chancellors will identify and develop the most effective means for promulgation of the role of radiology before the public, government, and third parties. The Board of Chancellors will identify and develop the capability for effective advocacy on behalf of radiology in the areas of economical and sociological concern; adopted 1979, 1989, 1999, 2009 (Res.30-k).

(b) F. FINANCES

1. MEMBERSHIP DUES

e. Encourage Funding of ACR Membership for Radiologists, and Radiation Oncologists and Medical Physicists
The leaders of all academic and private practice radiology and radiation oncology practice groups shall be encouraged to fund memberships in the ACR for their physicians and medical physicists from their practice group’s revenues; adopted 1999, 2009 (Res. 1-e).

(c) I. RELATIONSHIPS TO OTHER ORGANIZATIONS

7. LEADERSHIP DEVELOPMENT
The American College of Radiology strongly endorses, supports, and encourages radiology practices to allow the time and provide the necessary resources for their radiologists, radiation oncologists, and medical physicists to participate in and serve as leaders in both radiological and other medical societies, to effectively perform their duties for the benefit of patient care and the practice of radiology.

The ACR shall develop specific models, plans or examples to aid practices in their efforts to provide the time and resources to their colleagues for radiological and other medical societies service; adopted 1999, 2009 (Res. 30-i).
I. RELATIONSHIPS TO OTHER ORGANIZATIONS

9. RADIOLOGISTS VOLUNTEER SERVICES IN HEALTH ORGANIZATIONS

The American College of Radiology encourages all radiological professionals, radiation oncologists and diagnostic radiologists to volunteer to serve for service in voluntary health organizations (e.g., American Cancer Society) on a local, regional, and national health organizations and agencies; adopted 1999, 2009 (Res. 30-n).

(e) A. EDUCATION

3. CONTINUING EDUCATION AND COMPETENCE

a. Continuing Competence

Documenting Continuing Competence

The American College of Radiology will continue to develop standards of radiologic practice and quality assurance programs which lead to continued improvement in patient care and which in the future will serve as the basis for objective evaluation of radiologist continuing competence.

The ACR will be prepared to develop medical education programs which will address identified areas of deficiencies.

The ACR will provide radiological input to other organizations in the development of national standards of patient care; adopted 1989, 1999, 2009 (Res. 1-d).

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 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.

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

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 (a) promote optimal patient care and support the referring ordering physician/health care provider in this endeavor, (b) be tailored to satisfy the need for timeliness, and (c) 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 ordering physician or other relevant health care provider also shares in the responsibility for obtaining results of imaging studies he or she has ordered. Formulating an imaging interpretation requires the commitment and cooperation of administrators, clinicians, and referring physicians, interpreting physicians and 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, a working diagnosis, pertinent clinical signs and symptoms, or any combination thereof. 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 utilised 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, this 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 fully in the body of the report and briefly noted in the impression.

5. Standardized computer-generated template reports
   Standardized computer-generated template reports 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 patients upon their request after appropriate consent for release of this information has been given by the patient or other legally authorized person acting on his/her 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 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.

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 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 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 pneumothorax, pneumoperitoneum, or a significantly misplaced line or tube. These conditions are typically included in "critical values" categories in most health care institutions. Other urgent conditions that may be considered critical are also included in this group.

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

   a. 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.

   b. Findings that the interpreting physician reasonably believes may have a reasonable probability of seriously impacting the patient’s health and may not require immediate attention but, if not acted on, may worsen over time and 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 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 physician in time to provide the most benefit to the patient. Communication by telephone or in person to the treating or referring physician or a responsible health care provider, his/her representative, or the interpreting physician’s designee is appropriate and 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 may be considered reliable, such as reports created in a timely manner through voice recognition systems and 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/health care provider’s documentation of the informal consultation may be the only written record of the communication. Interpreting physicians who provide consultations of this nature in the spirit of improving patient care are encouraged to document those interpretations. A system for reporting outside studies is encouraged.

III. SELF-REFERRED AND THIRD-PARTY REFERRED PATIENTS

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

A. Self-Referred Patients

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

B. Third-Party Referred Patients

It is not unusual for patients to be referred for imaging studies by insurance companies, employers, federal benefits programs, and, in some instances, lawyers. In such cases, the reports of the studies are frequently communicated through the requesting entity to a clinician licensed provider or directly to the third-party–designated licensed provider clinician. The results of the examinations are then communicated to the patient either directly by the third party or by its designated licensed provider clinician. Regardless of the source of the referral, the interpreting physician 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.
Comments Reconciliation Committee
Leonard Berlin, MD, FACR  Katie Lozano, MD, FACR
Charles W. Bowkley III, MD  Mary S. Newell, MD, FACR
Philip S. Cook, MD, FACR  Matthew S. Pollack, MD, FACR
Richard Duszak, Jr., MD, FACR  Robert S. Pyatt, Jr, MD, FACR
Nancy A. Ellerbroek, MD, FACR  Timothy L. Swan, MD, FACR
Kate A Feinstein, MD, FACR  Christoph Wald, MD, PhD, FACR
David B. Haseman MD, MA, FACR

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:
Williams v Le, 662 S.E. 2d 73 (Va 2008)
Diaz v. New York Downtown Hospital, 784 N.E.2d 68 (N.Y. 2002)
Reed v. Bojarski, 764 A.2d 433 (N.J. 2001)
Duckworth v. Lutheran Medical Center, 1995 WL 33070 (Ohio App. 1995)
Daly v. United States, 946 F.2d 1467 (9th Cir. 1991)
Coureau v. Dodd, 773 S.W.2d 436 (Ark. 1989)
Phillips v. Good Samaritan Hospital, 416 N.E.2d 646 (Ohio App. 1979)

Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice parameter
1991 (Resolution 5)
Revised 1995 (Resolution 10)
Revised 1999 (Resolution 27)
Revised 2001 (Resolution 50)
Revised 2005 (Resolution 11)
Revised 2010 (Resolution 11)
Revised 2014 (Resolution 11)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SAR–SCBT-MR Practice Parameter for the Performance of Computed Tomography (CT) Colonography 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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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 2)*

ACR–SAR–SCBT-MR PRACTICE PARAMETER FOR THE PERFORMANCE OF COMPUTED TOMOGRAPHY (CT) COLONOGRAPHY 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 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, ___ N.W.2d ___ (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

Computed tomography colonography (CTC) is a minimally invasive structural examination of the colon and rectum to evaluate for colorectal polyps and neoplasms [1-13]. The goal of this examination is to establish the presence or absence of colorectal neoplasia by producing a diagnostic-quality study at the lowest feasible radiation dose. This practice parameter outlines the performance of CTC in adult patients.

Individuals undergoing this examination may fall into one of several risk populations, and the examination may be designated as screening, surveillance, or diagnostic. There are several evidence-based guidelines that, with minor variations, categorize individuals into specific risk groups with correlated recommendations for management [14-17].

Screening identifies individuals who have colorectal cancer or adenomatous polyps without signs or symptoms of the disease. Individuals without other risk factors are at average risk. The American Cancer Society (ACS) recommends screening begin at age 45, whereas the United States Preventive Services Task Force (USPSTF) recommends that screening begin at age 50 years of age or older for average-risk individuals [18]. Individuals with a single first-degree relative (mother, father, sister, brother, or child) who have had colorectal neoplasia before age 60 or multiple first-degree relatives with colorectal neoplasia diagnosed at any age are defined as being at moderate risk. Average- and moderate-risk individuals are candidates for screening by CTC. Individuals with a longstanding history of inflammatory bowel disease or who are from families with defined genetic syndromes are at high risk and should not be considered for screening by CTC.

Surveillance involves the ongoing monitoring of people with previously diagnosed colorectal neoplasm identified as belonging to the high-risk category. The degree of risk may be related to the underlying or prior pathology. Surveillance CTC is also performed on individuals in whom colonic polyps have been previously identified but not resected in order to assess stability of lesions that are considered low risk.

Diagnostic CTC examinations are performed on symptomatic individuals or as a follow-up to a prior but less definitive screening study. These individuals, by definition, are considered to be at greater risk of harboring colorectal neoplasia.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

The indications for a CTC examination include, but are not limited to, the following:

1. Screening examination in individuals who are at average or moderate risk for developing colorectal carcinoma. Screening of individuals who are at moderate risk for colorectal cancer may be managed individually based on clinical context or local practice patterns.

2. Surveillance examination in patients with a history of previous colonic neoplasm [19], depending on the appropriate clinical context.

3. Diagnostic examination in symptomatic patients, particularly in the setting of incomplete colonoscopy, including, but not limited to, those with the following:
a. Abdominal pain
b. Diarrhea
c. Constipation
d. Gastrointestinal bleeding
e. Anemia
f. Intestinal obstruction
g. Weight loss

4. Following incomplete screening, surveillance, or diagnostic colonoscopy and for characterization of colorectal lesions indeterminate on optical colonoscopy [20-24].

5. Patients who may be at increased risk for complications during optical colonoscopy (eg, advanced age, anticoagulant therapy, sedation risk, prior incomplete colonoscopy).

6. Follow-up of patients with a colonic stoma or after colectomy. Intubation of the stoma should be performed with caution to avoid colonic injury or perforation [25-27].

7. Prior to laparoscopic surgery for colorectal cancer in order to accurately localize the tumor or search for synchronous lesions.

B. Contraindications

1. The relative contraindications or conditions that require caution in performing a CTC examination include, but are not limited to, the following:
   a. Symptomatic acute colitis
   b. Acute diarrhea
   c. Recent acute diverticulitis
   d. Recent colorectal surgery
   e. Symptomatic colon-containing abdominal wall hernia
   f. Recent deep endoscopic biopsy or polypectomy/mucosectomy
   g. Known or suspected colonic perforation
   h. Symptomatic or high-grade small bowel obstruction

2. CTC is not indicated for the following:
   a. Routine follow-up of inflammatory bowel disease
   b. Hereditary polyposis or nonpolyposis cancer syndromes
   c. Evaluation of anal canal disease
   d. The pregnant or potentially pregnant patient (refer to the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [28])

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The physician shall be responsible for all aspects of the study. The responsibilities include, but are not limited to, reviewing all indications for the examination; specifying and monitoring the appropriate patient preparation for colonic cleansing prior to the examination; specifying the appropriate imaging protocol, the methods of image reconstruction, and the use and dosage of contrast and pharmacologic agents; interpreting all resulting images and generating an official report (recommended with the use of Colonography Reporting and Data System (C-RADS) and Extracolonic reporting and data systems (E-RADS) classification [30]); and ensuring the quality of the images and the interpretation.

Initial Training

1. For physicians with prior qualifications in general and/or abdominal-pelvic CT interpretation:

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29]
The radiologist or other physician who meets the qualifications of the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29] will have substantial knowledge of radiation biology; the physics of CT scanning include radiation dose lowering CT scanning techniques; the principles of CT image acquisition and postprocessing and including the use of diagnostic workstations; and the design of CT protocols, including rate and timing of contrast administration. The physician also will have substantial experience in CT interpretation, including CT of extracolonic structures that will be included on the CTC examination.

Supervising and interpreting physicians with prior qualifications in general and/or abdominal-pelvic CT interpretation shall also meet ONE of the following requirements (the supervising physician must have met initial qualifications):

a. For physicians who receive their training in CTC in a training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association, such training shall include the following:

i. Education regarding patient preparation, bowel insufflation, and CT image acquisition.

and

ii. Formal hands-on interactive training using dedicated CTC software, including the interpretation, reporting, and/or supervised review of at least 50 endoscopically confirmed CTC cases using primary 2-D and/or primary 3-D search with application of routine problem-solving techniques.

Ideally this collection of training cases will be chosen to demonstrate the gamut of appearances of colonic polyps and cancer and CTC interpretation pitfalls. Additionally, the cases should include examinations performed for a variety of indications (eg, screening, symptomatic, incomplete colonoscopy with subsequent validation) and acquisition techniques (eg, with and without fluid tagging and intravenous (IV) contrast).

or

b. For physicians who receive their training in CTC after completing their residency or fellowship, such training shall include the following:

i. Education regarding patient preparation, bowel insufflation, and CT image acquisition.

and

ii. Formal hands-on interactive training using dedicated CTC software, including the interpretation, reporting, and/or supervised review of at least 50 endoscopically confirmed CTC cases using primary 2-D and/or primary 3-D search employing commonly used problem-solving techniques.

Ideally this collection of training cases will be chosen to demonstrate the gamut of appearances of colonic polyps and cancer and CTC interpretation pitfalls. Additionally, the cases should include examinations performed for a variety of indications (eg, screening, symptomatic, incomplete colonoscopy with subsequent validation) and acquisition techniques (eg, with and without fluid tagging and IV contrast).

2. For physicians who do not have prior qualifications in general and/or abdominal-pelvic CT interpretation:

A radiologist or other physician who does not meet the qualifications of the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29] or who meets these qualifications only for a specific anatomic area outside of the abdomen-pelvis, requires more extensive training and experience in CT scanning with an emphasis on the abdomen-pelvis and specific experience in CTC. In addition to specific training in imaging interpretation, this training must include knowledge of the principles of CT image acquisition and postprocessing, including the use of diagnostic workstations, the design of CT protocols, including the rate and timing of contrast administration, and instruction on
radiation dose lowering CT scanning techniques. The physician must also meet the same requirements, or document equivalent training, as those delineated in the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29] with regard to knowledge of the physics of CT scanning and radiation biology. Some physicians will also require additional education in colon anatomy, physiology, and pathology.

Supervising and interpreting physicians without prior qualifications in general and/or abdominal-pelvic CT interpretation shall meet the following requirements:

a. Completion of sufficient training and experience to meet the qualifications of the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29]. For a physician who assumes responsibilities for CT imaging exclusively in a specific anatomical area, such as abdominal-pelvic CT and CTC, this includes the following:
   i. Completion of an ACGME-approved training program in their respective specialty in which they practice 200 plus hours of Category 1 CME in the performance and interpretation of abdominal-pelvic CT;
      and
   ii. Supervision, interpretation, and reporting of 500 CT cases, at least 100 of which must be abdominal-pelvic CT cases during the past 36 months in a supervised situation;
      and
   
   b. Education regarding patient preparation, bowel insufflation, and CT image acquisition;
      and
   
   c. Formal hands-on interactive training using dedicated CTC software, including the interpretation, reporting, and/or supervised review of at least 75 endoscopically confirmed CTC cases using primary 2-D and/or primary 3-D search with routine problem-solving techniques [31].

   Ideally this collection of training cases will be chosen to demonstrate the gamut of appearances of colonic polyps and cancer and CTC interpretation pitfalls. Additionally, the cases should include examinations performed for a variety of indications (eg, screening, symptomatic, incomplete colonoscopy with subsequent validation) and acquisition techniques (eg, with and without fluid tagging and IV contrast).

Maintenance of Competence

When feasible, CTC training should be followed by a period of mentored supervision and double-reading by an experienced CTC-trained physician. A variety of other techniques may also be helpful for improving interpretive skills at CTC, including the following:

- Self-directed individual study of formal texts, atlases, review articles, and teaching files
- Testing with feedback
- Computer-aided detection algorithms, which can be used as a second reader

A total of 50 cases every 2 years should be reviewed to maintain skills in CTC. This can be accomplished in several ways, such as:

- Performance of CTC with primary or overread interpretations in local practice, with follow-up of positive findings with endoscopy or surgery
- CME-sponsored reviews online, DVDs, or at review courses where case interpretation precedes disclosure of the correct answers
**B. Radiologic Technologist**

Qualifications of the radiologic technologist should include familiarity with the technical requirements of performing CTC, including selection of scanning parameters, rectal tip insertion, proper patient positioning, colonic insufflation of room air and carbon dioxide with manual and automated techniques, tube removal, and quality assurance of the examination prior to discharge of the patient.

**IV. SPECIFICATIONS OF THE EXAMINATION**

The written or electronic request for CT colonography 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. Colon Preparation**

Preparation of the colon for CTC should consist of include a combination of a cleansing laxative; tagging agent(s), such as barium to tag residual stool; and iodinated contrast material to tag remaining fluid [32]. Dietary restriction, hydration, saline cathartics, and/or low-volume polyethylene glycol agents and contact laxatives. The intent is to achieve a colon that is free of fecal material and excess fluid or as close to this ideal as possible [32-36]. The goal of tagging is to passively incorporate contrast into any residual fluid and stool in order to raise their inherent CT densities, which helps to discriminate these residua from the soft-tissue density of polyps or advanced cancers. Additionally, contrast surface coating can aid in polyp detection [37,38]. Magnesium citrate or polyethylene glycol are commonly used laxatives [32,36]. Preparations may also include a clear liquid diet the day before CTC [32].

When feasible, the use of tagging is recommended unless the patient refuses or cannot comply. The use of water-soluble contrast alone or in combination with low-volume barium is the preferred tagging method. The goal of tagging is to passively incorporate contrast into any residual fluid and stool in order to raise their inherent CT densities, which helps to discriminate these residua from the soft-tissue density of polyps or advanced cancers.

Noncathartic or reduced-cathartic approaches to CTC bowel preparation (also known as “prepless” or “minimal prep” CTC) aim to reduce patient discomfort associated with pre-examination bowel purgation. Although data supporting the success of this approach continue to emerge, a fully cleansed colon is generally recommended for patients who can comply [39-42]. For patients who cannot comply with a standard preparation or who are too fragile to undergo a standard preparation, sufficient data exist to justify limited cathartic or noncathartic CTC when combined with a tagging agent [13,43-47].

**B. Examination Technique**

1. The medical history, including patient compliance with the colon preparation, should be reviewed.
2. The patient should evacuate prior to insertion of the rectal tube. A soft (nonrigid) tip tube is recommended.
3. The rectal tube tip should be inserted by a physician or a trained assistant (radiologic technologist, nurse, or physician assistant). If a rectal retention balloon is used, inflation should be discontinued if the patient complains of persistent severe pain. This may indicate an increased risk of perforation.

4. If a rectal retention balloon is used, it should be deflated or advanced on one series to facilitate detection of low lying rectal lesions.

5. The use of antispasmodics is not considered necessary for routine examination, and the evidence for improved distention or patient comfort remains inconclusive. No benefit is seen with glucagon [48,49]. There may be some benefit with hyoscine N-butylbromide [50,51]. However, this agent is currently unavailable in the United States.

6. The preferred method of colonic insufflation is by means of mechanical insufflation using carbon dioxide [52]; however, manual insufflation with room air is acceptable. A sufficient volume of carbon dioxide or room air should be administered either with an automatic insufflator or manually to provide full colonic distention [53].

7. The adequacy of colon distention should be checked with a localizer to ensure a complete and full column of gas throughout the colon before each CTC acquisition.

8. Complete anatomic imaging of the colon and rectum should be obtained in at least two patient positions (usually such as supine and prone, supine and right lateral decubitus, or bilateral decubitus) [35,54,55]. If the patient is unable to tolerate prone positioning, a lateral decubitus can be substituted. Each series should be obtained in end expiration to minimize pressure effects of inflated lungs on the transverse colon.

9. Screening studies should be performed using a low-dose, nonenhanced CT technique on a multidetector CT (MDCT) scanner [3,56-59]. CTC colonography studies should be performed such that there is appropriate adaptation of computed tomography dose index volume (CTDIvol) to patient size, using either technique charts or automatic exposure control. The recommended radiation output CTDIvol for routine screening CTC for an average size subject should be 5 mGy or less per position. Generally, for scans performed at a tube potential of 120 kVp, this requires an effective mAs value of approximately 50, quantified using CTDIvol should be less than or equal to one half the diagnostic reference level for routine abdominal pelvic CT (2008 ACR CT Accreditation Program) or one quarter of this value per position (i.e., CTDIvol of 6.25 mGy per position or a total of 12.5 mGy for dual-position CTC). Generally, for scans performed at a tube potential of 120 kVp, this requires an effective mAs value between 50 and 80 (where effective mAs is equal to the tube current-time product (mAs) divided by the spiral pitch value). Because these factors may not be appropriate for every CT scanner model, the scan protocol parameters should be adjusted as necessary to obtain the required image quality at or below the suggested CTDIvol values (6.25 mGy per scan position or 12.5 mGy total for the supine and prone position scans).

10. The use of dose reduction techniques is encouraged. These include reductions in tube current (mA), exposure time(s), tube current-time product (mAs), or tube potential (kV). Automatic exposure control systems, image-based noise reduction algorithms, and iterative reconstruction techniques can also be used to effectively reduce dose [60-62]. Using these strategies, much lower radiation doses for screening CTC per position can be achieved, similar to or less than the average annual background level of radiation in the range of 3 mSv or less [63].

11. Additional imaging after repositioning and reinsufflation may be needed to adequately distend a colonic segment. Additional imaging (e.g., in right or left decubitus position) is appropriate when imaging in two positions fails to adequately display the colonic lumen and acquisition of additional data is likely to result in a diagnostic study [64]. Any additional imaging should be limited to the segment of interest in order to minimize additional radiation dose.

12. For morbidly obese patients, radiation dose should be appropriately increased to maintain diagnostic image quality [65].

13. Diagnostic CTC examinations should use the same CT parameters as screening CTC examinations. Diagnostic CTC may occasionally require IV contrast to characterize intracolic or extracolic structures or to address a second medical indication. When IV contrast is used, the dose on the contrast-enhanced series should be similar to a standard abdominal pelvic CT; the supine series is typically used for this. Thus, for diagnostic contrast-enhanced CTC, a typical order of sequences should include an initial low-dose noncontrast prone series followed by a supine series with IV contrast and normal dose.
14. CTC is optimally performed on a MDCT (≥16 slice) scanner. A section thickness of 1 to 1.25 mm with a reconstruction interval of ≤1 mm is optimal. The breathhold should not exceed 25 seconds.

15. Networking capability should be available to transfer the image data to a workstation with specialized software for CTC interpretation.

C. Quality Control

The following quality controls should be applied to all CTC examinations:

1. There should be complete anatomic coverage of the colon and rectum.
2. Colon cleansing and distention should be adequate for detecting polyps 1 cm or larger, at a minimum.
3. There should be complete anatomic coverage of the colon and rectum.
4. The luminal surface of each segment of the colon should be visualized in at least one position. Suboptimally visualized colonic segments should be reimaged. The use of lateral decubitus views or reinsufflation may be helpful in cases of suboptimal distention or excessive fluid [64].
5. Efforts should be made to ensure a diagnostic-quality examination before the patient leaves the facility.
6. The following is suggested for a quality control program:
   a. Radiologic, endoscopic, and pathologic findings should be correlated whenever available on a per patient basis.
   b. Detection rates for colorectal cancer and polyps of 1 cm or greater should be determined and periodically monitored. There should be an assessment of false-positive rates for all reported polyps in patients who undergo subsequent colonoscopy.
   c. Dose should be tracked as part of protocol optimization to follow “as low as reasonably achievable” (ALARA) principles.
   d. Participation in the ACR NRDR® CTC Registry (https://nrdr.acr.org/Portal/CTC/Main/page.aspx) is recommended, with regular comparison of facility data to national data to determine how local detection and complication rates compare with national rates and whether performance is adequate or if further internal review is indicated. Please note, the American Board of Radiology (ABR) has deemed that the CTC Registry meets the criteria for practice quality improvement toward the purpose of fulfilling requirements in the ABR Maintenance of Certification Program.

D. Data Interpretation

The purpose of CTC is to accurately evaluate the colon for the presence or absence of clinically significant neoplastic lesions. Abnormalities may range from discrete mucosal elevations or depressions (which may be malignant or at risk to become malignant) to infiltrating tumors. Lesion size, morphology (sessile, pedunculated, flat, mass), and segmental location should be reported.

1. Detection and characterization of colorectal findings
Workstations utilized for CTC interpretation should be able to display 2-D and 3-D data as well as prone and supine data side by side for interactive interrogation. The software should also allow the interpreting physician to perform basic 2-D and 3-D functions interactively and in real time (ie, 2-D: change the window width and level settings interactively and in real-time, zoom/pan to area of interest, measure region of interest (ROI), measure distance, etc; 3-D: view object of interest from any angle, assess color map attenuation, measure size/volume, etc). The software should allow easy correlation of a specific point on the 2-D image with the same point on 3-D and the reverse situation.

If an abnormality is suspected during either primary 2-D or 3-D searches:
   a. The abnormality should be interrogated with multiplanar reconstruction (MPR) and multiple endoluminal views to evaluate the morphology of the suspected lesion.
   b. Supine and prone data should be evaluated to determine if the lesion is mobile. Causes of mobility include residual fecal material, pedunculated polyp, or a rotating colon segment. Most true polyps can...
be identified in both the supine and prone views; potential lesions seen on only one view have a much lower predictive value.

c. The window setting should be adjusted between colon and soft-tissue settings to determine if the lesion shows homogeneous soft-tissue attenuation or is heterogeneous.

2. Measurement of colorectal findings

Polyps should be measured using optimized MPR (ie, axial, sagittal, or coronal view, which best elongates lesion) and/or 3-D images. Measurement of the size of the lesion should be based on the largest diameter of the polyp head (excluding stalk if present) or at the base of a sessile lesion [66,67].

3. Extracolonic findings

Extracolonic structures should be evaluated at the time of the review of the colon. Significant or potentially significant abnormalities should be included in the report. A study optimized for evaluating colon abnormalities may not be optimal for detecting and characterizing extracolonic abnormalities. Specifically, detecting incidental findings with low subject contrast may be limited with aggressive dose reduction on unenhanced images. This limitation is reduced somewhat by increasing the section thickness for the extracolonic reconstruction (eg, 5-mm-thick sections at 3-mm intervals), which reduces noise and decreases the number of images that need to be reviewed for incidental lesion detection. Abnormalities or questionable abnormalities in structures unrelated to the colon may be identified during the process of reviewing the 2-D axial images of the colon. A balanced approach for recommending further workup of extracolonic findings should weigh the likelihood of a clinically important finding against the increased cost, patient anxiety, and potential complications related to additional evaluation [30,68].

V. DOCUMENTATION AND COMMUNICATION OF RESULTS

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [69].

Any colonic segment that cannot be adequately evaluated for technical reasons should be documented as such. Polyps ≥6 mm should be identified and reported. Consistent with the 2008 American Cancer Society recommendations [70], these patients should be offered polypectomy at colonoscopy, understanding that clinical management may vary depending on the patient’s age, risk to undergo colonoscopy, other significant comorbidities, or the preference of the patient or the referring physician. Recommendations for clinical management options may be incorporated into the report. For patients with only 1 or 2 small (6-9 mm) polyps (ie, C-RADS C2), a 3-year surveillance CTC may be offered at some dedicated centers [30,71].

In patients with only diminutive polyps ≤5 mm, the risk of high-grade dysplasia or cancer is extremely low [6,10,72,73]. In fact, newer data show that cancer is virtually nonexistent in subcentimeter polyps [74,75]. Although there continues to be debate about patients with only diminutive polyps, the clinical risk of these diminutive polyps is extremely small [58,76,77]. The benefits of polypectomy versus 5-year surveillance need to be balanced with the broader risks, including the costs and complications of polypectomy. Namely, given the low risk of advanced neoplasia along with the low specificity of diminutive lesions at CTC, a large number of patients could be referred to endoscopy inappropriately [78]. Furthermore at colonoscopy, concern over decreased productivity for false-positive CTC examinations has been raised [79], in addition to the low rate of detecting small lesions at colonoscopy [80,81]. Current CTC acquisition techniques targeted at the index lesion size of ≥6 mm with low-dose techniques do not always optimize detection of diminutive lesions. Given these considerations, the ACR currently does not believe that reporting of these diminutive lesions is necessary [30].

Extracolonic abnormalities of potential medical significance should also be reported. As with any CT scan, good patient care mandates that CTC interpretation include full evaluation of the numerous extracolonic structures and that findings of potential clinical significance be reported and communicated in a clear and timely fashion. However, most extracolonic findings are not clinically significant in screening/asymptomatic cohorts. In screening cohorts, the prevalence of clinically significant extracolonic findings is low [76,82-88]. Caution should be used in the
interpretation and reporting of findings likely to be of low clinical significance in order to avoid unnecessary subsequent/serial diagnostic examinations and associated patient anxiety [30].

Clarity and consistency of reporting the colonic and extracolonic findings are critical for effective implementation. There is increasing use of the C-RADS, which is a consensus statement of a standardized reporting structure for CTC findings published in 2005, modeled after the Breast Imaging Reporting and Data System® (BI-RADS) reporting of mammography [30]. The reporting structure of C-RADS describes how to report lesion size, morphology, and location with a summary category score per patient.

VI. EQUIPMENT SPECIFICATIONS

Examinations should be performed with MDCT (generally ≥16 slice) equipment meeting all applicable federal and state radiation standards. The CT scanner should have the capability of providing section thicknesses of 1 to 1.25 mm and reconstruction intervals ≤1 mm at breathholds of less than 25 seconds. Equipment should provide diagnostic image quality and networking capability.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

For specific issues regarding CT quality control, see the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [29].

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [89].

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 Colon Cancer Committee of the ACR Commission on General, Small, Emergency and/or Rural Practice.

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

ACR
Judy Yee, MD, FACR, Chair
Kevin J. Chang, MD
Candice Johnstone, MD
David H. Kim, MD, FACR
Courtney Moreno, MD

SAR
Cecelia Brewington, MD, FACR
Perry J. Pickhardt, MD, FSAR

SCBT-MR
Elizabeth G. McFarland, MD, FACR

Colon Cancer Committee
(ACR Committee responsible for sponsoring the draft through the process)

Judy Yee, MD, FACR, Chair
Matthew A. Barish, MD, FACR
Cecelia Brewington, MD, FACR
Kevin J. Chang, MD
Abraham H. Dachman, MD, FACR
Joel G. Fletcher, MD
Marc J. Gollub, MD, FACR
Mukesh G. Harisinghani, MD, BS, MB, FACR

Charles D. Johnson, MD, FACR
David H. Kim, MD, FACR
Mark E. Klein, MD, FACR
Paul M. Knechtges, MD
Elizabeth G. McFarland, MD, FACR
Perry J. Pickhardt, MD, FACR
Michael L. Puckett, MD, FACR
Michael Zalis, MD, FACR

Committee on Practice Parameters – General, Small, Emergency and/or Rural Practices
(ACR Committee responsible for sponsoring the draft through the process)

Sayed Ali, MD, Chair
Marco A. Amendola, MD, FACR
Lynn Broderick, MD, FACR
Resmi A. Charalel, MD

Candice Johnstone, MD
Padmaja A. Jonnalagadda, MD
Steven E. Liston, MD, MBA, FACR
Tammam Nehme, MD

PRACTICE PARAMETER
CT Colonography
2019 Resolution No. 3
NOT FOR PUBLICATION, QUOTATION, OR CITATION

Brian D. Gale, MD, MBA  Samir S. Shah, MD
Carolyn A. Haerr, MD  Jennifer L. Tomich, MD
Charles E. Johnson, MD

Lincoln L. Berland, MD, FACR, Chair, Commission on Body Imaging
Robert S. Pyatt, Jr., MD, FACR, Chair, Commission on General, Small, Emergency and/or Rural Practice
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Kevin Smith, MD, FACR, Chair  Paul A. Larson, MD, FACR
Timothy Crummy, MD, FACR, Co-Chair  Barton Frederick Lane, MD
Sayed Ali, MD  Elizabeth G. McFarland, MD, FACR
Jacqueline A. Bello, MD, FACR  Courtney Moreno, MD
Lincoln L. Berland, MD, FACR  Mary S. Newell, MD, FACR
Cecilia Brewington, MD, FACR  Perry J. Pickhardt, MD, FSAR
Kevin J. Chang, MD  Matthew S. Pollack, MD, FACR
Richard Duszak, Jr., MD, FACR  Robert S. Pyatt, Jr., MD, FACR
Candice Johnstone, MD  Timothy L. Swan, MD, FACR
David H. Kim, MD, FACR  Judy Yee, MD, FACR

REFERENCES


PRACTICE PARAMETER

CT Colonography

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RESOLUTION NO. 4

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography (CT)

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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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.

2014 (Resolution 4)*

ACR–STR PRACTICE PARAMETER FOR THE PERFORMANCE AND REPORTING OF LUNG CANCER SCREENING THORACIC COMPUTED TOMOGRAPHY (CT)

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, ___ N.W.2d ___ (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

Lung Cancer Screening CT

2019 Resolution No. 4
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 revised collaboratively by the American College of Radiology (ACR) and the
Society of Thoracic Radiology (STR).

Thoracic CT is the only test that has been demonstrated to reduce mortality from lung cancer in high-risk current
and former cigarette smokers [1,2]. Screening with CT may have additional health benefits when associated with
smoking cessation [3-7]. The optimal performance of thoracic CT for lung cancer screening requires knowledge of
normal anatomy, anatomic variants, pathophysiology, and the risks associated with lung cancer screening. In
addition, attention to CT technical parameters to achieve lower radiation exposure levels than is characteristic of
standard adult thoracic CT examinations is important, particularly because a positive CT screening examination
may result in subsequent follow-up examinations that expose screen-positive individuals to additional ionizing
radiation, and screening CT may be repeated annually for several decades, depending on when an individual begins
screening. This practice parameter outlines the principles for performing high-quality thoracic CT in adults at high
risk for lung cancer.

Before participating in screening, individuals should consult with a health care provider about the risks and benefits
of lung cancer screening. It is recommended that radiology practices performing lung cancer screening participate
in a multidisciplinary approach that includes the specialties of radiology, pulmonary medicine, pathology, thoracic
surgery, medical and radiation oncology, and other related health care disciplines.

For current smokers, there should be a mechanism for referral to smoking cessation programs. Educational
messaging and materials promoting smoking cessation may be included in program-related patient correspondence.

The primary goal of lung cancer screening CT is to detect abnormalities that may represent lung cancer and may
require further diagnostic evaluation. In addition, examinations should be reviewed for other abnormalities in
accordance with the ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed
Tomography (CT) [8].

II. INDICATIONS AND CONTRAINDICATIONS

Screening thoracic CT is appropriate for asymptomatic individuals at high risk for lung cancer [9]. An individual’s
risk for lung cancer is primarily determined by:

- Smoking history and age [10-16].

Additional risk factors include the following [17-42]:
1. Emphysema and chronic obstructive pulmonary disease
2. Interstitial lung disease, such as pulmonary fibrosis
3. Occupational and environmental exposures, such as asbestos, arsenic, beryllium, cadmium, chromium, coal
smoke, diesel fumes, nickel, silica, and soot
4. High levels of radon exposure
5. History of cancer, including lung cancer, lymphoma, head and neck cancer, and smoking-related cancers
6. Family history of lung cancer
7. Extensive secondhand smoke exposure
8. Prior thoracic radiation therapy, as may occur for breast cancer and lymphoma

For other thoracic CT techniques beyond the scope of this practice parameter, please refer to the ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [8] and the ACR Practice Parameter for the Performance of High-Resolution Computed Tomography (HRCT) of the Lungs in Adults [43].

There are no absolute contraindications to screening thoracic CT. As with all procedures, the relative benefits and risks of the procedure should be evaluated prior to the performance of thoracic CT. Appropriate precautions should be taken to minimize patient risks, including radiation exposure.

Self-referred individuals are defined as those individuals with no health care provider, who decline having a health care provider, or for whom the health care provider declines responsibility. It is at the discretion of the facility’s medical director whether or not to offer screening to the self-referred individual. However, screening facilities that elect to accept self-referred individuals must have procedures for referring them to a qualified health care provider if abnormal findings are present.

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 [44].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [45]

IV. SPECIFICATIONS OF THE EXAMINATION [46-49]

A. Prior to the Examination

The written or electronic request for a lung cancer screening CT should provide sufficient information to demonstrate the medical appropriateness of the examination and allow for its proper performance and interpretation. This should include the patient’s age, smoking history in pack-years, and should identify the patient as a current smoker or as a former smoker with quit date.

B. Examination

A typical lung cancer screening CT of the thorax must be performed with multidetector helical (spiral) technique in a single breath-hold. The study must include axial images from the lung apices to the costophrenic sulci acquired and viewed at 2.5-mm slice thickness or smaller, with reconstruction intervals equal to or less than the slice thickness. The examination may be acquired and reconstructed at 1.0-mm slice thickness or smaller, and reconstruction intervals to allow for better characterization of small lung nodules [50]. Maximum intensity projection (MIP) reconstruction is a technique that may be useful to increase the sensitivity for lung nodule detection [51-55]. Multiplanar reconstruction (MPR) may be useful to further characterize nodules, particularly nodules located along the pleural surfaces (also known as perifissural nodules) [56-58].

Scans should be obtained in a suspended state of full inspiration whenever possible. Scans must be obtained through the entire lungs, from apices to bases, and the field of view must be optimized for each patient to include the entire transverse and anteroposterior diameter of the lungs.
The examination is conducted without the use of intravenous contrast medium.

Although many of the operations of a CT scanner are automated, a number of technical parameters remain operator dependent and may significantly affect the diagnostic quality of the CT examination. Wherever possible, scanning protocols should be preprogrammed and saved on the CT scanner console to reduce the operator input required. It is necessary for the supervising physician to acquire familiarity with the following:

1. Radiation exposure factors (including milliamperes, peak kilovoltage, gantry rotation time)
2. Detector configuration (including detector rows, width of each detector row, configurations allowed, etc)
3. Slice thickness and interval
4. Field of view and matrix size (eg, 512)
5. Window and level settings
6. Reconstruction algorithms
7. Reformatted images (MPR, curvilinear, MaxIP, and MinIP)
8. Advanced dose reduction techniques such as automatic exposure control and iterative reconstruction methods, if available

Optimization of the CT examination requires communication between the supervising physician, medical physicist, and radiologic technologist to develop and monitor appropriate CT protocols based on the clinical indications and associated risks. The technique should be set to yield a dose index volume (CTDIvol) of 3 mGy or less for a standard-sized patient. It should be reduced for smaller-sized patients and increased for larger-sized patients [46-48,59-67].

The protocol should be developed with attention to the organ system of interest, in this case primarily the lungs, for the specific purpose of lung cancer screening. Techniques should result in diagnostic quality images with the lowest possible patient radiation exposure. For each study, the protocol should specify:

1. Use of volumetric helical (spiral) acquisition
2. Collimation, table increment, and pitch as appropriate
3. Peak kilovoltage and milliamperes appropriate to body habitus
4. Superior and inferior extent of the area of interest to be imaged
5. Reconstructed image thickness and spacing (interval)
6. Reconstruction algorithm and level and window settings
7. Field of view and matrix size
8. Image reformatting

Examples of lung cancer screening protocols for several specific CT scanner manufacturers and models are available [68]. They should not be used for other manufacturers or models without careful review and adjustment with the assistance of a qualified medical physicist. The lung cancer screening protocol should be reviewed at regular intervals or with a change in screening equipment and updated annually.

V. INTERPRETATION AND REPORTING

Anatomically appropriate window and level settings should be used to view all of the anatomy within the obtained CT coverage, including the lung parenchyma, mediastinum, chest wall, bones, lower neck, and upper abdomen within the scanned field of view. Softcopy review facilitates evaluation.

Lung nodules and focal lung lesions should be reported with respect to anatomic location (lung lobe, segment) and series/image number to facilitate comparison to both prior and subsequent thoracic CT examinations. Nodules should be described with respect to size, attenuation (soft tissue, type of calcification, fat), opacity (solid, ground glass [also known as nonsolid], and part-solid, containing both solid and ground-glass components), and margins (eg, smooth, lobulated, spiculated) [69-75]. Comparison with prior imaging studies is an important part of nodule evaluation. Specific reference should be made to change, or lack thereof, from prior examinations when serial examinations are reviewed. If previous imaging studies, particularly thoracic CT examinations, are needed to determine the significance of positive findings, an attempt should be made to obtain and compare with the images directly and not rely on prior reports alone. When comparing changes in nodule size, opacity, and contour, efforts...
should be made to compare the oldest scans available in addition to the most recent prior scan to assess for changes over time, including subtle changes. Volumetric analysis or volume measurement of nodules may be incorporated into the report.

The use of computer-assisted nodule detection and volumetric assessment of nodule size and growth by computer workstation analysis can be valuable adjuncts to the evaluation and should be utilized, if available.

For the management of screen-detected lung nodules, standard guidelines should be followed within a practice or screening program [76-79] and should be included in the radiology report. Although a guideline about interpretation and follow-up may be useful as an attachment to the report, the interpreting radiologist should make recommendations for the appropriate management and follow-up specific to the individual patient whose CT is under review.

Screening results should be reported using a structured reporting system for lesion assessment, imaging-pathologic correlation, quality improvement, and medical outcomes auditing. Reporting and management recommendations of incidental findings are also important for lung cancer screening [80].

Review of the entire examination for other potentially significant findings should be performed and reported in accordance with the ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [8].

VI. DOCUMENTATION AND COMMUNICATION OF RESULTS

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [81].

A structured reporting system facilitates data management, patient care, and quality assurance activities. Such a system should include the adherence of radiologist recommendations to screening guidelines, patient tracking and storage of findings in a structured database, automatic generation of results-specific findings, triage of risk categories within the screened population, and appropriate referral of the small number of patients with suspicious findings who require multidisciplinary team management.

Imaging providers may wish to establish infrastructure in the form of a relational database application that facilitates and helps manage patient intake, scheduling, and follow-up.

Lung Cancer Screening Registry:

Studies performed for lung cancer screening under the Medicare program should also be reported to a CMS (Centers for Medicare and Medicaid Services) registry to meet quality reporting requirements. Data from the quarterly reports of the facility can be used for improving the lung cancer screening program. [https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Lung-Cancer-Screening-Registry](https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Lung-Cancer-Screening-Registry).

VII. EQUIPMENT SPECIFICATIONS

To achieve acceptable clinical CT scans of the thorax for lung cancer screening, a CT scanner should meet the current ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) [8] and meet or exceed the following capabilities:

1. Gantry rotation times: 0.75 seconds or less
2. Slice thickness: 2.5 mm or less (1.0 mm or less is preferred)
3. Detector rows: 16 or more detector rows are preferred
The CT scanner and/or the viewing platform should be capable of generating MIP and MPR images.

**VIII. EQUIPMENT QUALITY CONTROL**

The quality control program for CT equipment should be designed to minimize patient, personnel, and public radiation risks and to optimize the diagnostic quality of the examination. The program should be supervised by a medical physicist and follow the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [82].

**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 acceptable, 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](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](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).

A medical physicist and radiologist together should verify that any dose reduction devices or utilities maintain acceptable image quality while actually reducing radiation dose.

**X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION**

A rigorous quality assurance and medical outcomes audit program should be established at screening sites to document that performance and interpretation is of the highest possible quality. This is central to patient safety.
because of the potential morbidity and mortality associated with false-positive workups and biopsies. Methodology should be in place to evaluate the appropriateness of screening referrals.

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

It is recommended that a lung cancer CT screening program have a documented policy for collecting outcomes data, such as positive and negative screen rates, the rate of clinically significant incidental extrapulmonary findings, and false-positive finding rates.

For specific issues regarding CT quality control, see the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [45].

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [82].

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 Thoracic Radiology of the ACR Commissions on Body Imaging and the Committee on Practice Parameters – General, Small, Emergency, and/or Rural Practice of the ACR Commission on General, Small, Emergency, and/or Rural Practice in collaboration with the STR.

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

ACR
Reginald F. Munden MD, DMD, MBA, FACR, Chair
Subba R. Digumarthy, MD
Carolyn A. Haerr, MD
Terrance T. Healey, MD
Ann N. Leung, MD
Tammam Nehme, MD

STR
Paul Cronin, MB, BCh, BAO, FACR

Committee on Body Imaging (Thoracic)
(ACR Committee responsible for sponsoring the draft through the process)

Lynn Broderick, MD, FACR, Chair
William C. Black, MD
Daniel W. Brown, MD
Stuart L. Cohen, MD
Andetta R. Hunsaker, MD
Negar Knowles, MD

Elizabeth Lee, MD
Ann N. Leung, MD
Cristopher A. Meyer, MD, FACR
Reginald F. Munden, MD, DMD, MBA, FACR
Shawn D. Teague, MD, FACR
Charles S. White, MD, FACR
Committee on Practice Parameters – General, Small, Emergency and/or Rural Practices
(ACR Committee responsible for sponsoring the draft through the process)

Sayed Ali, MD, Chair
Marco A. Amendola, MD, FACR
Lynn Broderick, MD, FACR
Resmi A. Charalel, MD
Brian D. Gale, MD, MBA
Carolyn A. Haerr, MD
Charles E. Johnson, MD

Lincoln L. Berland, MD, FACR, Chair, Commission on Body Imaging
Robert S. Pyatt, Jr., MD, FACR, Chair, Commission on General, Small, Emergency and/or Rural Practice
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Eric Rubin, MD, Chair
Catherine Everett, MD, MBA, FACR, Co-Chair
Sayed Ali, MD
Jacqueline A. Bello, MD, FACR
Lincoln L. Berland, MD, FACR
Lynd Broderick, MD, FACR
Paul Cronin, MB, BCh, BAO, FACR
Subba R. Digumarthy, MD
Richard Duszak, Jr., MD, FACR
Carolyn A. Haerr, MD

REFERENCES


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

Development Chronology for this Practice parameter

2014 (Resolution 4)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 5

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Pediatric Spine

Sponsored By: ACR Council Steering Committee

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ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE PEDIATRIC SPINE

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, ___ N.W.2d ___ (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 Society of Neuroradiology (ASNR), and the Society for Pediatric Radiology (SPR).

Pediatric spinal imaging relies predominantly on magnetic resonance imaging (MRI) for the evaluation, assessment of severity, and follow-up of diseases of the pediatric spine. Ultrasound (US) is still utilized in neonates younger than 6 months (approximately 3 to 4 months) to assess for spinal contents; its utility, however, diminishes significantly afterward because of the lack of an adequate acoustic window [1].

A variety of imaging modalities can provide diagnostic information based on clinical indications. Of all the imaging tools available for evaluation of pediatric spine disorders, MRI is the most sensitive diagnostic test for detecting anatomic abnormalities of the spine and adjacent structures. However, spine MRI should be performed only for a valid medical reason. Interpretation of imaging findings often benefits from the correlation of findings with the patient’s clinical history, clinical examination, or physiologic tests. Adherence to the following practice parameter will enhance the probability of detecting such abnormalities.

II. INDICATIONS

Indications for pediatric spine MRI include, but are not limited to, the evaluation of:

1. Congenital spine malformations
   a. Spinal dysraphism
      i. Open: non-skin-covered and exposed neural elements
         • Meningocele and its spectrum of findings
      ii. Closed: skin-covered neural elements
         • Cutaneous stigmata—sacral dimple, skin tag, focal hirsutism, focal discoloration, capillary hemangioma, hairy nevus, or hyperpigmented patches
   b. Skeletal abnormalities and dysplasia
      i. Anorectal anomalies
      ii. Scoliosis
   c. Systemic syndromes associated with motor, bowel, or bladder dysfunction
      i. Caudal regression syndrome that involves partial or complete agenesis of the distal spinal column, imperforate anus, genitourinary anomalies, bilateral renal absence or dysplasia, pulmonary hypoplasia, and lower-extremity anomalies
      ii. Other associations such as Currarino triad, vertebral defects, anal atresia, cardiac defects, tracheoesophageal fistula, renal anomalies, and limb abnormalities (ie, VACTERL)
   d. Congenital spinal cord malformation
      i. Ultrasound (US) finding of a low-lying conus, fatty filum, thickened filum terminale, or intraspinal lesion
      ii. Suspicious cutaneous findings or high dermal pit or sinus
2. Inflammatory/autoimmune disorders
   a. Demyelinating disease
      i. Multiple sclerosis (MS)
      ii. Acute disseminated encephalomyelitis (ADEM)
      iii. Acute inflammatory demyelinating polyradiculopathy (Guillain-Barré syndrome)
      iv. Transverse myelitis
   b. Connective tissue disorders (eg, systemic lupus erythematosus)

3. Infectious conditions
   a. Spinal infection, including disc space infection, vertebral osteomyelitis, and epidural abscess
   b. Spinal cord infection, including abscess

4. Vascular disorders
   a. Spinal vascular malformations
   b. Spinal cord infarction

5. Trauma
   Nature and extent of traumatic injury to spinal cord, vertebral column, ligaments, thecal sac, and paraspinal soft tissues

6. Neoplastic abnormalities
   a. Intramedullary tumors
   b. Intradural-extramedullary masses
   c. Intradural leptomeningeal disease
   d. Extradural soft-tissue and bony neoplasms
   e. Planning for radiation therapy

7. Degenerative conditions
   a. Degenerative disc disease and its sequelae
   b. Spinal canal stenosis, including foramen magnum narrowing

8. Miscellaneous
   a. Spinal abnormalities associated with scoliosis
   b. Syringohydromyelia (multiple etiologies, including Chiari malformations, trauma, etc)
   c. Postoperative fluid collections and soft-tissue changes (extradural and intradural)
   d. Spondylolysis
   e. Osteoid osteoma

III. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [2], the ACR Manual on Contrast Media [3], and the ACR Guidance Document on MR Safe Practices [4].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [2].
V. APPLICATIONS OF MRI

A. Neoplasms

MRI is the preferred and most frequently utilized modality to evaluate tumors of the spine in the pediatric population. Superior contrast resolution and multiplanar capabilities allow delineation of the tumor, including, most importantly, the extent of intraspinal involvement. MRI is able to localize the tumor as epidural, intradural-extradural, or intramedullary, thus limiting the differential diagnosis. Limited CT may be a useful adjunct modality for assessing bone involvement and evaluating for aggressive margins, the matrix characteristics, and possible sequestrum [5-7]. The administration of gadolinium-based contrast agents further improves sensitivity for lesion detection, improves conspicuity of lesions, and distinguishes solid-enhancing components from cysts or syrinx. Specifically, this is helpful for guiding surgical resection of the solid component in intramedullary tumors associated with cysts [7].

Evaluation for the presence of drop metastasis or leptomeningeal spread of tumor is optimally evaluated using MRI with postgadolinium T1-weighted images in both sagittal and axial planes. Recently, steady-state free precession techniques and diffusion weighted imaging (DWI) have been used to evaluate for cerebrospinal fluid (CSF) tumor dissemination [8,9]. Metastatic osseous neoplasms are less common in the pediatric population, and screening is performed using a number of modalities that include skeletal survey, bone scintigraphy with single-photon emission computed tomography (SPECT), 18F-FDG PET, MIBG-I123 scintigraphy, and whole-body MRI [10,11]. However, when spinal involvement is suspected, MRI is the preferred modality to assess for soft-tissue invasion and associated compression of the spinal cord [5]. In young children, diffuse marrow infiltration by tumor may be more difficult to assess as the marrow signal is not normally diffusely hyperintense on T1-weighted images because of the residual hematopoietic marrow [12,13].

Spinal screening with MRI may be indicated in patients with multiple familial exostoses to look for occult intracanalicular lesions [14].

B. Infection

Compared with adults, infections of the spine and spinal cord are less common in children. The causative factors include bacterial, viral, fungal, or parasitic organisms. Structural abnormalities, such as dermal sinus tracts, are predisposed to infection. The infectious process can affect the spinal cord; nerve roots and meninges; epidural space, vertebrae, and the discs [15,16]. Vertebral involvement may result in osteomyelitis, spondylitis, and discitis, often referred to as “spondylodiscitis.” Spondylodiscitis often affects children between the ages of 2 and 8 years and commonly involves the lumbar or lumbosacral spine. Radiographs are usually normal in the early stages of the disease. Spine MRI has a high sensitivity and specificity in early detection of pyogenic infections of the vertebral body and intervertebral discs. An intravenously administered gadolinium-based contrast agent may increase the sensitivity of MRI, providing increased conspicuity of inflammatory changes in both the osseous and the disc components of the disease [17].

Diffusion weighted images (DWI) may help differentiate type 1 degenerative marrow changes from spondylodiscitis [18].

MRI also has a higher sensitivity than CT or radiographs in the detection of associated paravertebral soft-tissue inflammation or abscess.

Spinal epidural abscess is rare but represents a clinically significant condition in children that often requires immediate surgical management [19]. MRI is the imaging modality of choice in spinal epidural abscess. Gadolinium-enhanced T1-weighted sequences have the highest specificity in identifying epidural abscess by demonstrating the rim enhancement surrounding the purulent collection. DWI sequences are also useful in differentiating epidural abscesses from simple epidural fluid collections. Contrast-enhanced MRI is also the
imaging modality of choice in assessing infectious processes of the spinal cord and nerve roots. MRI is the initial modality of choice in children with clinically suspected infectious processes, including acute (often viral) myelitis, spinal cord abscess, and meningitis.

Postlumbar puncture extradural fluid collections are common and may be symptomatic but should not be mistaken for epidural abscess [20].

C. Trauma

MRI provides inherent superior contrast resolution in visualizing the spinal cord, discs, ligaments, and vessels. Hence it is the preferred imaging modality in pediatric patients presenting with posttraumatic neurologic symptoms and normal or equivocal radiographic or CT findings and children who are sedated or obtunded, limiting the neurologic assessment [21,22]. T1- and T2-weighted, gradient-echo T2* (T2-weighted gradient echo (GRE)* and short tau inversion recovery (STIR)-weighted MRI pulse sequences are preferred in patients with spinal trauma. Many findings related to trauma are readily assessed in the sagittal plane. Axial imaging is helpful in further characterizing injuries, assessing the paraspinal soft tissues for injury, and identifying unexpected vascular injury, such as arterial dissection. Dedicated magnetic resonance angiography (MRA) of the neck may be indicated if there is a concern for arterial injury on the basis of spinal fracture location (eg, transverse foramen), vertebral body subluxation, signal abnormalities of the arteries, and unexplained brain infarct.

MRI is the gold standard in the diagnosis of spinal cord injuries [23]. Cord edema, transection, and hemorrhage and disc injuries can be aptly detected, which aid in management and prognostication of acute traumatic spinal cord injury [24,25].

MRI is usually recommended between 24 to 72 hours or the earliest possible time depending upon the clinical feasibility of the scan, especially if cord injury is a consideration [26]. That being said, there is no evidence supporting a more precise guideline. The length of edema of the cord is proportional to the time of imaging posttrauma as it has been found that the length of edema increases by one vertebral level each 1.2-day delay [23,25].

Occult spine injuries can best be detected with MRI, and these include bone contusions, compression fractures, and cord and ligamentous injuries [27]. STIR technique, which is used to suppress the signal from fat, is valuable in these cases. Several common vertebral developmental variants can be mistaken for fractures or other pathologic conditions, thus MRI plays a pivotal role in the differentiation of these entities. Abusive head trauma has a high association with ligamentous cervical spine injury [28].

DWI of the spinal cord plays an important role in children with Spinal Cord Injury without Radiographic Abnormality (SCIWORA), especially in patients with a normal appearance of the spinal cord on T2-weighted sequences. Shen et al. have demonstrated the clinical utility of DWI and diffusion tensor imaging (DTI) in the evaluation of patients with SCIWORA [29].

D. Congenital spine lesions

Congenital spine and cord lesions include multiple features of dysmorphology in the pediatric population that start during embryonic development.

Congenital spine malformations are divided into open and closed spinal dysraphisms. Open spinal dysraphism demonstrates externally exposed neural elements through an osseous defect, whereas closed spinal dysraphism does not expose the neural elements; instead, cutaneous stigmata predominate the clinical findings and suggest the underlying dysraphism [30]. In addition, motor, bowel and bladder dysfunctions may suggest spinal dysraphism as well as skeletal dysmorphologies, such as caudal regression syndrome that manifests as agenesis.
of distal spinal column, imperforate anus, genitourinary and renal anomalies, pulmonary hypoplasia, and lower-extremity osseous anomalies [30].

Spinal dysraphism requires thorough investigation of the spine and its contents. Identification of other associated anomalies, such as tethering lesions, diastematomyelia, and Chiari malformation, is important [31].

E. Demyelinating and intramedullary diseases

Intramedullary diseases can be difficult to differentiate clinically, and MRI plays a key role in attempting to make an accurate diagnosis. Clinical features that remain important include characteristics of onset (immediate, rapid, or prolonged), sensory level, and results of CSF sampling. These clinical features play an important role in MRI interpretation.

Abrupt onsets (less than 4 hours to maximal deficit) of nontraumatic myelopathic symptoms are suggestive of either a vascular etiology, such as a cord infarction, or a viral etiology (ie, acute flaccid myelitis). Onset of myelopathic symptoms longer than 4 hours but less than 21 days, is a feature of a variety of noninfectious demyelinating or inflammatory conditions including MS, ADEM, neuromyelitis optica (NMO), lupus myelitis, and other etiologies. When the etiology is unclear, a diagnosis of idiopathic transverse myelitis (ITM) can be made [32]. It is important to note that ITM is not necessarily a final diagnosis, and after completion of all testing, a patient may be determined to have a specific cause for their myelopathy (such as the detection of autoantibodies to the aquaporin-4 water channel confirming a diagnosis of NMO). In young children with NMO, the aquaporin-4 antibodies may not be detected at initial diagnosis but may become positive later; such a patient may initially be diagnosed with ITM but with an eventual diagnosis of NMO. Imaging of the brain is indicated to evaluate for additional and sometimes typical regions of demyelination.

Although noninfectious demyelinating and inflammatory conditions of the spinal cord have a varied appearance, the lesions are most commonly visible as hyperintense on T2W imaging, and areas of active inflammation or demyelination often enhance after gadolinium administration. Therefore, MRI of the brain and total spine without and with contrast is often indicated for a suspected inflammatory or demyelinating intramedullary process or process affecting the nerve roots of the spinal cord. MS tends to have small lesions that are nonexpansile and peripherally located within the spinal cord, whereas ADEM, NMO, and lupus have long segments (>3 vertebral levels of involvement) of centrally located expansile lesions [33,34].

The long-segment expansile heterogeneously enhancing lesions of many noninfectious inflammatory processes can overlap in appearance with intramedullary spinal cord neoplasms. Prolonged symptom onset is more common in intramedullary spinal cord neoplasms than nonneoplastic entities. The presence of cystic or hemorrhagic changes within an intramedullary lesion or a focal scoliotic curvature at the level of lesion favors a neoplastic etiology [35]. In children, spinal cord neoplasms are most commonly astrocytomas and may have cystic or hemorrhagic changes. Intramedullary spinal ependymomas are rare in children outside the setting of Neurofibromatosis type II. Cord DTI may be an adjunct technique to determine resectability of a tumor.

F. Vascular Disorders

Vascular disorders involving the spine in children are similar to adults, but the clinical circumstances under which they occur differ. Risk factors that lead to spinal cord infarcts (SCIs) include systemic hypotension, iatrogenic causes, embolism (fibrocartilagenous) [36], trauma, and vascular anomalies [37]. Abrupt myelopathic signs should raise concern for spinal cord ischemia. Children, however, can have a more prolonged clinical presentation, which often results in delayed diagnosis. The symptoms that occur from cord ischemia vary with the region of the involved cord. Back pain is a very common symptom. Unfortunately, over 50% of cases of pediatric SCIs have no identifiable cause.
There are two general categories of vascular spine disorders: spinal cord ischemia and vascular malformations. MRI is the most sensitive method of detecting the presence of cord ischemia and infarction. Pediatric SCI can be caused by systemic hypotension in the setting of placental abruption, neonatal hypoxic ischemic injury, and congenital heart disease. The poor auto-regulatory mechanism of the neonate is a further confounding factor. SCI in neonates can also be iatrogenic, such as from complications that are due to umbilical artery catheterization. A high catheter tip placement, thrombus formation, injection of hypertonic solutions, and vasospasm can all lead to SCI. In the older child, SCI may occur because of complications during surgical instrumentation for scoliosis correction. More recently in the literature, awareness has arisen around the entity of fibrocartilagenous embolism (FCE) as a cause of pediatric SCI [36,38]. Although this has not been proven in human research, there is evidence in the scientific literature that this pathophysiologic entity occurs. Intervertebral annular disc tears can result in extrusion of the nucleus pulposus and reflux of fibrocartilagenous emboli into the arterial supply of the spinal cord [39]. The clinical and MRI findings correspond to anterior spinal artery (ASA) territory infarcts.

MRI can demonstrate classic findings of cord infarction, with hyperintense signal acutely involving the anterior two-thirds of the cord ("snake eyes" on axial T2-weighted image) in the vascular distribution of the ASA [40]. The appearance, however, is nonspecific and can mimic myelopathy of other etiologies, such as infectious myelitis [41]. DWI and T1-weighted postcontrast sequences may identify an adjacent vertebral body infarct, which in turn supports the diagnosis of cord infarct [42,43].

Vascular malformations that can affect the spinal cord in children include arteriovenous malformations (AVMs), arteriovenous fistulas (AVFs), and cavernous malformations [40]. Unlike in adults, AVMs are more commonly encountered than AVFs. Although AVFs cause cord ischemia secondary to arterial steal from direct arteriovenous shunting, cord injury in the setting of AVMs occurs secondary to chronic hypoxia. In children, AVMs can be classified into compact (glomus) or diffuse (juvenile) forms [44]. There are congenital disorders that are associated with an increased incidence of spine vascular malformations, such as hereditary hemorrhagic telangiectasia, Neurofibromatosis type 1, Klippel-Trenaunay-Weber syndrome, and Cobb syndrome. MR imaging is the most successful noninvasive method of assessing the spine for vascular malformations. MR findings that can indicate the presence of a vascular malformation include visualization of serpentine signal voids in AVMs or posteriorly draining enlarged veins in dural AVFs [45]. An MR finding that can be misinterpreted for a spinal vascular malformation is CSF flow artifact commonly encountered in the thoracic region of children. Spinal cord cavernous malformations typically present in adolescence and are clinically more aggressive than their brain counterparts [46]. They appear as focal lesions containing byproducts of hemoglobin degradation. In most cases, virtually no surrounding edema is present unless there has been recent bleeding. Identification of a spinal cord cavernous malformation warrants evaluation of the entire central nervous system (CNS) for multiple lesions. MR imaging is also sensitive to secondary changes in the cord, such as venous congestion and gadolinium enhancement. MRA, with or without contrast administration, can be helpful in depicting pial fistulas and dural AVFs and can be useful in guiding subsequent spinal angiography.

G. Miscellaneous

1. Spinal abnormalities associated with scoliosis

There are three general categories of scoliosis: congenital, neuromuscular, and idiopathic. The imaging modality of choice in the diagnosis, assessment, and surveillance of scoliosis is radiography. CT is utilized to better understand complex osseous deformities and aids in presurgical planning. MRI is the optimal imaging modality to detect and characterize intraspinal abnormalities that can cause scoliosis, such as tumors, syringomyelia cavities, spinal dysraphisms, and Chiari malformations. MRI is indicated in children with congenital scoliosis and may detect spinal cord abnormalities in approximately 40% of cases [47]. In the youngest of these children, sonography can be helpful to assess for intraspinal pathology as an initial imaging screening option. Indications for MRI in patients with neuromuscular scoliosis will vary based on the underlying medical condition and the clinical presentation. MRI is advised in children with scoliosis and concerning
clinical manifestations or atypical spinal curves. Indications for MRI in patients with idiopathic scoliosis are not clearly established. MRI is often obtained prior to corrective spine surgery.

Imaging sequences typically include sagittal T1- and T2-weighted sequences and axial imaging. Slice thickness will depend on the area to be imaged. Coronal imaging is useful in defining abnormalities of vertebral segmentation and formation and in assessing the spinal curve, which is typically less pronounced than on standing radiographs. Fat suppression techniques may confirm congenital fatty lesions. Painful scoliosis evaluation may benefit from fat suppressed T2 or STIR imaging to evaluate for osseous pathology. Contrast is generally not indicated unless there is concern for a spinal mass.

2. Syringomyelia

Syringomyelia is the examination of choice in diagnosing syringomyelia. MRI can clearly depict the size, location, and extent of syringomyelia and can readily identify congenital and acquired conditions that may cause syringomyelia, such as Chiari type I malformations, cervical stenosis, spinal dysraphisms, tumor, arachnoid webs, prior trauma, prior hemorrhage, and infectious or inflammatory conditions. Often, syringomyelia cavities are idiopathic. Septations within a syringomyelia cavity are associated with benignity [48]. Contrast-enhanced imaging is indicated if tumor is suspected. However, contrast-enhanced imaging may not be necessary to rule out a syrinx-associated spinal cord mass if diagnostic-quality sagittal and axial T2-weighted images are available for analysis [49]. Advanced imaging techniques, such as phase-contrast cine flow MRI, may be used to analyze CSF flow dynamics and further insights into syringomyelia formation [50].

Sagittal T1- and T2-weighted sequences and axial imaging are typically indicated. T1-weighted imaging facilitates the detection of fatty fila, dermoid cysts, and dermal sinus tracts. Axial T2-weighted imaging aids in accurately identifying the position of the conus, thickened fila, small syringomyelia cavities, dermal sinus tracts, and spinal cord and paraspinal pathology. Heavily T2-weighted sequence, such as 3-D constructive interference in steady state (CISS) or fast imaging employing steady-state acquisition (FIESTA) are helpful in assessing the internal structure of a syringomyelic cavity, identifying subarachnoid webs, and aiding in distinguishing signal loss within the subarachnoid space arising from pulsatile or brisk CSF flow and abnormal vasculature [51].

3. Postoperative fluid collections and soft-tissue changes

MRI is well-suited to identify postoperative seromas, hematomas, CSF leaks, and pseudomeningoceles. MRI has high sensitivity and specificity relative to CT and bone scintigraphy because of the superior soft-tissue contrast inherent to MRI and avoids ionizing radiation [52,53]. MRI can clearly depict the relationship between intraspinal and paraspinal post-surgical fluid collections and the spinal cord and nerve roots of the cauda equina.

Sagittal T1- and T2-weighted sequences with fat-saturation technique and axial imaging are typically indicated in detecting postoperative fluid collections. Postcontrast imaging is helpful in assessing arachnoiditis and neuritis. CISS or FIESTA sequences may define the location and integrity of the dura, demonstrate the margins of pseudomeningoceles, postoperative fluid collections and CSF leaks, and show internal septations within fluid collections. Postcontrast T1-weighted images with fat saturation and DWI may assist in differentiating sterile postoperative fluid collections from superinfected ones [54].

4. Spondylolysis

CT is considered the gold standard in diagnosing spondylolysis. However, CT also exposes the patient to ionizing radiation. Bone scintigraphy involves radiation and is hampered by sensitivity and specificity considerations, often requiring additional evaluation with CT or MRI to confirm the diagnosis of spondylolysis. Standard MRI sequences approaches the sensitivity of CT in diagnosing spondylolysis [55]. Utilizing a high spatial resolution spoiled 3-D GRE variant T1 technique in the sagittal plane is likely equivalent to CT for
diagnosis. MRI provides the added benefit of demonstrating stress injury of the pars interarticularis in patients without a frank pars fracture [56].

Sagittal T1-weighted imaging, T2-weighted sequences with fat saturation, and axial imaging are typically indicated in detecting pars interarticularis fractures. The sagittal slice thickness should be thin enough to allow visualization of the pars (usually 3 mm). Sequences with fat-saturation techniques are important to display marrow edema associated with acute and subacute pars fractures and stress injury. Spine radiography has a lower sensitivity than both CT and MRI in detecting spondylolysis but is a low radiation dose, low-cost, and widely available initial screening modality option.

Osteoid Osteoma

Osteoid osteomas of the spine have a predilection for the posterior elements [57]. CT is superior to MRI in diagnosing and characterizing osteoid osteomas and is used for radiofrequency (RF) ablation. CT readily depicts the characteristic nidus, periosteal reaction and osteosclerosis of osteoid osteomas [58]. Dynamic gadolinium-enhanced MRI may also demonstrate the enhancing nidus with sensitivities approaching that of CT [59]. The florid bone marrow and soft-tissue edema often associated with an osteoid osteoma is better depicted on MRI than on CT. However, these findings are not specific to osteoid osteomas, and MRI features can resemble other entities, such as osteomyelitis, aggressive tumors, acute and subacute fractures, and hyperostosis secondary to mechanical stress reaction [60]. Radiography has low sensitivity because of overlapping spinal anatomy. Bone scintigraphy is useful in confirming osteoid osteomas in atypical cases [58].

Sagittal T1- and T2-weighted sequences and axial imaging are typically indicated. T2-weighted imaging with fat-saturation technique is important to show marrow and soft-tissue edema. Postcontrast imaging with fat-saturation technique is helpful in detecting the nidus [58].

Application of this practice parameter should be in accordance with the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [2] and the ACR–SIR Practice Parameter for Sedation/Analgesia [61].

VI. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for MRI of the pediatric spine 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)

VII. 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 (potential hazards might include spinal
hardware if recently implanted, especially in the case of neoplasia or significant trauma). 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 imaging parameters, including pulse sequences and field of view, and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and optimized 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 [62]).

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 [61].

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

1. General Principles (highlighting pediatric imaging challenges, including the need for sedation)

MRI should depict structures as clearly as possible. Standard protocols that are appropriate for patients of different ages who are suspected of having spinal pathology should be created and implemented. The precise details of that performance may vary among equipment (magnets, coils, and software), patient, and the personal preferences of the radiologists who manage and interpret the studies. Generally, images should cover the relevant anatomy/pathology.

The MR signal that is produced from a region of the spine (cervical, thoracic, and lumbosacral) in response to a particular pulse sequence is often, but not always, detected using surface coil receivers, commonly in a phased-array configuration.

Contrast

In addition to images with contrast based on intrinsic MR properties of the spinal and paraspinal tissues, some images may be acquired after the IV administration of a paramagnetic MR contrast agent (eg, a chelate of gadolinium). This agent is used to detect regions in which the normal vascular circulation has been
altered by injury or disease. For example, the use of IV paramagnetic contrast is recommended for evaluation of infection and neoplasm. Routine use of gadolinium should be avoided as there is a potential for accumulation of the substance within the brain. Macrocyclic agents may not accumulate within the brain as much as other agents [63]. That being said, at this time, the clinical importance of gadolinium retention in humans is unknown.

Artifacts

Imaging sequences should minimize artifacts as much as possible.

Physicians in conjunction with technologists should determine the pulse sequences to be used. Physicians who interpret spine MR examinations must understand the artifacts associated with and the limitations of the various imaging pulse sequences. They must use techniques to minimize inherent artifacts (such as pulsation artifact) when it is likely to obscure pathology. Some of the techniques that are used to move/reduce artifacts include changing phase and frequency directions (to move pulsation artifact), increase resolution (to reduce frequency misregistration), apply saturation bands, flow sensitization (for CSF or blood), alterations in patient/coil position to improve comfort, and respiratory compensation.

Saturation bands, or spatial saturation zones, can be applied outside of the spinal region of interest. They suppress signal from these regions so that motion outside the intended field of view (eg, breathing, blood flow, bowel motion) produces less conspicuous artifact in the areas of clinical interest.

Physiologic motion suppression techniques and software may help reduce artifacts from patient motion.

When dealing with imaging around metal, such as fixation devices, STIR for fat suppression, high-receiver bandwidth, fat-water separation, or multispectral methods for metal artifact suppression may be helpful to reduce artifacts. Specialized metal reduction sequences are now available, depending on the software and hardware being used.

Non sedated pediatric studies should undergo sequence prioritization as time may be limited by patient cooperativeness. Children undergoing MR evaluation of the spine sometimes require sedation or anesthesia depending on age and developmental status. Recently, the Food and Drug Administration (FDA) placed warning labels on general anesthetic and sedation drugs because of concerns over the repeated use in young children. Recent retrospective reviews have not found any sequelae from brief exposures to anesthetic agents [64,65]. However, techniques should be employed to increase the success of a non sedated study, such as involvement of child life, simulation techniques, a preparation storybook, and the ability to present audio/visual material during the study [66]. In neonates, feed and wrap or bundling techniques may be employed to reduce the need for anesthesia [67].

2. Pulse sequences

The choice of MR pulse sequences is generally standardized for particular studies but can be guided by the clinical history and physical examination. Commonly used sequences in MRI of the spine include T1; intermediate TE, proton density, or fluid-attenuated inversion recovery (FLAIR); T2-weighted sequences; T2*; and various fat suppression techniques. These techniques can be employed as 2-D or 3-D acquisitions. Vascular techniques can be used for angiography. The types of fat suppression include frequency select fat saturation, STIR, and chemical shift techniques (Dixon) [68]. Although these techniques are not all T2 weighted, they can substitute for the T2-weighted sequences noted below.

For the purpose of comparison or subtraction, images with fat suppression are sometimes acquired both before and after administration of the contrast agent.
T2* or gradient-echo images have a good signal and contrast and are sensitive to local magnetic field heterogeneity (eg, greater signal loss at interfaces between bone and CSF or between bone and soft tissue) and are less sensitive to CSF flow–induced artifacts (eg, signal voids that are due to brisk or pulsatile CSF flow). This technique can be very useful in children as they commonly demonstrate accentuated pulsatility of the CSF. This sequence is also useful in evaluating for hemorrhage within the cord, but has limited use in defining other intramedullary pathology.

Additionally, because of the accentuated CSF motion in children, axial imaging should be performed without interleaving in order to reduce CSF flow artifact. T2-weighted steady-state free precession sequences also reduce CSF pulsation artifact and may be useful in evaluating for pathology in the CSF or along the surface of the cord and cauda equina. This sequence is helpful in evaluation of congenital abnormalities and leptomeningeal metastasis [8].

DWI sequences using read-out segmentation may be of additional help in evaluating spinal pathology in children. Evaluation of intra- and extramedullary disease may be improved with improved visualization and characterization [9].

In the cervical spine, wherein the neural foramina are small, T2 volume acquisition with reformations may improve the detection and characterization of neural foraminal pathology. In both congenital and acquired conditions, CT provides additional information about bony abnormalities that may narrow the neural foramina or compromise the spinal canal.

Minimum recommended pulse sequences for evaluating the spine for pain, radiculopathy, or suspected congenital abnormality may include:

- Sagittal T1 weighted
- Sagittal T2 weighted, STIR, or T2 Dixon
- Axial T2 weighted

Coronal STIR or T2-weighted sequences are very helpful, especially in the lumbar and thoracic spines. Axial T1-weighted sequences are sometimes performed, especially in the lumbar spine, for detection of fat in the filum terminale or after IV contrast administration for neoplastic, infections, or inflammatory involvement. Volumetric interpolated GRE sequences may replace routine spin-echo T1 sequences.

When evaluating spinal bone marrow for tumor, sagittal T1-weighted sequences should be performed. Fat-suppressed T2-weighted or STIR sequences, as well T2 Dixon techniques, can make focal lesions more conspicuous. When evaluating soft-tissue neoplasms, infections, trauma, muscles, and equivocal cord signal, an axial fluid–sensitive sequence may be helpful. For neoplasms, a contrast-enhanced study may be helpful to further define extrasosseous or intramedullary extension of a neoplastic process.

The addition of coronal imaging, typically a STIR sequence, may be useful in evaluating scoliosis to elucidate associated vertebral anomalies. Sagittal STIR sequence may also be more sensitive to cord pathology as compared with routine T2-weighted images [69].

### 3. Slice thickness and coil selection

The following are recommended maximum slice thicknesses for performing the typical spine examinations:

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Slice thickness</th>
<th>Gap</th>
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<tbody>
<tr>
<td>Cervical spine - sagittal</td>
<td>3mm</td>
<td>1mm</td>
</tr>
<tr>
<td>Cervical spine - axial</td>
<td>4mm</td>
<td>1mm</td>
</tr>
<tr>
<td>Thoracic spine - sagittal</td>
<td>3mm</td>
<td>1mm</td>
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</tbody>
</table>
When attempting to diagnose particular pathologies or in smaller patients, thinner slices may be appropriate. For example, when evaluating for a pars defect, sections that are 3 mm or less in the sagittal plane may be warranted. When attempting to detect and characterize spinal cord pathology, 2-mm sections may be appropriate. Interslice gaps will depend on hardware and software. Contiguous imaging has the advantage of not missing any anatomy.

Evaluation of voxel size may be of further guidance with variation according to patient size. Voxel size ranges from 0.6 to 0.9 mm are recommended.

4. Area of coverage

The imaging protocol should be designed to cover the area of clinical interest. Because the clinical situation is a crucial determinant of treatment, the following are general recommendations and not strict criteria. In addition to covering the area of clinical interest, technologists may further evaluate areas of pathology identified on scans while they are being performed. It is recommended that a physician’s request be obtained if the scope of the additional area imaged by technologist discretion includes a complete separate body region.

For routine imaging, for example, pain, trauma, weakness, or suspected congenital abnormalities:

Cervical spine: Sagittal and axial images should include from the atlanto-occipital joints through at least the C7 to T1 intervertebral disc.

Sagittal imaging should include the entire cervical spine, including parasagittal imaging through all of the neural foramina on both sides. Coronal imaging, if performed, should include the proximal brachial plexus unless there is a specific area of clinical concern, in which case that area should be covered.

Thoracic spine: Sagittal and axial images should include the area of clinical interest. If the entire thoracic spine is to be studied, C7 to L1 should be imaged in the sagittal plane, with axial images obtained as warranted. If no area of interest is identified, axial images should span the entire thoracic spine. In patients whose spines are curved, this may necessitate several axial sequences or reformatted images at different angles. For optimal imaging of the thoracic spinal cord on axial images, the plane of imaging should be as close as possible to perpendicular to the spinal cord (this may require a few sequences in patients with significant thoracic kyphosis). Coronal images may be helpful in cases of severe scoliosis.

For thoracic imaging, visualization of the craniocervical junction or first rib is useful for accurate localization of thoracic levels and pathology. The upper cervical spine can be obtained on a separate low-resolution sagittal sequence.

Sagittal imaging should include the entire thoracic spine, including parasagittal imaging through all of the neural foramina on both sides. Coronal imaging, if performed, should include the exiting nerves in the area of concern, as well as the proximal ribs.

Lumbar spine: The entire lumbar spine should be imaged in the sagittal sequences and include the entire neural foramina and immediate paraspinal soft tissue (T12 to S1). Contiguous axial images (not just through the disc) should be obtained through all levels. If 2-D or nonisotropic voxels are used, dedicated axial images parallel to the discs can be obtained as needed. Coronal imaging can be tailored to the pathology, often to include the exiting nerves at the lower lumbar levels. Imaging should provide enough anatomic
coverage to detect transitional anatomy at the lumbosacral junction. Tailored examinations may be appropriate for follow-up of known pathology. Imaging should permit counting of spinal levels, especially in cord tethering, and, if necessary, a low-resolution survey of the entire spine for counting purposes is useful.

For tumor and infection, sagittal and axial images should include the area of clinical interest, and fat suppression on the T2-weighted imaged and postcontrast images may be helpful. If other imaging modalities or the clinical evaluation narrow the levels of suspected abnormalities, then at times it may be appropriate to limit MRI to these areas of interest. If MRI is to be used as the only diagnostic imaging modality for clinically occult disease, screening of the entire spine may be indicated. For evaluation of intramedullary neoplasms and certain demyelinating conditions, it may be reasonable to image the brain as well.

Screening (entire spine):

In the pediatric patient, imaging may commonly involve screening the entire spine as clinically indicated. Evaluation for leptomeningeal metastasis as well as congenital anomalies (scoliosis) commonly requires imaging of the entire spine in the sagittal plane. Imaging the whole spine may also be useful to determine the level of pathology, as children may present with nonlocalizing symptoms and neurologic findings, or the position of the conus. Utilization of multiple-channel spine coils permits coverage of the entire spinal column in fewer imaging sequence sets than separate cervical, thoracic, and lumbar spine imaging, saving time and reducing motion artifact [70].

D. Special techniques

1. Parallel imaging

A potential limitation of MRI in the spine is the relatively longer acquisition time in nonsedated children. Lengthy scan times could result in increased motion-related artifacts and raise the number of sedated MRI studies. Parallel imaging is a technological innovation that allows accelerated MRI data acquisition that could substantially reduce the scan duration. Parallel imaging (PI) shortens the image acquisition time by using the spatial sensitivity information from phased-array RF coils to reduce the number of phase-encoding steps. Multiple-image reconstruction algorithms are available, including space domain–based techniques (SENSE), k-space regenerative techniques (SMASH, generalized SMASH, and GRAPPA), and other hybrid techniques [71,72]. Although many parallel imaging techniques exist, these can be broadly classified into two separate groups: (a) methods that work with aliased images and (b) methods that reconstruct missing k-space data. The maximum reduction in imaging time, reflected in parallel imaging acceleration factor, is 2 to 3 in each phase-encoding direction. A potential limitation of using parallel imaging is the reduction in signal-to-noise ratio (SNR), which can be compensated by the increased SNR at higher fields, improved surface coils, and advanced acquisition techniques. Parallel imaging is applicable to all pulse sequences and complementary to other existing acceleration methods. In spine imaging, pulse sequences with high contrast and spatial resolution can be combined with PI and allow evaluation of disc pathology, cord and nerve root impingement, and neural foraminal patency [73-75].

In the cervical spine, parallel imaging has been shown to reduce scan time by up to 50% of normal while preserving adequate image quality [76].
2. Cine imaging for CSF flow

CSF flow can be imaged with phase-contrast cine MRI evaluation. Cardiac gating with either electrocardiogram (ECG) or peripheral leads can be used to reduce cardiac-dependent flow artifacts. These approaches also permit quantitative velocity and qualitative vector measurements of CSF flow.

Typical parameters are as follows: Cardiac gating; flip angle 20°; repetition time and echo time (TR/TE), 20/5 ms; slice thickness, 5 mm; field of view, 180 mm; matrix, 256 × 256; and encoding velocity (venc) of either 5 cm/s or 10 cm/s.

Spinal CSF flow imaging is performed in the axial and/or sagittal planes. Sagittal acquisition allows evaluation of flow ventral to the cervicomedullary junction and dorsal to the cerebellar tonsils. Axial imaging can be performed to look for flow circumferential to the cervicomedullary junction, including evaluation of ventrolateral hyperdynamic flow, which is not evident on midsagittal imaging.

This is most commonly performed at the level of the foramen magnum in cases of known or suspected Chiari type I malformation or idiopathic syringohydromyelia. It is important to note that in the first 6 to 12 months of life, there are reduced CSF pulsation velocities that are due to the compliance of unfused cranial sutures.

3. Dynamic imaging

Dynamic MRI of the spine attempts to reproduce the relative position of various spinal elements during physiological loading or by imaging the spine in various anatomic positions. The conventional and most common form of dynamic imaging of the spine that may be employed in children consists of the flexion and extension images. Dynamic imaging studies are often performed in children with congenital/developmental disorders predisposing to structural instabilities of the spine, most commonly employed in patients with Down syndrome. The cervical spine is the most common location for these abnormalities. Dynamic MRI could offer a more robust imaging of the cervical spine in children with neurological symptoms or those with concern for hypermobility or instability on dynamic plain films. When performed, dynamic MRI of the spine should be performed under clinical guidance. Current imaging data do not support the routine use of dynamic MRI as a screening tool. Dynamic multiview radiography continues to be the initial imaging modality of choice. When interpreting dynamic studies, it is important to recognize the known alterations in spinal canal diameter and neural foraminal size between extremes of flexion and extension.

Capabilities to study the spine under physiologic load are limited on most conventional scanners. Although flexion/extension radiography is performed in an upright position to simulate physiologic loading, conventional MRI is performed recumbent. This deficiency has led to several technical developments in adults that more closely replicate physiologic loading by incorporating gravity and thus direct axial loading to the spinal axis. This includes upright MRI and compression devices that can provide an equivalent axial load to the spinal axis even while imaging in the supine position.

Upright MRI units in particular are designed to image the spine in a variety of normal physiologic conditions: supine, upright, sitting, flexion, extension, or a combination of postures. Moreover, these devices are designed to demonstrate anatomic changes between modes of positioning. Currently available literature does not support the use of upright MRI systems in children.

4. Diffusion and DTI

Spine DWI has been shown to be a useful tool in the evaluation of the spine and spinal cord in children. Although diffusion imaging comprises a standard sequence in the evaluation of brain pathology, technical
challenges have limited its application in the spine. Technical limitations in spine DWI are caused by artifacts from CSF pulsation and susceptibility artifacts that cause image distortion [77]. New techniques, such as reduced field of view (FOV) and readout-segmented echo-planar imaging (EPI) have considerably improved the diagnostic quality of spine DWI [78-81].

Spine DWI can detect and characterize disease that may not be apparent on conventional T1- and T2-weighted imaging. Marrow-replacing diseases encountered in childhood, such as metastatic neuroblastoma or leukemia, can demonstrate diffuse marrow restriction [82]. The increased amount of red marrow in children’s spines as compared with adults can make it difficult to appreciate the presence of disease without DWI. Drop metastases from primary pediatric brain tumors is a frequent mode of neoplastic spread of disease in children and can be detected effectively with DWI. High cellularity malignant pediatric brain tumors may not enhance avidly, and therefore spread of disease on T1 postcontrast imaging can be difficult to detect. Spine DWI has been shown to have the ability to detect hypercellular metastases that are not apparent on postcontrast imaging alone [9].

Spine DWI can also be helpful in characterizing fluid collections that can occur in and around the spine. A diffusion-restricting fluid collection in the clinical setting of infection is characteristic of an abscess. An isolated fluid collection occurring outside of the setting of infection with diffusion restriction is a classic imaging characteristic of a dermoid cyst. Differentiating degenerative changes from infection can be aided by identifying the characteristic “claw sign” that can occur by the diffusion-restricting reparative response that occurs with degenerative changes [18].

DWI is also helpful in the evaluation of spinal cord pathology. An acute spinal cord infarct can demonstrate acute diffusion restriction very early on during symptom onset [83]. DWI can identify areas of active demyelination within the cord [84]. It can also reveal the heterogeneous pathology of cord tumors and bring attention to areas of cellular proliferation that may indicate malignant degeneration. DTI tractography can highlight axonal disruption as seen as loss of fractional anisotropy from areas of white matter tract displacement. DTI can be helpful in differentiating benign from infiltrative high-grade tumors and in differentiating tumor from demyelination [85].

5. Perfusion imaging

In humans, MR perfusion studies of spinal cord lesions are limited to very few related articles, often in the cervical region. Perfusion weighted imaging (PWI) parameters are considered direct measures of tissue angiogenesis, vascular density, and capillary permeability in spinal cord tumors, thus providing information about microcirculation in these tumors. The most frequently used perfusion MRI techniques are the (1) dynamic susceptibility contrast (DSC, otherwise called T2* imaging), (2) dynamic contrast-enhanced MRI (DCE-MRI), and (3) arterial spin labeling (ASL). All techniques could offer noninvasive details of microvascular structures and hemodynamics, not immediately obtained from traditional MRI techniques. ASL perfusion study is performed without the use of intravenous IV contrast agent. DSC MR perfusion, which is sensitive to transient changes in magnetic susceptibility caused by a contrast bolus, readily offers quantitative measurement, which tracks T1 changes caused by IV contrast, assessing regional perfusion, including regional blood volume, blood flow, and mean transit time. DCE-MRI could provide details above the intravascular volume (Vp) as well as the rate of contrast leakage from the intravascular to interstitial space (K trans). DCE-MRI perfusion parameters have shown limited utility in differentiating local tumor recurrence in adult subjects with spinal metastasis undergoing high-dose radiation therapy [86]. Although perfusion MRI is routinely performed for certain intracranial pathologies, including stroke and tumor imaging, use of perfusion MRI is extremely rare in pediatric patients. Currently, substantial literature is not available to support perfusion MRI techniques in pediatric spinal pathologies.
6. Functional MRI

Functional MRI (fMRI) of the spine is a noninvasive MRI tool that can be applied to the pediatric spinal cord to study neuronal activity and spinal cord function during sensory and/or motor task paradigms [87]. Spinal fMRI is currently an investigative tool utilized in the research setting and is not yet optimized for clinical care in children. Potential future clinical applications for spine fMRI in the pediatric population may be in the investigation of spinal cord injury, MS, neuropathic pain, transverse myelitis, hydrosyringomyelia, and tethered cord, among others [88-90].

E. Other Techniques

1. T1-FLAIR versus T1 fast spin-echo (FSE) and T1 spin-echo imaging of the spine [91-94][72-75]

Though traditionally, T1 imaging of the spine has been performed with spin-echo technique, T1 FSE can provide anatomic detail at a relatively short acquisition time compared with conventional spin-echo imaging. Even though T1 FSE often suffers from poor image contrast, it can still generate diagnostic image quality while minimizing patient motion.

T1-FLAIR imaging is another effective way to obtain T1 contrast at a reasonable image acquisition time, minimizing patient motion. When implemented in an optimized fashion, it can achieve good nulling of the CSF signal, with effective T1 weighting and optimized contrast between the bone marrow, CSF, and spinal cord. Moreover, it can also potentially reduce artifact related to surgical hardware. However, care must be taken at effective implementation to ensure bone marrow contrast and lesion conspicuity. T1-FLAIR becomes even more advantageous at higher field strengths (especially 3T or greater).

2. Chemical shift imaging [95-99][76-80]

Chemical shift imaging, also known as opposed-phase or in-and-out-of-phase imaging, is a sequence that takes advantage of small differences in precession frequencies of lipid and water protons to determine the presence of intracellular lipid and water within the same imaging voxel. It can therefore aid in distinguishing between marrow-replacing processes and marrow-preserving processes. Specifically, the technique has shown promise in the ability to distinguish pathologic from benign compression fractures, and there are data that support the ability of opposed-phase imaging to differentiate benign vertebral lesions (hemangiomas, degenerative endplate changes, etc) from malignancy. The T1-weighted GRE sequences can be rapidly acquired, with a total scanning time of 5 minutes or less. Chemical shift imaging can also be used as a technique for fat suppression, and with newer techniques, may be acquired potentially at no additional imaging time.

VIII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [100].

IX. 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 magnetic field strength (dB/dt), maximum RF 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 Imaging (MRI) Equipment [101].

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Specific policies and procedures related to safety should be in place along with documentation that these policies and procedures are updated annually and that they are formulated under the supervision and direction of the supervising MRI physician. Guidelines that deal with potential hazards associated with MRI examinations should be provided to the patients 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 revised according to the process described under the heading The Process for Developing ACR Practice Guidelines 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 and the Committee on Practice Parameters – Neuroradiology of the ACR Commission on Neuroradiology, in collaboration with the ASNR and the SPR.

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

ACR
Sumit Pruthi, MBBS, Chair
Timothy N. Booth, MD
Asim F. Choudhri, MD
Susan Palasis, MD
Unni Udayasanakar, MD

ASNR
David Joyner, MD
Neel Madan, MD
Alexander McKinney, MD

SPR
Mariaem M. Andres, MD
Nancy Rollins, MD
Victoria Michelle Silvera, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACR
Committee on Practice Parameters – Neuroradiology
(ACR Committee responsible for sponsoring the draft through the process)

Steven W. Hetts, MD, Chair
Robert J. McDonald, MD
Kristine A. Blackham, MD
Alexander M. McKinney, IV, MD
Brian A. Conley, MD
David M. Mirsky, MD
Kavita K. Erickson, MD
Robin J. Mitnick, MD, FACR
Adam E. Flanders, MD
Lubdha M. Shah, MD
H. Simms Hardin, IV, MD
Raymond K. Tu, MD, FACR, Chair
John E. Jordan, MD, MPP, FACR
Max Wintermark, MD
Jacqueline C. Junn, MD


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*Practice 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 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. 6

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–ASER–SCBT-MR–SPR Practice Parameter for the Performance of Pediatric Computed Tomography (CT)

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 3)*

ACR–ASER–SCBT-MR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF PEDIATRIC COMPUTED TOMOGRAPHY (CT)

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, ___ N.W.2d ___ (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 Society of Emergency Radiology (ASER), the Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR), and the Society for Pediatric Radiology (SPR).

Computed tomography (CT) is a radiologic modality that provides clinical information in the detection, differentiation, and demarcation of disease. It is the primary diagnostic modality for a variety of presenting problems and is widely accepted as a supplement to other imaging techniques. In selected cases, CT is used for guidance of interventional procedures.

CT is a form of medical imaging that involves the exposure of patients to ionizing radiation. It should only be performed under the supervision of a physician with the necessary training in radiation protection to optimize examination safety. Medical physicists and trained technical staff must be available to evaluate the equipment and perform the examination.

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

Because children are more sensitive than adults to the effects of ionizing radiation, it is particularly important to tailor CT examinations to minimize exposure while providing diagnostic-quality examinations [1]. Protocols should include CT scan parameters, contrast administration, and anatomical coverage. CT scan parameters (e.g., rotation time, pitch, peak kilovoltage (kVp), milliampere-seconds (mAs), tube current modulation, beam collimation) should be tailored to the child’s body size. If contrast is used, the type of contrast, volume, method of administration (intravenous [IV], oral, rectal, intravesical), scan delay time, and rate of contrast injection should be specified [2-6].

Nonionizing imaging studies, such as ultrasound (US) and magnetic resonance imaging (MRI) should be considered in some cases as an alternative to CT when appropriate. Reasons to consider using CT over MRI include the availability of CT, higher spatial resolution, shorter examination, less need for sedation, and the presence of contraindications for MRI.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [7].
III. INDICATIONS

A. Chest

CT is the preferred cross-sectional imaging modality for detailed evaluation of anatomy and pathology of the lung and tracheobronchial tree. In addition to US and MRI, CT may also be used for evaluation of certain thoracic bony, mediastinal, and cardiac abnormalities.

Primary indications for CT include, but are not limited to, the following:

1. Chest wall abnormalities [8-15]
   a. Extent of chest wall developmental deformities, such as pectus excavatum, pectus carinatum, and thoracic insufficiency syndrome secondary to scoliosis or rib anomalies. CT scan for some chest wall deformities (eg, pectus excavatum) may be limited to the area of deformity using very low dose technique, although MRI is increasingly being used in these instances [16].
   b. Chest wall injury, including penetrating trauma and injuries that are not adequately addressed by radiography, such as sternal fractures, sternoclavicular dislocation, and occult rib fractures.
   c. Chest wall mass and mass-like conditions that include inflammatory/infectious processes. This also includes evaluation of posttreatment complications and residual or recurrent mass.

2. Extracardiac vascular disorder [17-23]
   a. Congenital and syndromic vascular abnormalities, such as vascular rings, pulmonary slings, pulmonary vein abnormalities (eg, anomalous course), systemic-to-pulmonary collateral vessels, coarctation of the aorta, or other congenital lesions with anomalous blood supply (eg, bronchopulmonary sequestration)
   b. Acquired disorders of the great vessels (eg, medium- or large-vessel vasculitides, aneurysms, stenoses, infectious or other inflammatory conditions) and posttraumatic evaluation. Assessment includes aortic dissection, transection, and pulmonary embolism.

3. Cardiac disease. See the ACR–NASCI–SPR Practice Parameter for the Performance and Interpretation of Cardiac Computed Tomography (CT) [7].

4. Tracheobronchial abnormalities, including tracheal rings; tracheobronchial narrowing secondary to vascular anomaly, mass, inflammatory/infectious process, suspected foreign body, or congenital anomaly; and postoperative complications of lung transplant [23-28]; and dynamic evaluation of the airway for the assessment of congenital or acquired tracheobronchomalacia [29].

5. Mediastinal congenital abnormalities and masses [30-32].
   a. Neoplasms—These include, but are not restricted to, germ cell tumors, lymphoma, or thymic tumors. Posterior mediastinal neurogenic tumors can also be imaged by CT, particularly with multidetector technology and reformats, but although MRI is often more useful to depict chest wall, or vertebral, neural foraminal, or intraspinal involvement.
   b. Congenital abnormalities, such as ectopic thymic tissue and bronchopulmonary foregut malformations that affect the mediastinum. The latter include bronchogenic cyst, esophageal duplication cyst, and neuroenteric cyst. Congenital abnormalities in a paraspin location may be better evaluated with MRI to assess for potential chest wall, or vertebral, neural foraminal, or intraspinal disease.
   c. Infectious or inflammatory processes affecting the mediastinum, such as lymphadenitis, mediastinitis, abscess, or sternal osteomyelitis.
   d. Trauma that is not adequately assessed by radiography. CT angiography can be considered for evaluation of suspected major thoracic vascular injury.

6. Lung—CT is the primary cross-sectional imaging modality to evaluate the lung parenchyma [33-51].
   a. Infection/pneumonia complicated by involvement of the pleural space (such as parapneumonic effusion, empyema, or bronchopleural fistula), the lung (such as cavitation/necrosis or abscess), or the
pericardium (such as purulent pericarditis). For evaluation of parapneumonic effusion and empyema, US should be considered as the first and primary imaging modality, with CT reserved for evaluation of aerated portions of the lung and more complicated cases with parenchymal complications. In patients with persistent or recurrent pneumonias or whose plain radiography film is atypical for pneumonia, CT is used to assess for possible underlying congenital lesion or mass. CT is also used to assess the sequelaes of respiratory infections (such as bronchiectasis and bronchiolitis obliterans). In immunocompromised patients, CT can be used in the absence of definite plain film radiography abnormality to detect early manifestations of opportunistic infections.

b. Diffuse/interstitial lung disease, either primary or related to systemic processes, such as collagen vascular, connective tissue, or autoimmune diseases. These studies may include inspiratory and expiratory scans. Additional limited imaging in a prone or decubitus position may help differentiate between dependent atelectasis and lung parenchymal abnormality. Some patients with cystic fibrosis may be followed with limited reduced-dose high-resolution CT.

c. Congenital pulmonary abnormalities that include bronchopulmonary foregut malformation, congenital pulmonary airway malformations (CPAM), congenital lung hyperinflation, pulmonary sequestration, bronchial atresia, tracheal diverticula, tracheal bronchus, pulmonary agenesis or hypoplasia, and related conditions, such as horseshoe lung and pulmonary arteriovenous malformation.

d. Malignancy, including patients with underlying extrapulmonary primary malignancy that may metastasize to lung and primary lung neoplasms, including inflammatory myofibroblastic tumor (plasma cell granuloma), pleuropulmonary blastoma, bronchial carcinoid, and mucoepidermoid carcinoma. In immunocompromised patients, CT is used in the evaluation for lymphoproliferative disease or smooth-muscle (spindle cell) tumors.

e. Traumatic injuries not adequately assessed by radiography, such as pulmonary contusions and lacerations.

B. Abdomen and Pelvis

CT of the abdomen and pelvis is the preferred cross-sectional imaging for evaluation of abdominal and pelvic trauma. MRI may be used as an alternative method for many abdominopelvic indications. CT can be used as an alternative study to MRI in evaluation of solid viscus and bowel. CT is often used as an adjunct or follow-up to US when findings are equivocal or when there is a need for additional anatomic detail or other information (eg, nephrolithiasis, solid viscus, bowel, and vascular pathology).

1. Hollow viscera [52-67]
   a. Inflammatory or infectious processes affecting the gastrointestinal (GI) tract, including the gastroesophageal junction, stomach, small intestine, colon, or appendix. These processes include, but are not limited to, appendicitis, infectious enteritis, inflammatory bowel disease, neutropenic colitis, or radiation enteritis, although MRI may also be used in some of these instances [68].
   b. Congenital abnormalities, including gastrointestinal duplication cysts, and complications of omphalomesenteric duct remnants, such as Meckel diverticulitis.
   c. Benign and malignant neoplasms, including, but not limited to, lymphoma (particularly Burkitt lymphoma), gastrointestinal stromal tumor (GIST), lipoma, and large polyps.
   d. Trauma, blunt or penetrating abdominal trauma, to demonstrate bowel injury including intramural hematoma and perforation.
   e. Bowel obstruction.

2. Liver and gallbladder [69-76]
   a. Primary or secondary hepatic neoplasms, including, but not limited to, hemangioma, hepatoblastoma and hepatocellular carcinoma, as well as liver metastases to evaluate for the presence and extent of tumor in the liver
   b. Blunt or penetrating trauma, including nonaccidental trauma, to assess the extent of parenchymal and hepatic vascular injury.
   c. Hepatic infection, including pyogenic or amebic liver abscesses.
d. Congenital abnormalities of the liver and biliary tree, including heterotaxy and associated anomalies.

e. Gallbladder and biliary tract disorders are typically best evaluated with US, MRI, and nuclear medicine studies. CT may be used in selected cases to supplement US in the evaluation of gallbladder and biliary tract disorders.

3. Pancreas [77-82]
   a. Complications of pancreatitis, including pancreatic hemorrhage or necrosis, peripancreatic vascular thrombosis, pseudocyst formation, secondary inflammation of hollow visceral structures, or duct abnormalities, including stones or dilation.
   b. Pancreatic tumors to further characterize the extent of lesion, staging, and involvement of adjacent structures.
   c. Blunt or penetrating abdominal trauma to evaluate the integrity of the gland, the extent of pancreatic injury, including fracture or pancreatic ductal injury, and injury to adjacent solid or hollow visceral structures.

4. Kidneys [83-92]
   a. Urinary tract stones in children with hematuria. CT may be used when US and radiographs do not provide enough information for optimal management.
   b. Renal or ureteral trauma. Additional delayed imaging may be useful if injury to the collecting system is suspected. Split-dose IV contrast in suspected renal trauma can demonstrate both parenchymal and collecting system injury with one imaging acquisition.
   c. Detection and staging of renal tumors (benign and malignant), including vascular invasion.
   d. Congenital anomalies of the genitourinary tract.
   e. Obstruction of the urinary tract secondary, but not limited to, nephrolithiasis, mass, infection/inflammation, or trauma.
   f. Complications of infection of the urinary tract (eg, acute pyelonephritis), including renal/perirenal abscess.
   g. Renovascular evaluation in the setting of traumatic injury, renal donor transplant evaluation, or regional masses. CT angiography can also be used in selected patients to evaluate for renovascular hypertension.

5. Adrenal gland [93-97]
   a. Evaluation of blunt or penetrating trauma with suspected adrenal hemorrhage.
   b. Adrenal neoplasms, such as neuroblastoma, ganglioneuroma, ganglioneuroblastoma, and adrenocortical neoplasms (adenoma and carcinoma), and pheochromocytoma.

6. Spleen [98-104]
   a. Splenic injury in the setting of blunt or penetrating trauma.
   b. Primary cystic or solid lesions of the spleen.
   c. Other conditions, such as infarction, sequestration (sickle cell disease), granulomatous disease, wandering spleen/torsion.

7. Pelvis [105-107]
   a. Mass or mass-like conditions of the pelvic organs, including inflammatory/infectious processes, vascular malformations, and evaluation of lymph nodes.
   b. Anomalies of the genital tract not adequately assessed by US or genitogram, or where MRI is contraindicated or not available.
   c. Bladder rupture after trauma or bladder surgery. Dedicated CT cystography techniques can be performed as indicated.

   a. Inflammatory or infectious processes affecting the mesentery, peritoneum, or omentum, such as an abscess and generalized peritonitis.
   b. Peritoneal fluid characterization and quantification, when appropriate.
c. Pneumoperitoneum.
d. Cystic malformations, including mesenteric/omental cyst and lymphatic malformation.
e. Benign or malignant neoplastic processes, including teratoma, sarcoma, and spread of disease to the peritoneum and/or retroperitoneum.
f. Omental infarction.
g. Posttraumatic abnormalities of the mesentery, abdominal wall, or diaphragm.
h. Congenital abnormalities of the abdominal wall or diaphragm.
i. Arterial and venous abnormalities, such as vasculitis, thrombosis, narrowing, aneurysm, dissection, and varices.

C. Extremities/Musculoskeletal

CT may supplement plain radiography for characterization and evaluation of extent of bone lesions and fractures, evaluation of orthopedic implant complications, and assessment of alignment deformities. CT is better than MRI in assessment of cortical and trabecular bone abnormalities. CT has lower contrast resolution and less sensitivity compared with MRI in evaluation of bone marrow and soft-tissues pathology, but CT can be used in selected cases where MRI is contraindicated or not readily available.

1. General indications [113-138]
   a. Bone abnormality not adequately assessed by radiographs
   b. Congenital bone malformations
   c. Inflammatory conditions, such as osteomyelitis and myositis, when MRI is contraindicated or unavailable
   d. Fractures and follow-up of fracture complications (such as premature growth plate fusion and intra-articular loose bodies)
   e. Tumors of the bone or soft tissues
   f. Osteochondral lesions, when MRI is contraindicated or unavailable
   g. Foreign bodies

2. Shoulder [123-125]
   Evaluation of glenoid morphology, glenoid dysplasia, and acquired glenohumeral deformity related to perinatal brachial plexus injury, although MRI is being increasingly used in these instances.

3. Pelvis, hip, and thigh [126-131]
   a. Congenital malformations not adequately assessed by radiographs or sonography, including postoperative assessment of reduction of developmental dysplasia of the hip
   b. Measurement of femoral and acetabular version
   c. Deformity related to epiphyseal osteonecrosis (including Legg-Calve-Perthes)
   d. Femoral head impingement syndrome
   e. Sacroiliitis
   f. Apophysitis

4. Knee and leg [132-134]
   a. Kinematic assessment of patellofemoral joint
   b. Preoperative tibial tuberosity trochlear groove assessment in patients with patellar tracking abnormalities
   c. Tibial torsion

D. Foot and ankle [135-138]

1. Fractures in the foot or ankle not optimally assessed by radiographs, including, but not limited to, Tillaux and triplane fractures of the ankle or other fractures involving the tibial plafond
2. Tarsal coalition, diagnosis, and follow-up after surgery
E. Head and spine

See the ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Brain [139] and the ACR–ASNR–ASSR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Spine [140].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for pediatric CT 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)

Images should be labeled with the following: (a) patient identification, (b) facility identification, (c) examination date, and (d) the side (right or left) of the anatomic site imaged.

Additionally, an attempt should be made to obtain and review prior studies.

A. General Considerations [2-6]

Pediatric CT may require different examination preparation and performance than in adults. Preparation includes ensuring appropriate NPO status if moderate sedation or general anesthesia is potentially necessary.

With the advent of faster CT scanner technology, general anesthesia or sedation can be avoided in many children. Patient/parent preparation, well-trained technologists, child life specialists, and distraction techniques/equipment are helpful in this regard. Additionally, reduced use of IV contrast when appropriate (eg, follow-up of lung metastatic disease) may allow for easier performance and greater acceptance of nonsedated CT scans.

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 [141] and the ACR Manual on Contrast Media [142].)

For scan performance, single-phase scanning is the standard rather than the exception. Only the necessary scan coverage should be obtained, and scan parameters—including beam collimation, tube current, gantry cycle time, pitch, and kVp—should be adjusted for the size of the child, the region scanned, and the clinical indications.

The physician responsible for the examination must supervise patient selection and preparation and be available for consultation. All personnel who inject intravascular contrast media (ICM) should be prepared to (1) recognize the variety of adverse events that may occur following ICM administration and (2) institute appropriate measures to manage the reaction. These measures include notifying the supervising radiologist (or his/her designee), monitoring
the patient, administering certain medications, and/or calling for additional assistance (emergency service providers, “code team,” etc). (See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [141] and the ACR Manual on Contrast Media [142].)

Appropriate emergency equipment and medications must be immediately available for consultation or to treat adverse reactions associated with administered medications. See Table 6 of the ACR Manual on Contrast Media [142].

B. Examination Technique [2-6,143-163]

General Observations:

Scanning parameters should be optimized to obtain diagnostic image quality while adhering to the as low as reasonably achievable (ALARA) principle. The scan area should be restricted according to the clinical indication, with areas not involved in the clinical problem excluded from the scan. The scanning parameters, including kVp and exposure time product (mAs), should be changed according to body size, regions of interest, and clinical indication. This can be achieved by using weight-based or cross-sectional size tables and by using automatic exposure control (see www.imagegently.org). In addition, mAs should be further reduced if noncontrast scans are performed only to evaluate calcifications or for cases in which only gross bony relationships are being evaluated, such as scans done for preoperative pectus excavatum evaluation. Noise-reducing reconstruction technique (eg, iterative reconstruction), if available, can be used to improve image quality and allow use of decrease dose [143].

1. Chest [2-6,152-159]
   a. Use of cutting-edge technologies for reducing exposure, such as dose modulation and iterative reconstruction, are preferred, if available [164,165]. The use of bismuth shields is controversial. Shielding can reduce dose to anterior organs, such as breast, lens of the eye, and thyroid in CT scanning. There are disadvantages associated with the use of bismuth shields. Bismuth shields may induce image artifacts and increased image noise, which limits measurements of attenuation. If used, the shield needs to be elevated from the anterior chest wall (eg, by laying it on several towels or a sponge), and it should be flat without internal bends to decrease artifacts. In order to avoid increased radiation dose to the patient, the shielding should NOT be in place during scout image acquisition when using automatic exposure control or tube current modulation because the radiation dose to the patient may increase. Other techniques, including automated tube current modulation or kilovoltage selection, can provide the same level of anterior dose reduction at equivalent or superior image quality.
   b. The examination may be conducted with or without IV contrast as clinically indicated. A contrast dosage of 1.5 to 2 mL/kg (to a maximum not exceeding the usual adult dose) is used routinely. Volume of contrast, rate of injection, scan delay time, and hand/power injection should be determined according to the location, size, and type of the IV access, the child’s body size, the underlying disease (such as congestive heart failure), and the clinical indication. The use of dual-energy CT and low-kilovoltage imaging may allow further reduction in the volume of contrast needed, particularly for angiographic applications [166,167].
   c. High-resolution algorithms for reconstruction of CT data may be useful if the primary indication is for the evaluation of interstitial lung disease, as sharper algorithms are helpful in the evaluation of lung parenchyma in older children. The original dataset can be reconstructed with both routine and high-resolution algorithms if both soft-tissue and pulmonary parenchymal information is needed, without need to rescan the patient. It is important to remember that not all diagnostic chest CT studies in infants and children require imaging of the entire anatomy of the chest. In certain clinical situations, if only a sampling of the lung parenchyma is required to answer a specific clinical question (eg, to rule out bronchiectasis or diffuse/interstitial lung disease), a limited number (eg, 4-6 slices) of 1 to 1.25 mm noncontiguous axial slices can be obtained and reconstructed in a high-resolution algorithm. The gap between the noncontiguous axial images may be increased incrementally as patient size increases. Expiratory images at larger intervals can be useful for evaluation of diseases of the small bronchi.
d. Postprocessing 2-D reformations, maximum intensity projection (MIP) reconstructions, and 3-D volume rendering may be useful adjuncts in displaying the anatomy. The 2-D reformation and sliding thin-slab MIP techniques have been found to increase sensitivity in the detection of lung nodules and arteriovenous malformations, and 3-D volume rendered images may also add value to presurgical planning and patient/family education, tumor and/or lung volume measurements, as well as be used for 3-D printing of illustrative models.

2. Abdomen [2-6,160-163]
   a. Scanning parameters should be optimized to obtain diagnostic image quality while adhering to the ALARA principle. The scan area should be minimized according to the clinical indication. The scanning parameters, including kVp, tube current, and exposure time (mAs), should be changed according to body size, area of interest, and clinical indication. This can be achieved by using weight or dimension-based tables or by using automatic exposure control (see www.imagegently.org). The testicles should not be included in the scanned area unless absolutely necessary for the clinical indication. If precontrast images are needed solely to determine whether calcification is present, these can be done with additional decrease in mAs. If dual-energy CT is used, noncontrast scans can be reconstructed after the scan, avoiding the use on precontrast scans.
   b. IV contrast injection is usually used in the CT evaluation of the pediatric abdomen because of the paucity of body fat in many pediatric patients. There are some exceptions, including renal stone evaluation. A routine dose of 1.5 to 2 mL/kg is generally used. Volume of contrast, rate of injection, scan delay time, and hand/power injection should be determined according to the location, size, and type of the IV access, the child’s body size, the underlying disease, and the clinical indication.
   c. Enteric contrast may be used in the CT evaluation of the pediatric abdomen. Choices of administration route (eg, oral, rectal, or enteric tube) and type of contrast (eg, positive or neutral attenuation) will depend on factors such as the clinical questions to be answered and patient age. Enteric contrast is not typically used in renal stone protocol, CT angiography, or acute trauma.
   d. In the evaluation of the pediatric patient for suspected appendicitis, IV contrast is typically used, particularly to avoid potential repeat scans that are due to equivocal findings. Precontrast scans and delayed scans are usually not necessary. Some centers use oral or rectal enteric contrast material. If oral contrast is given, sufficient time should be allowed to elapse for the contrast to reach the right lower quadrant prior to scanning. Rectal contrast is rarely used.
   e. Postprocessing 2-D reformations, MIP reconstructions, and 3-D volume rendering may be useful adjuncts in displaying the anatomy, especially in evaluation of vascular anatomy. The 3-D volume rendered images may be used for presurgical planning and patient/family education, tumor volume tracking measurements, as well as 3-D printing of illustrative models.

3. Extremities
   a. IV contrast is usually not necessary if only evaluation of the bone structure is needed. IV contrast may be necessary for assessment of blood vessels and soft tissues when indicated.
   b. Sharper reconstruction algorithms are needed for better spatial resolution and bone detail. Smoother algorithms are better for soft-tissue evaluation and 3-D postprocessing.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [168].

VI. EQUIPMENT SPECIFICATIONS

In the interest of pediatric patient safety, it is necessary to have a general knowledge of the CT equipment, including the use of weight- or dimension-adjusted mA and kVp, beam collimation, slice thickness, pitch, rotation time, matrix, image filter, noise-reducing reconstruction technique (eg, iterative reconstruction), display field of view

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(DFOV), and tube current modulation techniques (longitudinal and angular). In some CT scanners, the tube current can be automatically adjusted by a predetermined selection of the quality (eg, noise level or reference mAs) of the study. Other dose-reduction techniques include automatic exposure control or organ-based angular modulation that reduces mA to anterior organs, such as the breasts. Optimal kVp can be achieved by manual charts according to patient size and type of study (eg, routine or CT angiography) or with automated selection technology. The equipment should be in good working order, meet manufacturer and regulatory standards, and be operated safely. The equipment needs to be tested for spatial and low-contrast resolution and be well-calibrated at all times [178]. Technologists and radiologists should be aware of important artifacts and know how to avoid problems associated with them. [2-6,144-147,149-151,156,162]

A. Performance Standards

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

1. Gantry rotation time: ≤1 second
2. Detector width: ≤1 mm
3. Tube voltage: ranging from 70 to 120 kVp
4. Limiting spatial resolution: 8 lp/cm for ≥32 cm DFOV and ≥10 lp/cm for <24 cm DFOV

With the advent of dual-energy CT and spectral CT [169-172], which can be performed with doses comparable to single-energy CT [173], more centers are making use of this technology in the diagnosis of pediatric disease [174,175], as the process of material decomposition allows for:

1. Virtual noncontrast scans that can avoid dual-phase imaging and can show calcifications in kidneys, tumors, pancreatitis, and mural plaques in the presence of contrast. Virtual noncontrast images permit automated bone subtraction, improving visualization of vessels.
2. Low monoenergetic images, which improve CT angiography by boosting iodine signal-to-noise ratio (SNR), can salvage mistimed or poor bolus studies, and allow use of less iodine contrast in CT examinations.
3. Low monoenergetic images improve contrast-to-noise ratio (CNR) in soft tissues and thus lesion detection.
4. Low monoenergetic images to improve head CT gray-white matter differentiation and help in detection of low-contrast lesions and cerebral ischemia/stroke.
5. The use of virtual monoenergetic images allows to suppress artifact in the posterior fossa [176] and in the presence of metallic implants and surgical hardware.
6. Perfusion imaging iodine maps improve detection of pulmonary embolism, flow following repair of congenital heart disease, arteriovenous malformations, myocardial ischemia, and solid organ perfusion defects, such as pyelonephritis, and likewise demonstrate regions of hyperenhancement.
7. Iodine overlays are helpful to characterize indeterminate lesions and assess tumor vascularity.
8. Renal mass/cyst characterization. This technology can evaluate lesions “too small to characterize,” discriminate hyperdense or protein-laden cysts from solid lesions, identify renal calculi within contrast material, and gauge tumor vascularity/viability and treatment response.
9. Renal stone characterization

B. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. See Table 6 of the ACR Manual on Contrast Media [142]. The equipment, medications, and other emergency support must be appropriate for the range of age and size in the patient populations.
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).


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).

A Qualified Medical Physicist and radiologist together should verify that any dose reduction devices or utilities maintain acceptable image quality while actually reducing radiation dose.

Dose estimates for typical examinations should be compared against reference levels described in the ACR–AAPM–SPR Practice Parameter for Diagnostic Reference Levels and Achievable Doses in Medical X-Ray Imaging [177].

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).
Equipment monitoring and the continuous quality control program should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [178].

ACKNOWLEDGEMENTS

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Collaborative Committee

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

ACR
Monica Epelman, MD, Chair
Dorothy Leigh Gilbertson-Dahdal, MD
Kerri Highmore, MD

ASER
Michael Aquino, MD
Susan John, MD
George Koberlein, MD

SCBT-MR
Marilyn J Siegel, MD, FACP

SPR
Tushar Chandra, MBBS
Richard Southard, MD
Sjirk Westra, MD

Committee on Practice Parameters – Pediatric Radiology

(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACP, Chair
Timothy J. Carmody, MD, FACP
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACP
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACP

Richard A. Barth, MD, FACP, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACP, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACP, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACP, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Daniel Ortiz, MD, Chair
Greg Nicola, MD, FACP, Co-Chair
Michael Aquino, MD
Richard A. Barth, MD, FACP
Jacqueline A. Bello, MD, FACP
Priscilla Butler, MS, FACP
Tushar Chandra, MBBS
Joo Cho, MD

Kerri Highmore, MD
Susan John, MD
George Koberlein, MD
Mary S. Newell, MD, FACP
Beverley Newman, MB, BCh, BSc, FACP
Matthew S. Pollack, MD, FACP
Marilyn J Siegel, MD, FACP
Richard Southard, MD
REFERENCES


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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

2008 (Resolution 22)
Amended 2009 (Resolution 11)
Revised 2014 (Resolution 3)
RESOLUTION NO. 7

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SPR–SSR Practice Parameter for the Performance of Radiography for Scoliosis in Children

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 15)*

ACR–SPR–SSR PRACTICE PARAMETER FOR THE PERFORMANCE OF RADIOGRAPHY FOR SCOLIOSIS IN CHILDREN

PREAMBLE

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

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication 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, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Scoliosis is defined as a lateral curvature of the spine of 10° or more, usually with a rotary component [1-4]. It can be classified according to its etiology: congenital, idiopathic, traumatic, degenerative, or as part of a generalized disease or syndrome [3,5,6]. Radiography is a proven and useful procedure to confirm the presence of scoliosis, and characterize and classify the spinal deformity, and assess response to treatment [2-5,7].

This practice parameter outlines the principles for performing high-quality radiography of the spine for scoliosis in children.

Radiography for scoliosis in children should be performed only for a valid medical reason and with the minimum radiation dose necessary to achieve a diagnostic-quality study. Additional views or specialized examinations may be required. Although it is not possible to detect every abnormality associated with scoliosis, adherence to this practice parameter will maximize the probability of detection.

All radiographic examinations should be performed in accordance with the ACR–SPR Practice Parameter for General Radiography [8].

II. INDICATIONS

Indications for radiography of the spine for scoliosis include, but are not limited to, the following:

1. Alterations in normal spinal alignment on physical examination
2. Alterations in normal spinal alignment detected on other imaging studies
3. Evaluation of spinal curvature progression
4. Follow-up of treatment (orthotic or surgical)
5. Evaluation of individuals with a history of scoliosis in immediate family members
6. Evaluation of individuals at risk for scoliosis (eg, cerebral palsy, Duchenne muscular dystrophy, thoracic surgery, and radiation therapy) [9,10].

In the absence of clinical progression, scoliosis radiography examinations are not needed on a patient more frequently than once a year [11]. However, when risk of progression is highest (eg, during puberty), more frequent imaging may be needed, but not more than every six months.

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 [12].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Practice Parameter for General Radiography [8]. In addition, the interpreting physician should be familiar with the proper technique and assessment of scoliosis radiographs [1,13-15].
IV. SPECIFICATIONS OF EXAMINATION

The written or electronic request for a radiograph for a scoliosis evaluation 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. Scoliosis Survey

The number of views required for complete evaluation of scoliosis varies with the clinical indications. For scoliosis screening, a posteroanterior (PA) radiograph of the spine obtained in the upright position may be sufficient [3,14]. The field of view should extend from the cervicocranial junction to the proximal femurs. [1,3,7,14,16,17]. PA positioning of the patient decreases radiation dose to the thyroid and breast [3,4]. A supine view will suffice if the patient is unable to stand (eg, the very young child or patient with paralysis) [7]. An upright lateral radiograph facilitates assessment of sagittal deformity (abnormal kyphosis and lordosis), sagittal balance, [3] and spondylolisthesis. Spondylolysis may be detected, although this is best evaluated with dedicated images when relevant. Multiple studies have shown that there is a decrease in radiation dose with digital imaging systems compared with conventional radiography. These systems should be preferentially employed for imaging of known or suspected scoliosis [18].

The patient should stand (preferably) or sit before a vertical grid. When standing, the knees are placed together in full extension. In the lateral position, arms should be placed straight in front of the patient rather than above the patient’s head to prevent hyperextension of the spine. This can be facilitated with gentle support of the patient’s arms by an IV pole stand or similar structure [7,14]. For the lateral projection, arms should be extended with elbows flexed and fingers placed on the clavicles. This maximizes visibility of the cervicothoracic spine and preserves proper balance [19]. When possible, the PA image of the thoracolumbar spine should be obtained at a minimum source-to-receptor distance of 6 ft and an image size of either 14 in × 17 in or 14 in × 36 in. It is also acceptable to perform 2 exposures with the patient in unchanged position. With computed radiography (CR) and digital radiography (DR), some vendors provide software to “stitch” the 2 images into one [17,20-22]. Comparison of the source images with the stitched image is helpful to determine if any artifacts were generated during stitching and to confirm overlap or “missing” levels between original source images [23,24].

Studies have also evaluated the use of a slot scanning device and a dynamic flat-panel detector [25,26]. Although the study found higher skin doses and similar dose area product (DAP) for the dynamic flat-panel detector compared with the slot scanning device, other investigators have found that the dose savings are comparable to an appropriately filtered beam [26]. Image quality for the slot scanning device was also found to be comparable to the flat-panel detector [27]. Slot scanning systems with orthogonal x-ray tubes may be used to generate 3-D models to obtain measurements, such as the Cobb angle [26].

On the initial examination, the thoracic cage and pelvis may be imaged for correlation with clinical findings (eg, shoulder elevation, trunk shift, rib cage deformities, and congenital rib abnormalities). On the follow-up examinations, the x-ray beam should be collimated to the spine to increase image quality (because of the reduction of scattered radiation) and reduce the area of the patient exposed to radiation. Methods to decrease radiation
exposure may include the use of lead-acrylic filters, breast shields for anteroposterior (AP) examinations, increased beam filtration, and low-dose imaging systems [3,4,7,28-30].

Gonadal shielding may be used in boys, when appropriate, as per department protocol [31]. The use of gonadal shielding in girls is not encouraged controversial [32-34].

B. Additional Imaging Evaluation

For patients who are being assessed or clinically treated for scoliosis, additional images may include the following:

1. Right and left lateral bending images. These are usually obtained with the patient supine [7,14]. They are used to determine the flexibility of the curve(s) and to differentiate between structural and nonstructural curves [7,35].
2. Hyperextension and hyperflexion upright views to determine the flexibility of kyphosis and lordosis, respectively [7]
3. Images in an orthosis [36]
4. PA examination of the hand and wrist may also be performed to determine bone age.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [37].

A. Imaging Analysis of Scoliosis

1. General
   a. Vertebral abnormalities, such as fractures, scalloping, and congenital anomalies (eg, hemivertebrae, segmentation anomalies, dysraphism)
   b. Abnormalities of other osseous structures
   c. Evaluation of extraosseous structures included in the examination (eg, chest and abdomen)
   d. Note should be made of the presence of a brace, shoe lift, or other orthosis if this is known to the radiologist [17].
   e. Reporting should also include whether the patient is imaged standing, sitting, or supine.
   f. Imaging should include the triradiate cartilages [38].

2. Curve analysis may include the following (see appendix for definitions of terms):
   a. Presence and number of curves. If there is more than one curve, they can be referred to as “major” and “minor” (or “compensatory”) based on their Cobb measurements [15,39]. The terms “primary curve” and “secondary curve” should be avoided because these refer to chronology of development, which cannot be determined from a single study [3,6]. If lateral bending images are obtained, the curves can be further classified as “structural” or “nonstructural” [7,17,39].
   b. Curve pattern (cervical, thoracic, lumbar, cervicothoracic or thoracolumbar)
   c. Location of apical vertebra(e)
   d. Curve length (short or long)
   e. Curve measurement. The ends of the curve should be identified and are the basis for the Cobb angle. This is determined using the Cobb technique after identification of the first vertebrae, respectively [7,14,15,17,40]. If the end plates are poorly visualized, the pedicles can be used instead [7,41,42].
   f. Vertebral rotation. After identifying the apical vertebra, the degree of axial rotation can be estimated using any of several established techniques, including those of Nash and Moe [3,7,14,15,43] and Perdriolle [3,7,40,44].
g. Evaluation of lordosis and kyphosis. End vertebrae are identified according to the Cobb technique, using the lateral view. On occasion, the upper end vertebra is not well visualized; in this case, the superior end plate of T3 or T4 may be used [39].

h. Several parameters can be combined to create a classification to guide surgical management for adolescent idiopathic scoliosis [3,15,17]. These include those devised by King et al [45] or Lenke et al [46], the latter being more widely used [15].

i. Central sacral vertical line and C7 plumb line may be generated to determine sagittal and coronal balance of scoliosis [47-50].

3. Additional measurements may be obtained in special cases, such as the rib-vertebral angle in infantile idiopathic scoliosis [3,51].

4. Determination of skeletal age. This can be accomplished by analyzing the development of the iliac crest apophysis as described by Risser [7,15,49]. The Sanders Maturity Scale is another method for imaging scoliosis, which can provide lower dose studies of the spine and has the advantage of 3-D reconstructions [56-60].

5. Lateral radiographs, though not routinely performed at many institutions, can assist in evaluation of other suspected anomalies, such as kyphosis or spondylolisthesis.

VI. EQUIPMENT SPECIFICATIONS

Radiographic images shall be exposed only with equipment having a beam-limiting device with rectangular collimators.

Imaging options include a wall-mounted device that accommodates a 14 in × 17 in or a 14 in × 36 in image receptor or a digital radiography system capable of stitching 2 to 3 images into a single image. A low-dose biplane x-ray imaging system is another method for imaging scoliosis, which can provide lower dose studies of the spine and has the advantage of 3-D reconstructions

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment [61].

ACKNOWLEDGEMENTS

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

Collaborative Committee

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

ACR
Sue C. Kaste, DO, Chair
Kerri Highmore, MD
Tara M. Catanzano, MD, BCh
Carolyn A. Haerr, MD
Steven E Liston, MD, MBA, FACP
Sarah McKenney, Ph.D
Hamidreza Torshizy, MD

SPR
Nancy Chauvin, MD
Kirsten Ecklund, MD

SSR
Andrew Wilmot, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACP, Chair
Timothy J. Carmody, MD, FACP
Kerri A. Highmore, MD
Sue C. Kaste, DO
Committee on Practice Parameters – Pediatric Radiology

Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD
Terry L. Levin, MD, FACP
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACP

237

Committee on Body Imaging (Musculoskeletal)

(ACR Committee responsible for sponsoring the draft through the process)

William B. Morrison, MD, Chair
Jeffrey M. Brody, MD, FACP
Bethany U. Casagranda, DO
Mary K. Jesse, MD
Kenneth S. Lee, MD
Suzanne S. Long, MD
Kambiz Motamedi, MD
Catherine C. Roberts, MD
Aleksandr Rozenberg, MD
Naveen Subhas, MD

238

Committee on Practice Parameters – General, Small, Emergency, and/or Rural Practices

(ACR Committee responsible for sponsoring the draft through the process)

Sayed Ali, MD, Chair
Marco A. Amendola, MD, FACP
Resmi A. Charalel, MD
Brian D. Gale, MD, MBA
Carolyn A. Haerr, MD
Charles E. Johnson, MD
Candice Johnstone, MD
Padmaja A. Jonnalagadda, MD
Steven E. Liston, MD, MBA, FACP
Tammam Nehme, MD
Samir S. Shah, MD
Jennifer L. Tomich, MD

239

Richard A. Barth, MD, FACP, Chair, Commission on Pediatric Radiology
Lincoln L. Berland, MD, FACP, Chair, Commission on Body Imaging
Robert S. Pyatt, Jr., MD, FACP, Chair, Commission on General, Small, Emergency, and/or Rural Practice
Jacqueline Anne Bello, MD, FACP, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACP, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACP, Vice Chair, Committee on Practice Parameters and Technical Standards

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Comments Reconciliation Committee

Daniel Ortiz, MD, Chair
Johnson Lightfoote, MD, FACP, Co-Chair
Sayed Ali, MD
Richard A. Barth, MD, FACP
Jacqueline A. Bello, MD, FACP
Lincoln L. Berland, MD, FACP
Tara M Catanzano, MD, BCh
Nancy Chauvin, MD
Richard Duszak, Jr., MD, FACP
Kirsten Ecklund, MD
Carolyn A. Haerr, MD
Kerri Highmore, MD
Sue C. Kaste, DO
Paul A. Larson, MD, FACP
Steven E. Liston, MD, MBA, FACP
Sarah McKenney, Ph.D
William B. Morrison, MD
Mary S. Newell, MD, FACP
Beverley Newman, MB, BCh, BSc, FACP
Matthew S. Pollack, MD, FACP
Robert S. Pyatt, Jr, MD, FACP
Timothy L. Swan, MD, FACP
Hamidreza Torshizy, MD
Andrew Wilmot, MD

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REFERENCES


**APPENDIX**

- Cobb measurement of angle: the “end vertebrae” are identified. The end vertebrae are the vertebrae tilted maximally toward the concavity of the curve. Parallel lines are drawn along with superior endplate of the upper end vertebra and the inferior endplate of the lower end vertebra or through the pedicles if the endplates are indistinct. Lines are constructed perpendicular to these endplate lines. The angle subtended by these lines is the angle of curvature.

- **Scoliosis Research Committee (SRS) Terminology – Selected Terms [39]:**
  - Apical vertebra (apex): in a curve, the vertebra most deviated laterally from the vertical axis that passes through the center of the sacrum
  - Caudal end vertebra: the first vertebra in the caudal direction from a curve apex whose inferior surface is tilted maximally toward the concavity of the curve
  - Cephalad end vertebra: the first vertebra in the cephalad direction from a curve apex whose superior surface is tilted maximally toward the concavity of the curve

- **PRACTICE PARAMETER**

Scoliosis

2019 Resolution No. 7
Cervical scoliosis: a scoliosis with its apex at a point between C1 and the C6–7 disc

Cervical-thoracic scoliosis: a scoliosis having its apex at C7, T1, or the intervening disc space

Compensatory curve: a minor curve above or below a major curve that may or may not be structural

End vertebrae: the vertebrae that define the ends of a curve in a frontal or sagittal projection

Hyperkyphosis: a kyphosis greater than the normal range

Hyperlordosis: a lordosis greater than the normal range

Idiopathic scoliosis: a lateral curvature of the spine $\geq 10^\circ$ with rotation; of unknown etiology

Lumbar scoliosis: a scoliosis with its apex at a point between the L1–L2 disc space and the L4–L5 disc space

Major curve: the curve with the largest Cobb measurement on an upright radiograph of the spine

Minor curve: any curve that does not have the largest Cobb measurement on an upright radiograph

Nonstructural curve: a measured curve in the coronal plane in which the Cobb measurement corrects past zero on a supine lateral side-bending radiograph

Pelvic inclination: deviation of the pelvic outlet from the vertical, measured as an angle between the line from the top of the sacrum to the top of the pubis, and a horizontal line perpendicular to the lateral edge of the standing radiograph

Structural curve: a measured curve in the coronal plane in which the Cobb measurement fails to correct past zero on a supine radiograph with maximal voluntary lateral side-bending

Thoracic scoliosis: a scoliosis with its apex at a point between the T2 vertebral body and the T11–T12 disc

Thoracolumbar scoliosis: a scoliosis with its apex at T12, L1, or the intervening T12–L1 disc.

Vertebral axial rotation: transverse plane angulation of a vertebra. One method of measurement is with the Perdriolle technique (in degrees).

The recommended measurement of thoracic kyphosis from a lateral radiograph is the angle between the superior endplate of the highest measurable thoracic vertebra, usually T2 or T3, and the inferior endplate of T12.

The recommended measurement of lumbar lordosis from a lateral radiograph is the angle between the superior endplate of L1 and the superior endplate of S1.

Normal range for thoracic kyphosis: 20–50 degrees

Normal range for lumbar lordosis: 20–60 degrees

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.
Development Chronology for this Practice Parameter

2004 (Resolution 7)
Amended 2006 (Resolution 17, 35)
Revised 2009 (Resolution 32)
Revised 2014 (Resolution 15)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 8

BE IT RESOLVED,
that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Esophagrams and Upper Gastrointestinal Examinations 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 2013 (Resolution 29) *

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF ESOPHAGRAMS AND UPPER GASTROINTESTINAL EXAMINATIONS 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 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, ___ N.W.2d ___ (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.
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

An esophagram is the radiologic examination of the esophagus guided by fluoroscopy. It includes an evaluation of swallowing, esophageal emptying, when using the timed barium swallow (TBS), esophageal morphology and motility, evaluation of the gastroesophageal (GE) junction, and assessment for gastroesophageal reflux (GER). An upper gastrointestinal (GI) series is the radiologic contrast examination of the esophagus (identical to the routine esophagram), stomach, and duodenum guided by fluoroscopy.

Single-contrast and double-contrast (biphasic) examinations are proven and useful procedures for evaluating the esophagus and the upper GI tract [1-13]. Their goal is to establish the presence or absence, nature, and extent of disease with a diagnostic-quality study, using the minimum radiation dose necessary. The following practice parameters are for performing these examinations in adult patients.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications for an esophagram

1. Pertinent history and symptoms serving as indications for an esophagram include, but are not limited to:
   a. Dysphagia and atypical chest pain felt to be unrelated to cardiac or pulmonary disease
   b. Symptomatic or suspected GER [2-4,7,8,10,11]
   c. Dysphagia
   d. Suspected foreign body in the esophagus

2. The esophagram helps diagnose and evaluate is helpful in the diagnosis and evaluation of many conditions including, but not limited to:
   a. Suspected or known motility disorders [2,4,7,8,10]. The examination should include a TBS [14-16] in most patients with a suspected or known motility disorder, especially achalasia, to assess esophageal emptying. This is most effective in assessing treatment, especially achalasia treated with Botox, pneumatic dilation, Heller myotomy, and per oral endoscopic myotomy. As such, it should be performed both before and after intervention.
   b. Esophagitis [2-4,7,8,10,11]
   c. Strictures [2-4,7,8,10]
   d. Varices [7,8]
   e. Suspected esophageal perforation [7,17,18]
   f. Neoplasms [3,4,7,8,10]
   g. Postoperative assessment: to assess for leak or abnormal connection to bowel, such as a fistula as well as treatment of achalasia or other severe motility disorders
   h. Suspected foreign body

PRACTICE PARAMETER

Upper GI Adults
2019 Resolution No. 8
B. Indications for upper GI examination

1. History and symptoms serving as indications for an upper GI examination include, but are not limited to:
   a. Symptomatic or suspected GER (i.e., dysphagia, chest pain, heartburn, or regurgitation) [2-4,7,8,10,11]
   b. Abdominal pain
   c. Epigastric distress or discomfort
   d. Dyspepsia
   e. Nausea
   f. Vomiting
   g. Anemia
   h. Weight loss
   i. Gastric band slippage
   j. Signs and/or symptoms of upper GI bleeding

2. The upper GI examination helps diagnose and evaluate is helpful in the diagnosis and evaluation many
   conditions, including, but not limited to:
   a. Suspected or known gastritis or duodenitis [13]
   b. Peptic ulcer disease [1,5,6,12,13]
   c. Hiatal hernia [7,8]
   d. Varices [12]
   e. Suspected perforation [17,18]
   f. Neoplasms [7,9]
   g. Gastric outlet obstruction [12]
   h. Preoperative anatomical evaluation, such as prior to bariatric surgery
   i. Postoperative assessment [17,18]
   j. Gastric or duodenal masses [9,12]

Esophagrams and upper GI examinations may be indicated to evaluate aid in the evaluation of anatomy in
postsurgical patients for detecting spontaneous, posttraumatic, or postsurgical leaks from the esophagus, stomach,
or duodenum. In general, if a leak or perforation is clinically suspected, water-soluble contrast should be used for
the initial evaluation. If aspiration or esophageal-tracheal or bronchial fistula is suspected, thin barium, iso-osmolar
nonionic or low-osmolar contrast or barium agents should be considered. (See section IV C.5.) Extravasation of
thin barium in the mediastinum or pleural space does not cause complications [19]. Additionally, if a leak is
suspected and not identified with water-soluble contrast, barium should be administered [17,19]. If a leak is
suspected, obtaining images in the prone, supine, and both lateral decubitus positions is suggested to evaluate
the various surfaces of the esophagus and/or duodenum.

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 [20].

C. Contraindications

Patients who have undergone recent esophageal or gastric surgery or recent trauma, or who are unable to cooperate
with the examination, are not candidates for a double-contrast examination. Relevant patient history should be
obtained prior to the procedure to determine the appropriate type of procedure and contrast medium. In these
instances, assuming that the patient can cooperate, a single-contrast examination should be performed. At
times, for evaluation of the stomach, contrast can be introduced via a nasogastric (NG) tube if patient is
unable to swallow.
III. QUALIFICATIONS OF PERSONNEL

For qualifications of physicians, medical physicists, radiologist assistants, and radiologic technologists, see the ACR–SPR Practice Parameter for General Radiography [21].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for an esophagram and upper GI examination 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. Patient Preparation

For a routine esophagram, the patient should be instructed to refrain from taking anything by mouth for a minimum of 2 hours before the procedure. For an upper GI examination, the patient should be instructed to refrain from taking anything by mouth after midnight the night before or at least 6 hours before the procedure. Examinations may be performed with shorter fasting times as clinically indicated. Patients may generally take scheduled medications on the morning of the examination with a small cup of water.

B. Examination Preliminaries

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

A preliminary (“scout”) image of the abdomen is often useful, particularly in postsurgical patients for delineation of staple lines. A preliminary image of the chest may be obtained prior to an esophagram, particularly if there is history of prior intervention (stent, surgery, or endoscopic treatment).

C. Examination Technique

The physician should tailor the examination procedure to the individual patient, as warranted by clinical circumstances and the condition of the patient to produce a diagnostic-quality examination. Images should be taken with an appropriate field of view, manually collimated as much as possible in order to limit radiation exposure to the patient, so that radiation exposure to the patient is limited.

1. Single-contrast esophagram

a. Using a low-density (60% weight per volume [weight/volume]) barium suspension, the anatomic structure and motility of the entire esophagus should be evaluated fluoroscopically. Appropriate spot images should be obtained to document normal and abnormal findings. The examination should include barium-distended and, when appropriate, collapsed mucosal relief views of the esophagus, including fluoroscopic evaluation of motility. This is optimally performed with the patient in the prone or the
prone right anterior oblique (RAO) position, depending on the patient’s condition and the presence of risk factors, such as the potential for aspiration. Specific, appropriate small field-of-view (FOV) images of the esophagogastric junction should also be included.

b. With the patient in the semiprone position (RAO), using single, small swallows, esophageal motility should be assessed. Four to five separate swallows of barium should be observed, with each swallow separated by 25 to 30 seconds [22].

c. Fluoroscopic assessment for GER should be performed. This may include patient motion, Valsalva maneuver, leg raise, and water siphon test.

d. If the patient has symptoms suggesting oropharyngeal or swallowing dysfunction, then rapid sequence images or video recording for evaluating the pharynx and cervical esophagus should be considered. (See also the ACR–SPR Practice Parameter for the Performance of the Modified Barium Swallow [21].)

e. For a patient with solid food dysphagia, a barium tablet or other solid food bolus should be given whenever possible, and passage should be observed with the patient in an upright position [7]. Water or barium may be given to assist passage. Any symptoms the patient experiences from ingesting the solid material should be reported. Care should be taken to not bias or lead the patient. Before starting the examination, many experienced fluoroscopists will ask the patient to report any symptoms experienced during the examination. In some patients where the dysphagia is only to a specific food (bolus-specific dysphagia), the patients should be requested to bring the offending food during the examination; otherwise, a re-evaluation with the specific food should be recommended. If the patient has achalasia, the barium tablet will obstruct at the lower esophageal sphincter.

f. For a patient with liquid dysphagia, one should strongly consider starting the examination with TBS. Liquid dysphagia is almost always caused by a severe motility disorder, such as/most often achalasia. If the patient has achalasia, flooding the poorly emptying esophagus with gas-producing crystals and high-density barium may compromise the remainder of the examination. Furthermore, most gastroenterologists and esophageal surgeons request the timed study for assessing the effect of treatment. Once the barium has emptied from the esophagus, a motility examination can be performed to confirm the presence or absence of dysmotility.

g. At the end of the fluoroscopic examination, “overhead” images can be obtained as part of the routine protocol when using non–remote control fluoroscopic units (conventional table side control). (Overhead images are taken while the patient is drinking low-density barium in the RAO position.)

h. The quality control indicators specific to this study are:

i. Fluoroscopic observation of the entire esophagus while distended with barium, with appropriate spot images to document normal and abnormal findings.

ii. Sufficient radiographic technique to penetrate the barium-filled esophagus on images.

iii. Visualization of the GE junction to exclude local pathology.


v. In patients with liquid dysphagia or in patients with a suspected dysmotility disorder, esophageal emptying should be assessed with TBS.

vi. In cases with penetration or frank aspiration, the study should be terminated and a modified barium swallow study suggested.

2. Double-contrast (biphasic) esophagram

a. An effervescent agent that releases carbon dioxide into the lumen of the stomach should be administered to provide distention if the patient can tolerate this agent.

b. Fluoroscopic observation of the esophagus and gastric cardia and fundus should be performed in double contrast using a high-density (210%-250% weight/volume) barium suspension with the patient in an upright oblique position. Appropriate spot images should be taken to document normal and abnormal findings.
c. Fluoroscopic observation of esophageal motility and the distended esophagus should be performed using the single-contrast technique while the patient is drinking barium and is in a prone-oblique position. Appropriate spot images should be obtained as described previously.

d. Fluoroscopic assessment for GER should be performed (see above).

e. If the patient has symptoms suggesting a swallowing function abnormality, then rapid sequence imaging or video recording for evaluating the pharynx and cervical esophagus should be considered.

f. For a patient with solid food dysphagia, a barium tablet or other solid food bolus may be given whenever possible, and passage should be observed with the patient in an upright position [7]. Water or barium may be given to assist passage. Symptoms should be reported.

g. For a patient with liquid dysphagia, one should strongly consider not performing a double-contrast (biphasic) esophagram and start the examination with a TBS (see above). If the effervescent agent and high-density barium is given to a patient with achalasia, the patient may aspirate or immediately regurgitate the ingested agents as the esophagus is often partially or completely filled with foam, saliva, fluid, and/or food. Furthermore, once these agents are ingested, any subsequent examination that day will be hampered.

h. The quality control indicators specific to this study are as follows:

   i. Fluoroscopic observation of the entire esophagus by both single-contrast and double-contrast techniques, with appropriate spot images to document normal and abnormal findings.

   ii. A double-contrast view of the gastric cardia and fundus to exclude pathologic conditions in this adjacent anatomic region.

   iii. Sufficient radiographic technique to penetrate the barium-filled esophagus.

3. Single-contrast upper GI examination

a. Fluoroscopic assessment of the morphology and function of the entire esophagus, stomach, and duodenum should be performed. Although the protocol for a single-contrast examination may be tailored to the specific indication, it is best to start the patient in the upright position. The stomach should be palpated after the patient has ingested two or three swallowed barium. Palpation can be achieved with a lead-gloved hand, paddle, or spoon. This process can identify mucosal abnormalities, including ulcers and masses. The patient should be rotated, keeping the portion of the stomach palpated overlaying the spine, allowing for compression of the stomach between the compressing device or gloved hand and the spine. After palpation and rotation, more barium should be ingested to distend the stomach to assess for contour abnormalities and extrinsic masses. After this portion of the examination, the patient is placed in the horizontal position, where other portions of the stomach are assessed. Suggested views include barium-distended and, when appropriate, collapsed mucosal relief views of the esophagus, as well as barium-distended, mucosal relief, and/or compression views of the stomach and duodenum. Many fluoroscopists place the patient in the prone position, placing a paddle underneath the epigastric area. Insufflation of the paddle balloon will compress the stomach and facilitate identification of mucosal abnormalities. At the end of the examination, it is important to examine the gastric fundus in both the barium-filled, as well as gas-filled views. Gas-filled views are facilitated by placing the patient right side down/left side up in the horizontal, or 45° erect positions. Sometimes, maximum gas distension is achieved with the patient totally upright. A sufficient number of spot images should be obtained to adequately document normal and abnormal findings. Suggested views include barium-distended and, when appropriate, collapsed mucosal relief views of the esophagus as well as barium-distended, mucosal relief, and/or compression views of the stomach and duodenum. At the end of the examination, overhead images can be obtained as part of the routine protocol. At the end of the examination, overhead images can be obtained as part of the routine protocol when using non–remote control fluoroscopic units. (Overhead images are taken posterioranterior (PA), RAO, and right lateral positions).

b. The quality control indicators specific to this study are radiographic technique and graded compression that permit radiographic penetration of the barium suspension in the areas being examined.
4. Double-contrast (biphasic) upper GI examination

a. A hypotonic agent may be used to induce gastric and duodenal hypotonia.

b. An effervescent agent that releases carbon dioxide into the lumen of the stomach should be administered to provide distention.

c. After ingestion of high-density barium, fluoroscopy should be used to visualize all segments of the esophagus, stomach, and duodenum in double contrast. Appropriate spot images should be obtained to document normal and abnormal findings.

d. Fluoroscopy may be used to evaluate the esophagus, stomach, and duodenum after ingestion of low-density barium without and with palpation and rotation (see above). Additional spot images may be used to document normal and abnormal findings. Manual or mechanical compression of the accessible portions of the stomach and duodenum may be used.

e. At the end of the examination, overhead images can be obtained as part of the routine protocol when using non–remote control fluoroscopic units (see above).

5. Water-soluble contrast examination

Water-soluble contrast may be preferred to barium when there is concern for subdiaphragmatic bowel perforation into the peritoneal cavity and in the patients who are not at risk for aspiration when there is concern for tracheoesophageal communication.

If the patient is at risk for aspiration, iso-osmolar nonionic, or low-osmolar contrast agents are recommended for use by many. However, in patients with possible esophageal perforation who are at risk for aspiration, barium is used by some, as there has been no proven harm related to the presence of extravasated barium within the mediastinum.

a. Water-soluble contrast in concentration sufficient for fluoroscopic and plain radiographic visualization should be used. Risks of aspiration should be considered prior to the study.

b. Fluoroscopic observation of the esophagus, stomach, and duodenum should be performed, with specific attention to any areas of suspected leakage.

c. If no leak is identified or the study is inconclusive in patients with possible esophageal leak, a single-contrast barium examination may provide additional diagnostic information [17,18]. In addition, prone, supine, and both lateral decubitus positioning of the patient may be helpful to detect a leak.

d. Appropriate spot images should be taken to document normal and abnormal findings. At the end of the examination, overhead images can be obtained as part of the routine protocol when using non–remote control fluoroscopic units.

6. Portable technique

Portable technique may be used only when the patient is too unstable for examination in the fluoroscopy suite and or when portable technique will not compromise examination accuracy:

a. Gastrostomy or jejunostomy tube placement and patency may be ascertained by using portable radiography after injecting the tube with water-soluble contrast at the bedside. The images must be reviewed by the radiologist prior to using the tube. It is important to obtain a plain radiograph before injecting the contrast. After contrast injection, some sites obtain both a frontal and a
cross-table lateral image of the abdomen, which provide orthogonal images for detection of potential leak(s) and determine the tube position. Good-quality, portable, cross-table lateral images, without a Bucky grid, are a challenge for a technologist. Dedicated initial evaluation in the fluoroscopy suite should be encouraged assuming that the patient is medically stable for such an examination.

b. If the portable examination does not provide adequate diagnostic accuracy or confidence level, the patient should be brought to the fluoroscopy suite for a targeted problem-solving examination.

7. The following quality control indicators should be applied to all esophagram and upper GI examinations:
   a. When examinations are completed, patients should be held in the fluoroscopic area until the images have been reviewed by the physician.
   b. An attempt should be made to resolve questionable radiologic findings before the patient leaves. If necessary, repeat targeted fluoroscopy should be performed for problem solving.
   c. Radiologic, endoscopic, and pathologic findings should be correlated whenever feasible.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [23].

It is recommended that radiation dose data be recorded for all fluoroscopy procedures in accordance with the ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures [24]. If patient dose information from an automated dosimetry system is not available, the fluoroscopic exposure time and the number of acquired spot images should be recorded in the patient’s medical record.

VI. EQUIPMENT SPECIFICATIONS

Examinations must be performed with fluoroscopic and radiographic equipment meeting all applicable federal, state, and local radiation standards. The equipment should provide diagnostic fluoroscopic image quality and recording capability (film, digital image, video, or both, or digital). The equipment should be capable of producing kilovoltage greater than 100 kVp. Equipment necessary to compress and isolate accessible regions of the stomach and duodenum should be readily available.

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

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [25].

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).


ACKNOWLEDGEMENTS

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

Review Committee
Eric M. Rubin, MD, Chair
Mark E. Baker, MD, FACR
Lovick Thomas, MD, MS, FACR
William E. Torres, MD, FACR
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 parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

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Revised 2008 (Resolution 35)
Amended 2009 (Resolution 11)
Revised 2013 (Resolution 29)
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NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 9

BE IT RESOLVED, that the American College of Radiology adopt the ACR–SAR Practice Parameter for the Performance of Excretory Urography

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 14)*

ACR–SAR PRACTICE PARAMETER FOR THE PERFORMANCE OF EXCRETORY UROGRAPHY

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

This practice parameter has been developed by the American College of Radiology (ACR) and the Society of Abdominal Radiology (SAR) to assist physicians supervising the performance or interpretation of excretory urography (EU).

Properly performed EU is a diagnostic radiologic imaging test that can provide information about the kidneys and urinary tract. It is not possible to detect all abnormalities using EU, such as small renal masses or other renal parenchymal abnormalities.

Currently, excretory urography (EU) is as in patients with known or suspected ureteral obstruction or urinary leak.

EU is a radiographic examination in which anatomic and physiologic abnormalities of the urinary tract are detected by obtaining a timed series of images of the abdomen and pelvis before and after the injection of intravenous (IV) iodinated contrast media. Before the advent of cross-sectional imaging examinations, this examination was, for several decades, the primary imaging method for evaluating the urinary tract. Although largely it has now been almost completely supplanted by cross-sectional imaging techniques, particularly computed tomography CT urography in adults and MR urography in children. Occasionally, EU is still plays an occasional role performed for imaging of the urinary tract. Typically, an EU includes one or more images of the abdomen before an IV contrast medium is administered (referred to as “scout images” or “preliminary images”) and sequential images after contrast medium administration. Tomograms may be obtained when appropriate and technically feasible.

The terms “intravenous urography” and “intravenous pyelography” are used as synonyms for EU. In this practice parameter, the term “contrast media/medium” refers specifically to water-soluble iodinated contrast media that are administered intravenously.

II. INDICATIONS, CONTRAINDICATIONS, AND CAUTIONS

A. Indications

Relative merits of EU versus other imaging examinations including ultrasound (US), CT, nuclear medicine, and MR imaging should be considered in selecting the most appropriate test for the specific patient [1-5].

The indications for an EU examination include, but are not limited to, the following:

1. Evaluation of patients with suspected or known ureteral obstruction.
2. Assessment of the integrity of the urinary tract following trauma or therapeutic interventions, especially when cross-sectional imaging is inappropriate or unavailable. One example of such an indication is an examination performed in the operating room when a trauma patient is too unstable to undergo cross-sectional imaging prior to surgery.
3. Assessment of the urinary tract for suspected congenital anomaly, when thought to be more appropriate than cross-sectional imaging.
4. Assessment of the upper urinary tract (renal collecting systems and ureters) for urothelial lesions that may explain hematuria and for identification of urinary tract abnormalities that may predispose to infection, especially when cross-sectional examinations using US, CT, or MR imaging are either unavailable or felt to be inappropriate for the clinical circumstance.
5. Follow-up of patients with recurrent renal/ureteral calculi, with a limited number of images obtained before and after contrast medium pre- and postcontrast administration. Such limited studies may reduce the patient’s radiation burden compared with repetitive CT studies.

Although EU was not be used to assess the kidneys for parenchymal lesions, as it and masses in the past, with nephrotomography required for optimal assessment of the parenchyma. EU has only 67% sensitivity in detecting renal masses ≤3 cm in diameter [6]. Without tomography, the sensitivity is even lower. More than half of small tumors were not visualized or were missed on the initial IVU in one series [7]. Because cross-sectional imaging studies outperform EU in renal parenchymal evaluation [7], they are the study of choice for this indication.

B. Contraindications and Cautions

Issues related to use of intravascular iodinated contrast media administration, including relative contraindications to its use and when premedication should be considered, are discussed in detail in the ACR Manual on Contrast Media and other publications [8-11].

Pregnancy is a relative contraindication to EU. For the pregnant or potentially pregnant patient presenting with acute abdominal pain, a limited EU may be indicated in special circumstances (with a minimal number of radiographs obtained). A low-dose CT or MR is preferably to a limited EU [12].

For additional information concerning the performance of imaging studies requiring contrast media injections or ionizing radiation on the pregnant or potentially pregnant patient, see the ACR Manual on Contrast Media [8] and the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [13].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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

The interpreting physician should have documented formal training in the performance, interpretation, and reporting of EU and integration of other imaging examinations in the evaluation of the urinary tract, such as US, CT, nuclear medicine, and MR imaging.

The interpreting physician must also:

1. Be familiar with the disease processes for which the patient is being evaluated and understand the urographic manifestations of these diseases as well as variants of normal anatomy and congenital anomalies.

2. Have an understanding of and experience in proper imaging technique, image sequencing, and the use of tomography, as well as the volume and concentration of appropriate IV contrast media.

3. Be available in person or via electronic connection (remote access to PACS or other teleradiology connection) to monitor the examination and tailor the imaging sequence to answer the clinical question.

A physician must be available to assess and treat the patient in the event of a contrast reaction. The physician should have training in the recognition and treatment of adverse reactions to IV contrast media [8-12].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for EU 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). 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

Appropriate history should be obtained and a preprocedure screening should be performed by personnel familiar with the various risk factors, preparation, and premedication strategies [8,9,15,16]. Patients should be evaluated for factors predisposing them to anaphylactoid or idiosyncratic adverse reactions to iodinated contrast media, possible renal impairment, or other conditions that could increase the chances of an adverse reaction to contrast media. Appropriate precautions should be taken in any patient in whom risk factors are identified.

The physician must be aware of relative contraindications to EU, including a history of prior contrast reactions. Substantially decreased renal function is another relative contraindication to EU because patients with poor renal function may not be able to excrete the administered contrast material at a sufficient rate or amounts to obtain a diagnostic examination.

B. Injection of Iodinated Contrast Media

After intravenous access is obtained, the contrast medium is injected. Care and preparation of IV access sites are the responsibility of the health care professional who injects the contrast medium. The contrast medium used for the study may will vary with the institution. In most cases, the contrast used for other imaging studies such as CT is appropriate for EU as well. The dose of contrast medium instilled will vary with the institution as well, with factors such as patient’s body weight and presence of both kidneys versus a solitary kidney (whether functionally or anatomically solitary) coming into consideration.

The physician or, if state and local regulations permit, the radiologic technologist, registered nurse, or other appropriately credentialed health care practitioner may inject the contrast media. An appropriately trained individual who is aware of the signs and symptoms of adverse reactions to contrast medium must monitor the patient for the development of these signs and symptoms during the examination [9,10,17,18]. Appropriate personnel must be available to respond promptly to any adverse reactions that might occur.

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. Image Acquisition:

Image acquisition should be tailored to the specific needs of the patient to optimize the examination and yet limit radiation exposure.

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2 See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media.
1. Preliminary image(s) should be evaluated prior to the injection of contrast media to check patient positioning and technique and to assess for radiopaque urinary tract calculi. Imaging should delineate the obtained image should include the abdomen from just above the kidneys to a level below the symphysis pubis [5,15,19,20]. When indicated, an additional image centered over the kidneys should be obtained to assess for renal calculi, in addition to an 14x17-inch image of the abdomen and pelvis.

2. Postcontrast sequential images should be obtained to evaluate the kidneys, upper collecting systems, ureters, and urinary bladder. These images should be tailored to address the clinical question(s) [5,19,20]. When indicated, nephromograms are necessary to optimize only for renal parenchyma evaluation in a patient who has no recent cross-sectional imaging studies, recognizing that EU is not as sensitive as CT, MR, or US in detecting a small renal mass.

3. In some clinical circumstances (eg, pregnancy), a limited examination may be appropriate.

4. Imaging with abdominal compression may be useful in optimally distending and opacifying the collecting systems. The appropriateness of compression should be assessed in individual patients as abdominal compression may be contraindicated in patients with a large abdominal aortic aneurysm, a history of recent abdominal surgery, ostomies, or trauma, as well as in other clinical situations. Severe flank pain after application of compression may indicate forniceal rupture; an image of the abdomen should be obtained immediately and compression released if extravasation is demonstrated.

5. When indicated, the addition of oblique images of the abdomen may be also useful for optimal assessment of the entire collecting systems and ureters. Prone images may assist in opacification of dilated ureters [21]. An additional radiograph with the patient upright can be obtained in patients with suspected urinary tract obstruction; such an image is sensitive for detecting low-grade obstruction.

6. Images centered over the pelvis may be obtained for assessment of the a full bladder for wall irregularities and intraluminal masses. A postvoid image may be useful to assess bladder emptying or facilitate visualization of bladder masses; in some patients, bladder masses are more easily seen on a postvoid image. An additional radiograph with the patient upright can be obtained in patients with suspected urinary tract obstruction, as such an image is sensitive for detecting low-grade obstruction. Incomplete drainage of the collecting systems and ureters on an upright radiograph suggests that there is some degree of obstruction.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [22].

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 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)


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 exposure and diagnostic image quality.
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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment [23].

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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 – General, Small, Emergency, and/or Rural Practices of the ACR Commission on General, Small, Emergency, and/or Rural Practices in collaboration with the SAR.

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

ACR
Elaine M. Caoili, MD, Chair
Richard H. Cohan, MD, FACR
James H Ellis, MD, FACR
Gary M. Israel, MD
Jeffrey H. Newhouse, MD, FACR
Samir Shah, MD

SAR
Robert P. Hartman, MD, FSAR
Stuart G. Silverman, MD, FSAR

PRACTICE PARAMETER Excretory Urography 2019 Resolution No. 9
Committee on Practice Parameters – General, Small, Emergency and/or Rural Practices
(ACR Committee responsible for sponsoring the draft through the process)

Sayed Ali, MD, Chair
Marco A. Amendola, MD, FACR
Lynn Broderick, MD, FACR
Resmi A. Charalele, MD
Brian D. Gale, MD, MBA
Carolyn A. Haerr, MD
Charles E. Johnson, MD

Candice Johnstone, MD
Padmaja A. Jonnalagadda, MD
Steven E. Liston, MD, MBA, FACR
Tammam Nehme, MD
Samir S. Shah, MD
Jennifer L. Tomich, MD

Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Chair

Robert S. Pyatt, Jr., MD, FACR, Chair, Commission on General, Small, Emergency and/or Rural Practice
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Elaine Lewis, MD, FACR, Chair
Eric Friedberg, MD, FACR, Co-Chair
Sayed Ali, MD
Richard A. Barth, MD, FACR
Jacqueline A. Bello, MD, FACR
Priscilla F. Butler, MS, FACR
Elaine M. Caoli, MD
Richard H. Cohan, MD, FACR
Richard Duszak Jr., MD, FACR
James H. Ellis, MD, FACR
Robert P. Hartman, MD, FSAR
Gary M. Israeli, MD
Mary S. Newell, MD, FACR
Jeffrey H. Newhouse, MD, FACR
Matthew S. Pollack, MD, FACR
Robert S. Pyatt Jr, MD, FACR
Samir Shah, MD
Stuart G. Silverman, MD, FSAR
Timothy L. Swan, MD, FACR

REFERENCES


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Amended 2006 (Resolution 17,35)
Amended 2007 (Resolution 38)
Revised 2009 (Resolution 35)
Revised 2014 (Resolution 14)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 10

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SPR Practice Parameter for the Performance of Fluoroscopic and Sonographic Voiding Cystourethrography in Children

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 13)*

ACR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF FLUOROSCOPIC AND SONOGRAPHIC VOIDING CYSTOURETHROGRAPHY IN CHILDREN

PREAMBLE

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

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

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing. ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

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

I. INTRODUCTION

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

Voiding cystourethrography (VCUG) is a radiographic and fluoroscopic study of the lower urinary tract. It requires aseptic bladder catheterization, instillation of iodinated contrast media, fluoroscopic observation, and image documentation of the findings. The purpose of the examination is to assess the bladder, the urethra, other opacified structures, the presence or absence of vesicoureteral reflux (VUR), and micturition. Contrast-enhanced voiding urosonography (ceVUS) is an alternative method of assessment, in which ultrasonography of the kidneys is performed after the intravesical administration of a sonographic contrast agent.

II. INDICATIONS AND CONTRAINDICATIONS [1-9]

Clinical indications for VCUG voiding cystourethrography include, but are not limited to, the following:

- Hydronephrosis and/or hydroureter
- Abnormal US (any degree of hydronephrosis, uroepithelial thickening, scarring) after first urinary tract infection (UTI), especially if febrile or non-Escherichia coli (E. coli)
- Febrile Recurrent urinary tract infection UTI particularly if recurrent [9]
- Congenital anomalies of the urinary tract
- Dysfunctional voiding, such as neurogenic dysfunction of the bladder
- Urinary incontinence
- Bladder outlet obstruction
- Postoperative evaluation of the urinary tract
- Dysuria/difficulty voiding
  - Incontinence
- Hematuria
- Trauma

In some circumstances a retrograde urethrogram (RUG) may be preferred over a VCUG, particularly in children with trauma or dysuria. There are no absolute contraindications for VCUG. Potential benefits must outweigh the minor risks of the procedure. Alerts for However, one should proceeding with caution if the child has had a may include prior significant reaction to iodinated contrast media, known or suspected latex allergy [10], acute UTI urinary tract infection, recent urethral or bladder surgery, potential urethral trauma, and or high spinal injury (risk of autonomic dysreflexia). The risk of postprocedure UTI is very low. Routine antibiotic prophylaxis is not necessary, but increased vigilance is warranted in children with significant anatomic
abnormalities, particularly high-grade VUR [11]. In young infants at risk for UTI antibiotic prophylaxis could be considered for a few days prior to and following the study.

ceVUS is a radiation-free alternative to evaluate for VUR or urethral pathology [12]. See later paragraph.

Nuclear voiding cystography may have a lower radiation dose and is may also be used as an alternative study for the evaluation of reflux in children, especially when detailed anatomic visualization of the urethra, bladder, and kidneys is not required. especially in females with normal renal and bladder anatomy demonstrated by sonography, males with previously demonstrated reflux and normal urethral anatomy, children in whom allergy to iodinated contrast material might be a problem, and in situations in which male and female asymptomatic siblings of patients with reflux and normal renal and bladder anatomy are to be evaluated [11]. In the era of modern digital, grid-controlled fluoroscopic equipment with a flat detector, filtration, and low pulse rate, the radiation dose from fluoroscopic VCUG and nuclear VCUG is similar [13,14].

The voiding study chosen will vary depending on locally available equipment, expertise, and personnel.

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 [15].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR-SPR Practice Parameter for General Radiography [16].

IV. SPECIFICATIONS OF EXAMINATION

The written or electronic request for VCUG 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). 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

The study should be performed only for an appropriate clinical indication. Consultation with referring physicians helps to clarify which children may benefit from VCUG.

B. Technique

Preparation and Sedation

Voiding cystourethrography VCUG can typically be performed without sedation when parents and children receive adequate preparation and support. When available, child-life specialists may provide education, distraction and relaxation techniques that are be useful in facilitating catheterization as well as patient cooperation during
and the remainder of the examination through use of education, distraction, and relaxation techniques [17,18]. The use of warmed contrast material may also decrease patient distress [17,19].

When clinically indicated in selected patients, sedation may help alleviate patient distress and can be performed safely, without negatively affecting the examination [17,20,21]. If sedation is used, the child must undergo a presedation evaluation and must be monitored both during and after the examination, as outlined in the current practice parameter (See the ACR–SIR Practice Parameter for Sedation/Analgesia [22]).

**Review and Preliminary Imaging**

If a recent abdominal image is not available, a preliminary abdominal image may be obtained and reviewed before instilling contrast media in order to detect findings that would affect the performance of the study, such as contrast in the GI tract, opaque calculi, calcifications, and skeletal anomalies. Selective use of a lateral image may be helpful to evaluate the sacrum if there is a concern for sacral anomalies. In many cases, fluoroscopic image capture is sufficient, but a digitally acquired spot image or radiograph may be preferable in specific clinical situations needing superior spatial resolution.

Prior to the start of the examination, it is helpful to review the child’s history and prior imaging findings, particularly any recent studies where residual contrast may be present. Formal scout radiographs make a significant contribution to the dose of the study while their yield is relatively low [23]. Instead a pre-contrast fluoroscopy grab image may be acquired at the start of the study. In those specific situations requiring superior spatial resolution, a digitally acquired spot image or radiograph may be obtained [23-26].

**Catheterization**

Aseptic bladder catheterization of children should be performed by experienced personnel. Latex precautions should be observed, especially in those children with known latex allergy, multiple surgeries, or those with a diagnosis of myelomeningocele.

In males, to diminish sensation or pain, a topical anesthetic may be instilled retrograde into the urethra with aseptic technique; anesthetic gel may be applied externally in both males and females [27,28].

The catheter size should be appropriate for the child’s age or urethral caliber. In premature or extremely small infants, a 5-French catheter is preferred. Above this age, an 8-French catheter is preferred, unless a smaller catheter is appropriate for the urethral anatomy (such as in the case of urethral stricture) or if there is inability to catheterize with the larger catheter. A catheter larger than 8-French may be used in adolescents. In order to avoid intravesical looping and knotting of the catheter, which may require invasive retrieval, excessive catheter length should not be inserted into the bladder. Importantly, in uncircumcised males, if the foreskin is retracted at catheterization, it should be repositioned over the glans immediately following catheterization, in order to avoid secondary paraphimosis.

Catheters may be secured by use of tape or by using catheters with balloons, filled to the appropriate volume. For balloon catheters the syringe used to inflate the balloon should be retained to deflate the balloon prior to voiding. For catheters without balloons, in girls the catheter may be secured in place with tape to the perineum or in older girls, to the thigh. In older girls, in boys, once the catheter is inserted, a strip of tape may be placed on the catheter extending longitudinally along the dorsum of the penis to the symphysis. Circumferential placement of tape around the penis is discouraged. Inflation of a balloon in the bladder to secure the catheter is discouraged as it may obscure pathology.

After the catheter placement, the bladder should be drained prior to instillation of contrast media. A sterile urine specimen may be retained for culture if clinically indicated. The size of the catheter should be recorded, unless previously placed in another department.
Contrast Media

Iodinated contrast media (typically 12% to 18% weight/volume solution) should be administered via the bladder catheter by gravity drip. The height of the bottle controls the infusion pressure, but while the diameter of the tubing somewhat limits this pressure, making the exact bottle height somewhat less relatively unimportant. However, 3 feet above the table height is typically sufficient [29]. The amount of contrast agent to be administered depends on the bladder capacity, and can be estimated using the following formulas [30]: <2 years: weight (kg) x 7; >2 – 14 years: in ounces age in years + 1 and in mL (age in years x 30) + 30; >14 years: 500 mL. The bladder filling should continue until voiding, filling with more than twice the estimated bladder capacity if there is no voiding.

If recent bladder surgery has been performed, such as augmentation, gravity infusion should be performed with the container bottle of contrast positioned as low as possible above the table height to assure low-pressure filling, and Contrast infusion bladder volume should be limited, stopping infusion should be stopped when the patient has symptoms of pain, when contrast refluxes retrograde into the ureters beyond the ureteral stents (if present), or if contrast extravasates.

Very few patients have allergic reactions to intravesical contrast. Very few patients have allergic reactions to intravesical contrast [31]. However, in the event that a patient has had prior anaphylaxis to intravenous contrast, one could consider allergy prophylaxis or an alternative imaging study (See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [22] and the ACR Manual on Contrast Media [32]).

Fluoroscopy and Imaging

Pulsed fluoroscopy, last image hold, and fluoroscopic image capture result in reduced radiation dose and should be used when available [24,33]. Video recording of the examination may also be useful for later review. Estimators of radiation exposure, such as fluoroscopic parameters used and fluoroscopy time, should be documented. Fluoroscopy time should be monitored and minimized. The use of antiscatter grids should be limited to older patients, generally patients weighing more than 40–50 lbs, or when the body part examined is greater than 12 cm in thickness. The examination should be collimated to the region of interest.

Standardization of an optimized imaging sequence should be employed as much as possible. Early-filling last-image capture of the bladder with a small amount of contrast may reveal an intravesical ureterocele or other mass, which might be obscured by larger contrast volume. Early oblique views can be obtained if necessary. While further bladder filling occurs, continuous imaging is not necessary [34].

Oblique radiographs of the bladder are obtained when the bladder is estimated to be full, prior to voiding to profile each ureterovesical junction in relation to the bladder neck (as delineated by the catheter). The approximate bladder capacity (mL) may be estimated by multiplying the patient’s age in years, plus 2, by 30, i.e., (age in years + 2) x 30. However, bladder capacity varies and depends on toilet habits, voiding frequency, and social attitude. Concluding a study when reaching the predicted bladder capacity may miss children with functional or neurological abnormalities (eg, infrequent voider syndrome that is characterized by a large capacity bladder). One should also be aware that in some patients overdistension of the bladder may result in inability to void [35]. If reflux did not occur prior to voiding and is seen during voiding, the oblique images of the bladder should be repeated. Lateral imaging of the urinary bladder may be helpful in certain indications such as for evaluation of urachal pathology.

Cyclical filling of the bladder (filling to capacity followed by voiding and refilling 2 to 3 times with the catheter in place) may be helpful in infants (1 year of age or younger) who void at low volumes and in patients with a high pretest probability of reflux to increase detection of reflux in patients with a high pretest probability of reflux. The latter group includes patients with recent UTI, urinary tract infection, a prior history of reflux, periureteral (Hutch) diverticulum, and evidence of pyelonephritis. Cyclical voiding is also helpful in patients who reflux into a
very dilated ureter on the first fill; in these patients the refluxed contrast may will be diluted by the large amount of unopacified urine, and additional voiding cycles will optimize visualization of the ureter and collecting system [36,37]. Cyclical voiding is also helpful in cases of suspected ectopic ureter inserting below the bladder base [38].

The full bladder oblique images that are obtained before voiding should profile each ureterovesical junction in relationship to the urethra (as outlined by the catheter). When vesicoureteral reflux (VUR) occurs, the degree of reflux should be documented by imaging the renal fossae in the frontal projection. Additionally bladder volume at the onset of reflux should be recorded. Post void residual should be estimated [30].

For optimal imaging of the urethra, the field of view and patient positioning should be prepared before the child begins to void. Visual inspection of the perineum will reveal when the patient begins to void and avoids unnecessary and excessive fluoroscopy. Older males might be able to void more easily if the fluoroscopic table is tilted to 30 to 45 degrees or if they are able to stand.

Once voiding is detected, the male urethra may be imaged prior to removal of the catheter, since pertinent pathology may be demonstrated with the catheter in place [39]. However, it is preferable to also obtain images of the urethra after the catheter has been removed, especially in males. In neonates and young infants who may void sporadically, if the bladder has moderately emptied prior to catheter removal, it is best wise to wait until it refills before removing the catheter, as the child may not void again without a full bladder.

The entire urethra should be demonstrated during the voiding phase. To image the urethra, boys should be positioned slightly obliquely from the lateral position during voiding, with slight offset of the hips such that they are not superimposed. In most young boys, the entire urethra will be visible on a single voiding image. In adolescent boys, separate images of the posterior and anterior urethra may be necessary. The female In girls the urethra is generally imaged in the frontal projection, and catheter removal is not necessary for optimal views. Lateral imaging of the female urethra is performed in special circumstances, such as evaluation of urogenital sinus anomalies.

Spot Images of the renal fossae immediately after voiding should be obtained to document the presence and grade of reflux or its absence. The maximal degree of vesicoureteral reflux (VUR) should be accurately described and graded (see Appendix A). When an obstructive process, such as obstruction at the ureteropelvic or ureterovesical junction, coexists with reflux, refluxed contrast will be diluted by the indwelling unopacified urine, with decreased density of the refluxed contrast. In such situations, it is not possible to grade the reflux, since the degree of dilatation is not necessarily secondary to the reflux alone; this situation can lead to significant overestimation of the degree of reflux [40].

If there is concern for coexistent obstruction, the rate of contrast drainage from the pelvicalyceal pyelocalyceal system and ureter may be estimated by obtaining a delayed image, usually 10–20 a few minutes after voiding.

If a toilet-trained patient is unable to void during the fluoroscopic portion of the examination for psychological reasons, after adequate bladder distension and after a reasonable amount of time and coaxing, he or she may be allowed to void in the restroom if it is sufficiently adjacent to the fluoroscopy room, to obtain quickly postvoid images. Postvoid images should be obtained immediately after voiding, with an estimate of the time interval between completion of voiding and imaging recorded. As in postvoid imaging on the table, images should be obtained over the renal fossae and bladder to document the presence or absence of reflux and degree of bladder emptying. This limitation of the voiding portion of the examination must be documented.

Assessment of the study should include the following:

- Appearance of the spine and pelvic bones
- Documentation of opaque calculi, calcifications, or foreign bodies, when present
- Bladder contour, location, capacity, diverticulae, and residual volume,
- Bladder lumen and filling defects, such as ureteroceles, clot, or other masses
• Absence or presence and greatest degree or absence of reflux including intrarenal reflux
• When during the examination reflux, if present, first occurred (i.e., approximate bladder volume when reflux first occurs)
• Site of insertion of ureter(s) when visualized by reflux
• Grade of greatest reflux and at what point in the examination it occurred
• Intrarenal reflux should be noted if present
• Appearance of the entire urethra
• Presence or absence of extravasation or evidence of fistula

V. DOCUMENTATION

The findings of the voiding cystourethrogram should be reported in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [41].

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

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

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment [42].

CONTRAST ENHANCED VOIDING UROSONOGRAPHY (ceVUS)

VIII. INTRODUCTION

The intravesical administration of ultrasound (US) contrast agent and the demonstration of refluxing microbubbles into a ureter or renal collecting system is known as contrast enhanced voiding urosonography, or ceVUS [43-45]. In 2016 the Food and Drug Administration (FDA) of the United States approved the use of an US contrast agent (Lumason, Bracco) for use in vesicoureteric reflux detection in children. Studies of ceVUS versus VCUG have demonstrated that ceVUS is more sensitive in detecting vesicoureteric reflux and is comparable in the evaluation of the urethra [44,45]. Unlike VCUG there is no exposure to radiation.

IX. INDICATIONS AND CONTRAINDICATIONS

The indications for ceVUS are the same as for VCUG. The study is contraindicated if one or both kidneys are difficult to visualize sonographically, which may occur in a morbidly obese child or a child with severe lumbar scoliosis [12]. There are no known side effects related to intravesical administration of US contrast agents [46].

X. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

ceVUS is performed by sonographers or radiologists trained in bladder catheterization and sonography of the bladder, ureters, kidneys and urethra. It is best to have 2 persons present for the exam; one performing the catheterization and administration of intravesical US contrast and the other performing the US itself. The ceVUS is documented with static images and clips.

XI. SPECIFICATIONS OF EXAMINATION

The request for the study, patient selection and preparation, review of prior imaging and catheterization process are similar to those for VCUGs. The study must be carried out with an US scanner equipped with a contrast specific modality. Scout sonographic images should be obtained prior to catheterization. The US contrast agent is prepared as per the instruction of the manufacturer. The microbubble solution is mixed immediately before its use as the bubbles disintegrate over time.

A 0.2% suspension of the US contrast agent and normal saline may be administered into the bladder catheter via gravity drip. Alternatively, 0.5-1.0 mL of the contrast agent may be administered via the bladder catheter followed by a normal saline infusion [47]. The height of the infusion and the volume of suspension or normal saline administered are similar to those for VCUG.
Bladder filling is carried out under US monitoring with the patient supine. This is followed by alternate scanning of the right and left kidneys (supine or oblique if necessary) and the bladder. During voiding, additional suprapubic and/or transperineal scanning of the urethra are performed with the catheter in place as well as once the catheter has been removed. Patients may be scanned from the back while sitting on a potty or, in males, while standing and using a urinal, thus allowing a more physiological position for voiding.

Additional postvoid scanning of the bladder and kidneys is subsequently obtained. The appearance of echogenic microbubbles within a ureter or renal collecting systems indicates vesicoureteric reflux. Vesicoureteric reflux is graded in a similar way to VCUG [43]. As with a VCUG, cyclical filling may be necessary in neonates and infants [47].

Assessment and reporting is similar to VCUG with the exception of structures not applicable to US such as the bony pelvis and fluoroscopic radiation.

ACKNOWLEDGEMENTS

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

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

ACR
Beverley Newman, MB, BCh, BSc, FACR, Chair
Kassa Darge, MD, PhD, FSAR
Terry Levin, MD, FACR

SPR
Ellen Chung, MD
Hansel J. Otero, MD
Anil G. Rao, DMRD, DNB

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Safwan Halabi, MD
Kerri A. Highmore, MD

Sue C. Kaste, DO
Tal Laor, MD
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Pallavi Sagar, MD
Richard B. Towbin, MD, FACR

Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Sonia Gupta, MD, Chair
Kevin Smith, MD, FACR, Co-Chair
Richard A. Barth, MD, FACR
Paul A Larson, MD, FACR
Terry Levin, MD, FACR
Mary S. Newell, MD, FACR


APPENDIX A

Grading System of the International Reflux Study of 1985 [30] (See Figure 7 from Pediatric Voiding Cystourethrography, a Pictorial Guide) [34]

1. Reflux only into the ureter.
2. Reflux into the entire ureter and pelviccalyceal system, no dilatation.
3. Mild pelvic or ureteral dilatation, with mild or no blunting of the fornices.
4. Moderate dilatation of the pelvis and ureter, with moderate dilation of the calyces.
5. Massive ureteral or pyelocalyceal dilatation.

Grading system for contrast enhanced voiding urosonography (ceVUS) is similar to VCUG [43].

*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 8)
Amended 1995 (Resolution 24, 53)
Revised 1999 (Resolution 34)
Revised 2004 (Resolution 9)
Amended 2006 (Resolution 17, 35)
Revised 2009 (Resolution 33)
Revised 2014 (Resolution 13)
RESOLUTION NO. 11

Abusive Head Trauma

WHEREAS, abusive head trauma is currently the most inclusive term to reflect the injury patterns inflicted on young infants and children which cannot be explained by a natural disease process or accidental trauma; and

WHEREAS, abusive head trauma is the leading cause of fatal head injuries in children younger than two years old; and

WHEREAS, the financial cost to society is extremely high, with an estimated lifetime cost of $13.5 billion, for over 4000 abusive head trauma cases in the US in 2010; and

WHEREAS, in medical practice, the diagnosis of abusive head trauma is typically established by multidisciplinary assessment of radiologic findings in addition to clinical, laboratory, forensic and social investigation and a careful evidence-based exclusion of alternative diagnoses of underlying disease and accidental trauma; and

WHEREAS, in courts of law, defense attorneys routinely cast doubt on the legitimacy of this abusive head trauma diagnosis and suggest that common accidents and undiagnosed disease mechanisms are equally likely explanations; and

WHEREAS, the abusive head trauma diagnosis has been mischaracterized by lawyers, judges, the news media, and the Swedish Agency for Health Technology Assessment and Assessment of Social Services (1) as a rote over-diagnosis based solely upon a so-called triad of medical findings (subdural hemorrhage, encephalopathy, retinal hemorrhage); and

WHEREAS, contra-factual claims that child abuse is over diagnosed or that shaking or shaking with impact cannot cause traumatic brain injury undermines prevention efforts and deters parents and caregivers from seeking necessary medical care; and

WHEREAS, medical societies serve to educate and provide guidance on questions of science and public health; and

WHEREAS, many pediatric organizations including American Academy of Pediatrics, Royal College of Radiologists, Royal College of Paediatrics and Child health, Canadian Pediatric Society and others have adopted a formal position on abusive head trauma; and

WHEREAS,
WHEREAS, the American College of Radiology (ACR) has not yet adopted a formal position statement addressing this challenge of mischaracterization of the diagnosis of abusive head trauma; and

WHEREAS, support for the scientific accuracy of the abusive head trauma diagnosis can easily be found in the recent consensus statement from the Child Abuse Committee of the Society for Pediatric Radiology; and

WHEREAS, the above consensus statement has been endorsed by the ACR and a number of other national and international societies; therefore,

BE IT RESOLVED, that the ACR affirms that shaking of young infants and children with force, other than that of the normal handling of an infant or child, can potentially cause significant injury to the brain; and

BE IT FURTHER RESOLVED, that the ACR affirms that there is a public health concern created by mischaracterization of diagnosis of abusive head trauma; and

BE IT FURTHER RESOLVED, that the ACR affirms that providing opinions and testimony regarding abusive head trauma, unsupported by the medical evidence, poses a risk to infants and children by undermining child abuse prevention efforts (i.e., by falsely suggesting that shaking is not dangerous) and deterring parents and caregivers from seeking medical care (i.e., by falsely suggesting that child abuse is over-diagnosed).

Sponsored by: Board of Chancellors
             Council Steering Committee
Fiscal Note

Abusive Head Trauma

To support the resolution Abusive Head Trauma, the ACR would incur the following estimated costs:

Costs:

- De minimis (<$10,000)
RESOLUTION NO. 12

Continuing Certification

WHEREAS,

the American College of Radiology (ACR) strongly supports lifelong learning by all radiologists; and

WHEREAS,

validation of radiologist lifelong learning has traditionally typically been performed by the American Board of Radiology (ABR) through its Maintenance of Certification (MOC®) program; and

WHEREAS,

growing concerns within the radiology community and physician community more broadly have accelerated regarding continuing certification processes mandated by the American Board of Medical Specialties (ABMS) and its 24 member boards (of which the ABR is one); and

WHEREAS,

the ACR has recently provided written comments to the drafting body of the Vision Initiative writing group commissioned by the ABMS, in which it called for open certification board elections, increased board decision making transparency, opportunities for public comment on all proposed certification changes or new initiatives, practice tailored certification opportunities, and caution about the antitrust activities of said boards; and

WHEREAS,

in response to concerns raised by multiple members regarding a variety of issues related to ongoing certification by radiologists, the ACR Board Chair recently appointed a Task Force on Continuing Certification in Radiology to study these issue and make recommendations to the Board of Chancellors; therefore,

BE IT RESOLVED,

that the Council of the American College of Radiology strongly, fully, and enthusiastically supports the ACR Board Chair’s decision to appoint a Task Force on Continuing Certification in Radiology; and

BE IT FURTHER RESOLVED,

that the Council of the American College of Radiology strongly and fully supports the volunteer members who have agreed to serve on this critically important and timely body; and

BE IT FURTHER RESOLVED,

that the American College of Radiology shall strongly and fully support those task force members, in whatever manner necessary (e.g., through legal counsel, ethics committee, etc.) to ensure that they can diligently carry out their requested duties in an unimpeded manner without fear of undue influence.

Sponsored by:  Tennessee Radiological Society
Council Steering Committee
To support the resolution *Continuing Certification*, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
### RESOLUTION

<table>
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| 13. | **Ten-Year Extension of Policies**  
(a) PUBLIC HEALTH AND RADIATION PROTECTION  
(b) RADIOLOGICAL PRACTICE AND ETHICS  
5. MISCELLANEOUS RADIOLOGIC PRACTICE AND ETHICS POLICIES  
1. Support of Clinical Patient Management by Vascular and Interventional Radiologists  
(c) TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS  
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| 15. | **ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology** | REVISED PP |
| 17. | **ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Brain** | REVISED PP |
| 18. | **ACR–ASNR Practice Parameter for the Performance of Non-Breast Magnetic Resonance Imaging (MRI)-Guided Procedures** | REVISED PP |
| 19. | **ACR–ASNR–SPR Practice Parameter for the Performance of Myelography and Cisternography** | REVISED PP |
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| 23. | **Imaging Guided Procedures Core Privileges** | NEW POLICY |
| 45. | **Firearm Injury Prevention Consensus Statements** | NEW POLICY |

### ACR STAFF:

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<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
<tr>
<td>Director</td>
<td>Dina Hernandez</td>
</tr>
<tr>
<td>Moderator</td>
<td>Deanna Hafer</td>
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<tr>
<td>Recorder</td>
<td>Dee Salem</td>
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<tr>
<td>Assistant</td>
<td>Karen Orozco</td>
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<tr>
<td>Attorney</td>
<td>Gloria Romanelli</td>
</tr>
<tr>
<td>Observer</td>
<td>Pam Platt</td>
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</tbody>
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RESOLUTION NO. 13

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) H. PUBLIC HEALTH AND RADIATION PROTECTION

10. PNEUMOCONIOSIS
The ACR and its constituent chapters will aid the National Institute of Occupational Safety and Health and the Department of Labor in quality control by whatever means may be most appropriate to local circumstances; adopted 1979, 1989, 1999, 2009 (Res. 1-g).

(b) I. RADIOLOGICAL PRACTICE AND ETHICS

5. MISCELLANEOUS RADIOLOGIC PRACTICE AND ETHICS POLICIES

I. Support of Clinical Patient Management by Vascular and Interventional Radiologists
The American College of Radiology (ACR) recognizes the importance of the development of a clinical service by interventional radiologists in order to appropriately manage patients.

The ACR opposes any attempt to prohibit vascular and interventional radiologists from being granted admitting and other clinical privileges based solely on their designation as radiologists.

The ACR affirms the importance of vascular and interventional radiologists establishing physician-patient relationships that are also customarily maintained by other physicians who provide comparable services.

The ACR encourages and supports the establishment of interventional radiology clinical services within the practice of radiology groups including the following:

- Establishment of an adequate clinical team.
- Dedicate adequate space for clinical visits.
- Inpatient admitting service.
- Dedicated time for seeing inpatients and patients in a clinic.
- Noninvasive vascular laboratory.
• Clerical services for scheduling, insurance authorization and billing of procedures and evaluation/management services.
• Support for time and materials for promotional and educational efforts; adopted 1999, 2009 (Res. 22-a).

(e) J. TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS

17. STATE LICENSURE OF MEDICAL RADIOLOGICAL PHYSICISTS

The American College of Radiology strongly supports the concept of state licensure and or equivalent rulemaking that recognizes board certification mechanisms for medical radiological physicists; adopted 1989, 1999, 2009 (Res. 1-i).

(d) L. THIRD PARTY CARRIERS AND COMPENSATION

2. ACR CARRIER ADVISORY COMMITTEE NETWORKS

The American College of Radiology shall develop a state model for coordination and communication of local Carrier Advisory Committee (CAC) activities.

The American College of Radiology shall encourage, assist and coordinate the maintenance of local sub-specialty advisory panels to aid local CAC members in the review of local carrier policies.

The American College of Radiology shall act as the central repository of communication and information for the radiology and radiation oncology CAC networks; adopted 1999, 2009 (Res. 30-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)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 14

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–ASNR–ASSR–SIR–SNIS Practice Parameter for The Performance of Image-Guided Epidural Steroid Injection

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


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 reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it

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

This practice parameter was developed collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS).

Interventional spine procedures comprise a broad spectrum of treatment techniques (e.g., facet joint and sacroiliac joint injections, vertebral augmentation) that are beyond the scope of this manuscript. This document focuses on epidural steroid injections (ESIs), which are commonly performed for the nonsurgical treatment of neck and low back pain (LBP) after other conservative and noninvasive treatments, such as physical therapy and oral medications, have failed [1]. It is critical to determine appropriate utilization of ESI and to identify optimal techniques. An added challenge in evaluating spinal interventional techniques is that the practices of different specialties are highly variable even for the commonly performed procedures and treatable conditions.

Although numerous studies pertaining to all aspects of interventional pain management have been published, there is still some controversy concerning the effectiveness of ESIs because of the variability of the methods in various studies [2] (FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM394286.pdf). Additionally, there have been technical advances in procedures that enable precise needle placement to a 1- to 2-mm target zone in 3-D space with confirmation of placement with the flow of contrast prior to the administration of the medication distribution by real-time observation of contrast flow [3].

Injections are often done for diagnostic and therapeutic benefit. Local anesthetic injection provides information regarding whether the pain generator is coming from the targeted location (ESI, intra-articular facet, nerve root, etc). The main controversy surrounding these injections is the therapeutic benefit derived from the steroid component of the injectate.

After the U.S. Food and Drug Administration (FDA) issued a warning in April 23, 2014, that “injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death” (https://www.fda.gov/Drugs/DrugSafety/), and a Warning was added to the drug labels of injectable corticosteroids to describe these risks. In response to this, an expert working group with facilitation from the FDA Safe Use Initiative and representatives from leading specialty societies reviewed the existing scientific evidence and assembled consensus clinical considerations aimed at reducing the risk of severe neurologic complications [4]. A review article by Manchikanti et al emphasized alternate techniques to traditional teachings, including avoidance of particulate steroids and utilization of a blunt needle, and understanding of the risk factors of approach, particularly transfemoralal ESIs, to improve safety [5]. With ESIs, as with any invasive procedure, the optimal outcome for the patient is when the appropriate procedure is performed by qualified physicians with consideration of all risks and benefits.

A review of the literature was performed. When published data were felt to be inadequate, data from the expert panel members’ own quality assurance programs were used to supplement. Thresholds for quality assurance have been updated in accordance with available data in the literature.

These practice parameters are intended to be used in quality improvement programs to assess ESI procedures. The most important processes of care are (1) patient selection, (2) performing the procedure, (3) monitoring the patient,
II. DEFINITIONS

The epidural space is essentially continuous from the craniocervical junction to the second sacral segment [6], with some anatomic compartmentalization by dorsal median connective tissue [7]. It is filled with compressible fat and venous structures [8]. The epidural space can be accessed using different approaches (eg, caudal, interlaminar, and transforaminal). Once the needle is in the epidural space, the medication is injected and epidurography with contrast media is usually performed to verify the proper needle position, and subsequently navigates cranially and caudally within the epidural space. ESIs are performed in the cervical and lumbar spine and less often in the thoracic spine.

Interlaminar ESI:

The epidural needle can be advanced in the midline between adjacent spinous processes or paramidline between the target laminae to traverse the ligamentum flavum and enter the dorsal epidural space. Although usually possible in all cases, in those patients with ossification of the supraspinous ligament or Baastrup disease, the paramidline approach may be preferred. Blunt-tip needles have been advocated for overall safety (eg, decrease risk of dural puncture [9]). Bevel tip orientation may result in inadvertent nonepidural needle penetration during fluoroscopically guided lumbar interlaminar ESI (ILESI), particularly if the needle is directed toward the superior lamina approach and the bevel tip is caudally orientated [10].

During an ILESI, inadvertent intrafacet injection [11] can occur because of needle entry into the retrodural space of Okada, an anatomic space located dorsal to the ligamentum flavum that allows communication between bilateral facet joints and the interspinous bursa at a single spinal level [12,13]. Needle entry into this space can mimic the loss of resistance normally felt during entrance into the epidural space. However, this nontarget delivery of medication results in decreased effectiveness of the procedure as the medication is not treating the intended pathology. The incidence of inadvertent intrafacet injection during attempted ILESI by using fluoroscopic guidance is reportedly 0.75% to 1.2% [14,15], which may be an underestimation, whereas that of ILESI performed under CT guidance is 7.5% [15]. Recognizing this false-positive position is important for redirection and appropriate needle tip placement. As such, CT-guidance can be of benefit in situations where conventional fluoroscopic guidance may be challenging or has proven unsuccessful.

The multispecialty FDA Safe Use Initiative Expert Working Group proposed that cervical ILESI be performed at C7-T1, which is based on reports that at other segmental levels the cervical epidural space is often narrow, making the dural sac and spinal cord more susceptible to penetration and injury [16-19].

Transforaminal ESI:

Although ESIs are effective in managing lumbar disc herniation regardless of the approach used (interlaminar, caudal, or transforaminal), the basic principle is to select the approach that will allow injection closest to the source of the pain. Corticosteroids delivered as close as technically feasible to the site of the lesion will generally obtain optimal results (and allows for lowest dose of medication for clinical effectiveness). The transforaminal approach for ESIs is a target-specific approach allowing maximal delivery of medication to the relevant nerve root. With this approach, the injectate flow is directed toward the anterior and lateral epidural space (ie, the inflammatory site between the herniated disc and the anterior nerve root dural sleeve), and may extend over 1 to 2 spinal levels [20,21]. For a lateralized lumbar disc herniation, a preganglionic transforaminal ESI (TFESI) (at the supra-adjacent intervertebral disc level or one level superior) is preferred by some over a paramidline interlaminar injection [22,23]. If there is migration of the disc, ganglionic TFESI (at the exiting nerve root level) may be useful [24].

In a lumbar TFESI, the needle may be placed in an intervertebral foramen via a subpedicular/supraneural or infraneural/retrodiscal approach. With the subpedicular approach, the needle is advanced inferior to the pedicle and superolateral to the spinal nerve of interest, toward the “safe triangle” [25]. The supraneural approach decreases risk of damage to the nerve, dorsal root ganglion, and dural sleeve [26,27]. The disadvantages of this approach...
include intraneural injection, neural trauma, technical difficulty in the presence of fusion and/or hardware, intravascular injection, intradiscal injection, and spinal cord trauma [28-35].

The infraneural/retrodiscal approach is an alternative TFESI trajectory using Kambin's triangle, which is defined as a right triangle over the dorsolateral disc [36]. In addition to avoiding epidural bleeding and scarring, the advantage of this approach is the decreased risk of intravascular penetration. Murthy et al. reported that the artery of Adamkiewicz (or artery) runs through the “safe triangle,” and this may result in injection of medications within the artery or directly damage a feeding vessel [37]. By spinal angiography, the radiculomedullary artery is located in the superior half of the intervertebral foramen in 97% of cases and is never seen in the inferior one-fifth of the intervertebral foramen [37]. The authors concluded that the safest needle placement for a TFESI, particularly at L3 and above, may be in an inferior and slightly posterior position within the foramen and relative to the nerve. Although there is decreased risk of injuring a radiculomedullary artery, this approach still carries 6.6% risk of vascular injections [38]. Although some authors have found the risk of inadvertent vascular injection during lumbosacral transfemoral injections comparable between blunt-tip and pencil-point needles [39], others have found that blunt needles had decreased incidence of vascular penetration and paresthesias [40]. Other risks of infraneural/retrodiscal TFESI include inadvertent intradiscal penetration (4.7%) [38,41] and subarachnoid or subdural extra-arachnoid injection (3.1%) [38].

In the cervical spine, a TFESI is performed by inserting the needle posteriorly along the neural foraminal axis, which avoids the anteriorly positioned vertebral artery and the intraforaminal spinal nerve. The interventionalist must be aware of spinal segmental arteries arising from the deep or ascending cervical artery, which enter at variable locations and often course through the foramen, penetrate the dura, and join the anterior and posterior spinal arteries. In addition to the risk of exiting nerve or vessel injury, injection of the particulate steroid directly into one of these vessels can lead to catastrophic spinal cord injury [4].

Given the potential of catastrophic neurologic complications after cervical TFESI, some authors have questioned the continued use of TFESI in this setting [42] and advocate interlaminar midline or paramidline approaches in the cervical spine regardless of disease categories or laterality of symptoms because of the overall safety of an interlaminar approach and possible greater patient comfort [24]. Choi et al. found no statistically significant difference in symptom improvement between interlaminar and transfemoral approaches [43] and lower inadvertent vascular uptake and patient discomfort with the latter. Others advocate technical strategies to improve the safety of the procedure [44,45] or alternative approaches, which potentially carry fewer risks [42,46]. One such alternative is intra-articular facet steroid injections [46,47]. Anatomically, the facet joint ventral recess is in close proximity to the exiting spinal nerve root, and leakage of contrast into the foramen can be seen during a facet injection. Therefore, using a facet joint injection approach to deliver corticosteroids in the vicinity of the target spinal nerve root may be a viable alternative to the riskier transfemoral approach [46,48].

Selective nerve root block:
A selective nerve root block has a similar approach as a TFESI; however, the needle tip is not advanced as medially into the neural foramen. Rather, the goal of this approach is to cover the target nerve, particularly when isolated spinal nerve root irritation is suspected. Selective nerve blocks are often requested to provide more specific diagnostic information via delivery in a selective fashion [49].

Caudal ESI:
The epidural space is accessed via the sacral canal through the sacral hiatus coccygeal ligament using fluoroscopic guidance [50]. With the caudal/interlaminar route, the flow of injectate is predominantly into the posterior epidural space [20]. This is an alternative approach when transfemoral or interlaminar approaches are technically challenging or contraindicated.

III. OVERVIEW

In the appropriate patient population, ESIs can improve mobility and function.
Multifactorial degenerative changes, such as herniated intervertebral disc material, thickening of the ligamentum flavum, and productive osteophyte formation along endplates and facet joints, are the leading cause of neck pain and LBP. A disc herniation may cause spinal nerve compression and inflammation, resulting in radicular pain [51]. The mechanical compression may result in nerve root microcirculatory changes, leading to ischemia, venous congestion, and inflammatory changes around nerve roots [52,53]. The ensuing intraneural edema and demyelination have been shown to be critical factors for the production of pain in association with nerve root compression [53]. There may also be a chemical radiculitis [54]. Because an inflammatory reaction is recognized as at least partly responsible for the irritation of the spinal nerve, corticosteroids are logically part of the treatment armamentarium. The injected corticosteroids contribute to pain reduction by interrupting the synthesis of prostaglandins, blocking conduction of nociceptive C fibers, and controlling edema around the nerve root [55-59].

For radiculopathy, the AHRQ report found that the evidence slightly favored ESIs over placebo interventions in mean improvement of pain and in function at immediate-term (≤2 weeks) follow-up and risk of surgery at short-term (>2 weeks to ≤3 months) follow-up [60]. However, there were no differences between ESIs and placebo interventions in likelihood of experiencing a successful pain, function, or composite outcome or likelihood of undergoing surgery in the long term [60]. There were no clear differential effects of the epidural approach used, different corticosteroids, different doses, use of imaging correlation, restriction to patients with herniated disc, duration of symptoms, or exclusion of patients with prior surgery. For spinal stenosis or nonradicular back pain treated with ESIs versus placebo interventions, the limited evidence showed no differences in outcomes related to pain or function [60]. Of note, the trials assessed used placebo interventions—such as epidural local anesthetic injection, epidural saline injection, soft-tissue injections, and no injection—and it is possible that these interventions may have had some therapeutic effects [61]. In addition, using different data points in different papers makes the literature less generalizable to the wider patient population. Other studies report that TFESIs and ILESIs are clinically effective for short-term and long-term relief of radicular pain and radiculopathy [51,62-64], although the paucity of high-quality randomized trials literature continues to confound the evidence.

The efficacy of ESIs is thought to be primarily due to the anti-inflammatory effect of the steroids by inhibiting phospholipase A1 and decreasing cell-mediated inflammation. Steroids may have additional effects: reversible local anesthesia [57,65-69], decreased transmission in unmyelinated C-fibers [70], diminished excess neurotransmitter release, dilution/dispersion of inflammatory compounds, alteration of the osmolality benefiting nerve function, suppression of the ectopic discharges from injured nerves, reduction of collagen formation/scarring, improvement of perfusion, and decreased capillary permeability/edema induced by herniated nucleus pulposus [65].

However, some studies have shown that epidural injections with or without steroids are efficacious in various spinal degenerative pathologies [5,71], suggesting that the mechanism of action of ESIs may not be the anti-inflammatory effect of the steroid as it is traditionally thought. Many corticosteroids activate not only the target glucocorticoid receptor (GR) but also the mineralocorticoid receptor, which may have proinflammatory effects countering the effects of GR activation [72]. A recent multicenter randomized controlled trial on ESI (interlaminar or transformaminal) for spinal stenosis, the largest trial (n = 386) to date in this population, found that epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone [73]. Similarly, a long-term randomized, double-blind, active-control trial of 120 patients comparing lumbar interlaminar epidural injections of local anesthetic with a mixture of local anesthetic and steroids found that lumbar interlaminar epidural injections of local anesthetic with or without steroids provide relief in a significant proportion of patients with lumbar-central spinal stenosis at 2 years follow-up [74].

Preservative-free local anesthetic, often added to the steroid injectate, inhibits nerve excitation/conduction by blocking sodium channels, suppresses nociceptive transmission, and decreases release of proinflammatory cytokines. The anti-inflammatory effects also contribute to long-term pain relief [75]. Caution should be used with anesthetic in cervical TFESI as inadvertent intravascular injection of bupivacaine can lead to arteriole vasospasms and increases the risk of central nervous system infarction [75]. Local anesthetics and steroids may affect other pathophysiologic mechanisms of chronic pain, including noxious peripheral stimulation, excess nociception,
resulting in the sensitization of the pain pathways at several neuronal levels, phenotype changes as part of neural
plasticity, and excess release of neurotransmitters causing complex central responses, including hyperalgesia
[74,76-83].

The neuromodulating effects of local anesthetics have been understudied and underappreciated. The mechanisms
of pathological pain have been well demonstrated in the literature. The pathological and neurochemical milieu is
different in acute nucleus pulposus rupture as compared to that in chronic spinal stenosis [84]. Cytokines and
interferon-y, among other proinflammatory agents, are not nearly as active in the nonacute setting. Anesthetics can
mitigate neurotransmitter release at the sites of injury and inhibit the physiological cause of pain. Short-acting
anesthetics are known to have a neuromodulating effect, possibly delaying or preventing the transition of acute pain
into the chronic pain syndromes. The individual biology and psychological effects of pain clearly adds to the
different patient outcomes [85]. The role of local anesthetic in the postoperative patient has been studied as well
and supports the concept of preventing acute migration into a chronic pain syndrome [86]. Rehabilitation after
injections can also play an additive positive role. Such is the reason that multidisciplinary teams are necessary for
the best outcomes, and most of the literature supports this integrative medicine.

The injected volume itself have analgesic effects, and higher volumes are associated with better outcomes [87,88].
The proposed mechanism may be that the injected fluid leads to the lysis of neural adhesions by means of stretching
along the dura and nerve roots [89].

IV. INDICATIONS AND CONTRAINDICATIONS

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

1. Radiculopathy: complex of symptoms that can arise from nerve root pathology, including paresthesia,
hypoesthesia, anesthesia, motor loss, and pain [90]; specific observable physical examination and
electrophysiologic findings. Radiculopathy may be confined to a single nerve root distribution (mono-), or
more than one (poly-).

2. Radicular pain: single symptom of pain that can arise from one or more cervical, thoracic, or lumbar spinal
nerve roots [90], which are inflamed and irritated [91]; diagnosed by a combination of physical
examinations (eg, straight leg test) and controlled selective nerve blocks. Radicular pain and radiculopathy
that are due to nerve root compression from local malignancy may also be amendable by palliative treatment
with ESIs.

3. Spinal stenosis: mechanical pressure on the spinal cord, dura, or nerve roots that is due to a multitude of
degenerative causes; pain, numbness, or upper- or lower-extremity weakness have a gradual onset and
improve with forward flexion, “shopping cart sign” [92]

4. Axial pain: symptoms exacerbated by forward flexion [92]; sources of axial LBP include the facet joint,
sacroiliac joint, intervertebral disc, vertebral end plates, paraspinal muscles, and fascia. These various
targets are beyond the scope of this document.

5. Postsurgery syndrome or failed back surgery syndrome (FBSS): residual or recurrent back pain and
disability after surgical intervention, which reportedly accounts for up to 40% of patients with chronic LBP.
It may be possible to manage some etiologies with interventional techniques, including epidural fibrosis,
sacroiliac joint pain, disc herniation, discogenic pain, spinal stenosis, recurrent synovial cysts, seromas,
other collections, and facet joint pain [93-100]. Caudal ESIs have been reported to be effective in managing
FBSS [101,102], with long-term pain relief achieved by adding hyaluronidase [102].

6. Persistent/incomplete pain relief following vertebral augmentation (kyphoplasty, vertebroplasty).

Contraindications [103,104]: Prior to performing an interventional spine procedure, pre-existing conditions must
be evaluated to avoid complications.
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Absolute contraindications:

1. Coagulopathy not correctible
2. Concurrent systemic infection
3. Infectious spondylitis
4. Acute spinal cord compression
5. Myelopathy or cauda equina syndrome
6. Inability to obtain informed consent

Relative contraindications:

1. Uncorrected anticoagulation therapy – ILESIs and TFESIs are considered intermediate-risk procedures with moderate risk of bleeding [105]
2. Local skin infection at the puncture site – An entry site avoiding the area of skin infection may be an option
3. Hypersensitivity to administered agents – allergy to contrast may be treated with premedication with antihistamine agents or an alternative approach (such as using CT guidance with air as the contrast medium may be considered.
4. Pregnancy – Although such interventions may be performed without image guidance in pregnant patients, there is a 30% rate of incorrect placement [106]. Other options include MRI-guided injections and ultrasound-guided injections as image-guided procedures have a significantly greater margin of safety and should be utilized when feasible [107].
5. Hepatitis – When performing neuraxial blockade in hepatitis C patients, thrombocytopenia must be excluded in order to avoid hematoma formation and its associated neurologic complications [108].
6. Uncontrolled diabetes mellitus- Insulin-dependent diabetics are at risk of elevated blood sugars after steroid injections.
7. Congestive heart failure – The steroid may lead to fluid retention
8. Immunosuppressed state- Preprocedural antibiotics may be considered
9. Patient improving on medical and physical therapy
10. Severe spinal canal stenosis
11. No response to previous well-performed ESI
12. Complication to steroid therapy (Cushings, etc)

Factors have been reported that negatively affect outcomes of ESIs: smoking, chronic pain syndrome, axial-only pain or diffuse pain, opioid dependence, and patients undergoing personal injury legal and disability claims [109].

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

In general, the requirements for physicians performing image-guided ESI may be met by adhering to the recommendations listed below:

1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of ESI procedures to demonstrate competency as attested by the supervising physician(s).

or

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

or

3. A physician who did not successfully complete an ACGME-approved radiology residency or fellowship
program that included the above may still be considered qualified to perform ESI provided the following
can be demonstrated: the physician must have at least 1 year of experience in performing percutaneous
image-guided spine procedures, during which the physician was supervised by a physician with active
privileges in these spine procedures. During this year, he or she must have performed (with supervision) a
sufficient number of image-guided spine interventional procedures, particularly ESIs as primary operator
with outcomes within the quality improvement thresholds of this practice parameter.

and

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must have written substantiation that they
are familiar with all of the following:

   a. Indications and contraindications for ESIs.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient, and
      particularly the recognition and initial management of procedural complications.
   c. Appropriate use and operation of fluoroscopic and radiographic equipment, digital subtraction systems,
      and other electronic imaging systems.
   d. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements, as well
      as principles of ALARA, as they apply to both patients and personnel.
   e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
   f. Pharmacology of contrast agents and implanted materials and recognition and treatment of potential
      adverse reactions to these substances.
   g. Technical aspects of performing this procedure. These include proper sterile techniques.

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the
chief of musculoskeletal radiology, the chief of interventional neuroradiology, or the chair of the department of the
institution in which the physician will be providing these services\(^2\). Substantiation could also come from a prior
institution in which the physician provided the services, but only at the discretion of the current interventional,
neurointerventional, or neuroradiology chief, or the chair who solicits the additional input.

and

5. Physicians must possess certain fundamental knowledge and skills that are required for the appropriate
application and safe performance of ESIs:
   a. In addition to a basic understanding of spinal anatomy, physiology, and pathophysiology, the physician
      must have sufficient knowledge of the clinical and imaging evaluation of patients with spinal disorders
      to determine those for whom ESIs are indicated.
   b. The physician must fully appreciate the benefits and risks of epidural steroids and the alternatives to
      the procedure.
   c. The physician is required to be competent in the use of fluoroscopy, CT, and MRI or interpretation of
      images in the modalities used to evaluate potential patients and guide the epidural steroid procedure.
   d. The physician should be able to recognize, interpret, and act immediately on image findings.
   e. The physician must have the ability, skills, and knowledge to evaluate the patient’s clinical status and
      to identify those patients who might be at increased risk, who may require additional perioperative care,
      or who have relative contraindications to the procedure.
   f. The physician must be capable of providing the initial clinical management of complications of ESIs,
      including administration of basic life support, initiation of treatment for cerebral/spinal cord ischemic
      injury, intrathecal anesthetic or steroid inadvertent injection, spinal fluid leaks, and recognition of spinal
      cord compression.

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\(^2\)At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ.
Training in radiation physics and safety is an important component of these requirements. Such training is important to maximize both patient and physician safety. It is highly recommended that the physician has adequate training in and be familiar with the principles of radiation exposure, the hazards of radiation exposure to both patients and radiologic personnel, and the radiation monitoring requirements for the imaging methods listed above.

Maintenance of Competence

Physicians should perform a sufficient number of ESI procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence depends on participation in a quality improvement program that monitors these rates. Regular attendance at postgraduate courses that provide continuing education on diagnostic and technical advances in ESIs is necessary.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [110].

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice 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 Physics 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), (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [110]

The appropriate subfield in medical physics for this practice parameter is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

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/ASRT (American Society of Radiologic Technologists) 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)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

D. Radiologic Technologist

The technologist, together with the physician and the nursing personnel, should be responsible for patient comfort. The technologist should be able to prepare and position the patient for the ESI procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under the supervision of the Qualified Medical Physicist.

The technologist should have appropriate training and experience in the ESI procedure and be certified by the American Registry of Radiologic Technologists (ARRT) and/or have an unrestricted state license.

E. Nursing Services

Nursing services are an integral part of the team for perioperative patient management and education and may assist the physician in monitoring the patient during the ESI procedure, particularly if conscious sedation is given.

VI. SPECIFICATIONS OF THE PROCEDURE

Technical Requirements

A. Guidance

1. No image guidance: Historically, ESIs were performed without any imaging guidance, resulting in erroneous placement in up to 30% of injections [106]. Because of this and the potential for intrathecal and intravascular injections, image guidance is strongly recommended for spine interventions.

2. Fluoroscopic guidance: According to the multi-specialty FDA Safe Use Initiative Expert Working Group, image guidance for all cervical and lumbar interlaminar injections is recommended to avoid inadvertent spinal cord penetration, intra-vascular, or intrathecal placement. Lateral or oblique views are recommended to gauge depth of needle insertion [4]. Fluoroscopic guidance allows accurate needle placement when combined with contrast medium injection [106,112,113]. Both C-arm and bi-plane fluoroscopy provide multiplanar imaging of the target anatomy, which can help reduce procedural time [114] and are important to perform the procedure safely.

3. CT/CT fluoroscopic guidance (CTF): CT guidance and CT-fluoroscopic guidance is being increasingly used for various procedures, including biopsies, drainages, ESIs and TFESIs, as this allows for highly accurate needle guidance. CT guidance delineates the soft tissue (eg, nerve, vessels, dura, fat, and muscle) and osseous structures unlike fluoroscopic guidance which only provides visualization of bony landmarks. Radiation dose to the patient and interventionalist can be minimized with the use of intermittent fluoroscopy and a low mA [115-117]. Additionally, modification of planning CT can reduce the radiation exposure in CTF lumbar spine injections [118]. CTF guidance enables real-time cross-sectional visualization of needle placement into the epidural space to avoid neural and vascular structures as well as osseous structures, particularly when there is spinal stenosis or interlaminar narrowing [119]. In addition, CT and CTF enable the evaluation of spinal canal and paraspinous regions before insertion of the needle, to permit diagnosis of synovial cysts or cysts of the ligamentum flavum, severe spinal stenosis, epidural scarring and postoperative thecal sac deformity in patients, which may be potential causes of inaccurate needle placement or procedure failure. CTF is the recommended approach for cervical ESI.

The overall radiation dose from CTF is small compared with a diagnostic CT scan. Tube current selection for CTF procedures ideally balances the need for adequate anatomic visualization against the desire for individual patient dose reduction. Patient body habitus affects the radiation dose from such procedures; decreasing body size results in increases in organ dose during CTF-guided interventions. Therefore, small patients should have tube current reduced compared to average patients to avoid relatively increased organ...
dose. Tube current of 30 to 40 mA is adequate for lumbar interventions in most average sized patients. Modified tube current settings of 10 to 20 mA and 50 to 70 mA would be appropriate for small and oversized patients, respectively [120]. However, dose considerations must not supersede the need for adequate anatomic visualization sufficient to allow for technical success and to minimize procedural complications.

4. Ultrasound (US): Ultrasonography is highly effective in accurately guiding the epidural needle placement and produces comparative treatment outcome as fluoroscopy [50]. US-guidance offers the advantages of delineating vessels in the needle trajectory [121] and no radiation exposure. However, US has significant limitations based on body habitus and pathology, and operator dependent skills, and is typically not used for performing these procedures.

B. Technique

With conventional fluoroscopy, the loss of resistance technique is used to determine if the needle is in the epidural space after traversing the ligamentum flavum in ILESI. However, this technique can be unreliable, compared with use of test injections of contrast material [122-125]. To confirm needle placement in the epidural space, a test dose of contrast agent is injected (0.1 to 0.3 mL). Myelographically safe contrast is used in case there is inadvertent intrathecal injection. Contrast is advocated in TFESIs, in particular, because of the increased risk of intravascular injections [31]. Intravascular uptake is reported at a rate of 8% for all lumbar injections, 2% for ILESI, 11% for TFESI, and 21% for TFESI at the S1 level [126]. Negative aspiration will fail to detect intravascular penetration ~50% of the time [31]. Some authors have cautioned that the lack of vessel opacification after contrast administration during a spine intervention with CT/CTF guidance may give a false sense of security [127] because it may be that intravascularly injected contrast is washed away by the time CT is performed and/or that the given vessel enters the cord at a different level and is therefore not imaged [128]. This may be a theoretical disadvantage of CT/CTF. To reliably exclude inadvertent direct vessel puncture, some have advocated real-time imaging with digital subtraction angiography when performed with fluoroscopy [129-131].

In patients that are severe or anaphylactic reaction to contrast media, CO₂ air can be used in the same way as iodinated contrast. Air can be injected to verify that the needle is within the epidural space and not intrathecal. Although air can be used with conventional fluoroscopy, CT-guidance provides exquisite discrimination between air and soft-tissue [132].

The choice of image guidance is a matter of operator preference and patient characteristics. In either case, there are several technical requirements to ensure safe and successful ESIs. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum requirements for any institution in which interventional spine pain management procedures are to be performed:

a. A procedural suite large enough to allow safe and straightforward transfer of the patient from bed to procedural table with sufficient space for appropriate positioning of patient monitoring equipment, anesthesia equipment, respirators, etc. There should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other staff within the room without contaminating the sterile conditions.

b. The majority of these procedures are performed under fluoroscopic guidance. A high-resolution image intensifier or flat-panel detector and video system with adequate shielding, capable of rapid imaging in orthogonal planes and with capabilities for permanent image recording is strongly recommended. The fluoroscope should be compliant with IEC 601-2-43 [133]. Imaging findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the “as low as reasonably achievable” (ALARA) radiation safety guidelines.
c. The facility must provide adequate resources for observing patients during and after spine pain interventional procedure. Physiologic monitoring devices appropriate to the patient’s needs—including blood pressure monitoring, pulse oximetry, and electrocardiography—and equipment for cardiopulmonary resuscitation must be available in the procedural suite.

C. Medications

1. Steroids

The steroids used in ESIs may be particulate versus nonparticulate preparations, which is based on the solubility of the synthetic corticosteroids within water and on their aggregation characteristics. Particulate corticosteroids, such as triamcinolone acetonide, triamcinolone hexacetonide, methylprednisolone acetate, and prednisolone acetate, are esters and can precipitate out of solution and crystallize within a hydrophilic environment. Most of the particles range in size between 0.5 and 100 μm [134]. Particulate steroids have a delayed but sustained anti-inflammatory effect [135]. In contrast, nonparticulate steroids dissolve immediately and are taken up rapidly by cells [135]. Dexamethasone sodium phosphate, a non-particulate steroid with a typical particle size of 0.5 μm [56,75,134], is freely water soluble. Betamethasone preparations are commonly a mixture of betamethasone acetate (insoluble needing esterase activation) and betamethasone sodium phosphate (in solution) and have characteristics of both particulate and nonparticulate steroids [56,75,134].

The propensity of different corticosteroid particles to aggregate into larger particles depends on the chemical ingredient (esters have larger particulate size), on the varying concentrations, on the drug vehicle, or on the drug mixtures with local anesthetics and/or contrast media prepared in situ for pain treatment [75]. These aggregates, particularly the larger particle sizes, have the potential to embolize with risk for occlusion of small vessels and subsequent neural ischemic injury [136]. Of the different steroids used for ESIs, dexamethasone sodium phosphate is considered safer because its particles have been shown to be the smallest size, approximately one-tenth the size of a red blood cell, and the particles do not aggregate, even in mixtures [56,136]. Given this pharmacokinetic profile, the multispecialty FDA Safe Use Initiative Expert Working Group has recommended dexamethasone as the first-line agent for lumbar transforaminal injections rather than particulate steroids [4], which have been implicated in all cases of severe neurologic complications. However, there has been a case of conus medullaris infarction after a TFESI using dexamethasone [137].

Although it may be speculated that patients obtain longer lasting relief of symptoms after epidural injection of particulate steroids compared with nonparticulate steroids, the literature is not strongly supportive of this at this time. The particulate nature and the added preservatives in the particulate mixtures pose the additional risk of intravascular emboli. Therefore, especially in the cervical spine, nonparticulate steroids are considered the safest. Recently, nonparticulate steroids (dexamethasone) have also been shown to have fewer systemic effects compared with particulate steroids in which suppression of the pituitary axis can occur for up to 3 weeks [138].

The differences in steroid doses and the effectiveness of various types have been evaluated in multiple observational studies. Methylprednisolone acetate, available in 40- and 80-mg/mL doses, and triamcinolone are equivalent [139] with relative strength approximately 5 times that of hydrocortisone. Bethamethasone combines a short- and long-acting form and has approximately 30 times the strength of hydrocortisone. A minimal effective dose of corticosteroid is recommended to expose the patient to the least adverse effects. For example, a study comparing 40 and 80 mg of methylprednisolone found comparable results, with a less adverse profile with the 40-mg dosage [140]. Similarly, there was equivalency of 10, 20, and 40 mg of triamcinolone in TFESI for lumbar radicular pain that was due to a herniated disc, such that the 10-mg dose was recommended by the authors [141].

PRACTICE PARAMETER Epidural Steroid Injection 2019 Resolution No. 14
There are numerous studies suggesting timing and frequency for ESI. A systematic review of literature by Manchikanti et al provides guidelines for frequency of interventions, regardless of approach [80]. The evidence is scanty for repeated injections at regular intervals if there is partial response to the initial ESI. Resolution of pain does not warrant a second injection.

Preservative-free local anesthetics inhibit nerve excitation and conduction. Local anesthetics act mainly through inhibition of sodium-specific ion channels on neuronal cell membranes, preventing the development of an action potential in the neuron, thus inhibiting signal conduction. They are administered to induce cutaneous analgesia at the time of a procedure and are also given for local relief at sites of spinal and musculoskeletal pain. Local anesthetics are often administered in conjunction with corticosteroids both as a diagnostic tool but also to provide the patient with immediate relief of symptoms.

There are two groups of local anesthetics: esters (eg, cocaine and procaine) and amides (lidocaine, bupivacaine, ropivacaine). The ester preparations are associated with a risk of severe allergic reactions secondary to the breakdown product paraaminobenzoic acid, whereas true allergic reactions are much less common with amide preparations. Increasing the dose of administered local anesthetic increases the degree of anesthesia and duration of action but does not change the time of onset of anesthesia. Nearly all these preparations can be formulated with epinephrine to prolong their duration of action by approximately 50% [142].

A review of corticosteroids and local anesthetics by MacMahon et al. [75] provides an overview on the potencies of local anesthetics used in spine interventions. Lidocaine is approximately half as potent as bupivacaine. Although lidocaine has a quicker onset, it has a shorter duration of action than does bupivacaine. Ropivacaine is similar in potency to bupivacaine. The most commonly administered local anesthetic in spine procedures is bupivacaine because of its greater potency and longer duration of action as compared with lidocaine. Typical doses of bupivacaine range from 0.5 to 2.0 mL in concentrations of 0.25% or 0.50%. Recommendations for maximum doses, although not evidence based, are meant to prevent toxicity. The maximum dose of lidocaine is 300 mg, and if there is added epinephrine, then the maximum dose increases to 500 mg. For bupivacaine, the maximum safe dose is approximately 150 mg (2 mg/kg) and that for ropivacaine is 375 mg. It is important to note that the plasma concentration of the anesthetic is affected by the site of injection, which is not taken into account by these doses.

The use of amide-type anesthetics in patients with known hypersensitivity is contraindicated. The most well-known and established adverse effects from local anesthetics are neuro- and cardiotoxicity after intravascular or inadvertent intrathecal injection [143]. Bupivacaine has greater neuro- and cardiotoxicity as compared to lidocaine and ropivacaine [75]. In the experimental setting, all local anesthetics are myotoxic in clinical concentrations, with a dose-dependent rate of toxicity [144,145] that is in part due to a fast and permanent increase in intracellular calcium levels [146]. However, in the clinical setting, myotoxicity is relatively rare because of rapid and complete recovery with complete tissue regeneration. Because most local anesthetics are vasodilators at clinical doses, epinephrine, a vasoconstrictor, is added in some mixtures to reduce the rate of drug absorption and increase the duration of anesthetic effect [147]. Mixtures with epinephrine and ropivacaine, which is vasoconstrictive, should be avoided in TFESI as this could potentially result in intravascular or perivascular injection and cause significant vasoconstriction of arterioles with increased risk of central nervous system (CNS) infarction.

Surgical and Emergency Support

Although serious complications of ESIs are infrequent, there should be prompt access to advanced imaging for diagnosis, surgical, interventional, and medical management of complications.
A. Patient Care

1. Preprocedural care
   a. The clinical history and findings, including the indications for the procedure, must be reviewed and recorded in the patient’s medical record by the physician performing the procedure. Specific inquiry should be made with respect to relevant medications, prior allergic reactions, and bleeding/clotting status. Refer to multisociety guidelines for interventional spine procedures in patients on antiplatelet and anticoagulant medications [148].
   b. The vital signs and the results of physical and neurological examinations may be obtained and recorded.
   c. The indication(s) for the procedure, including (if applicable) documentation of 6 weeks of physical therapy and failed medical therapy, must be recorded.
   d. Preprocedure imaging should be reviewed.
   e. Informed consent obtained prior to any sedation
   f. A formal “time out” and verification of the correct patient, along with a checklist introducing each member of the team, correct patient, correct consent, marking of site, anticipated blood loss, fire risk, medications, imaging, etc, is mandated to ensure proper patient site and location

Preprocedure imaging assessment of the posterior epidural space is important to determine that there is sufficient epidural space at the target segmental level to allow safe needle placement. Contents of the epidural space include the epidural fat, spinal nerves, extensive venous plexuses, lymphatics, and connective tissue (eg, plica mediana dorsalis and scar tissue after previous surgical intervention). The amount of posterior epidural fat increases with caudal progression, measuring approximately 0.4 mm at C7 to T1, 7.5 mm in the upper thoracic spine, 4.1 mm at the T11 to T12, and 4 to 7 mm in the lumbar regions [149,150]. Age and body weight affect the amount of posterior epidural fat [151,152], which decreases with age. Epidural lipomatosis (ie, excessive hypertrophy and abnormal accumulation of epidural fat) may also be seen with long-term exogenous steroid use, obesity, and ESIs.

There are important indications for reviewing imaging prior to performing an ESI. Although the randomized controlled trial by Cohen et al found that MRI does not improve outcomes in patients who are clinical candidates for ESI and has only a minor effect on decision making [153], cross-sectional imaging, particularly MRI, is helpful to exclude “red flags,” such as fracture, tumor, and instability, which would be unsafe conditions for injections. Secondly, MRI may help decide whether a patient will benefit from an ESI and improve outcomes by delineating the site of pathology for appropriate targeting [154]. A retrospective observational study examining the associations between imaging characteristics of compressive lesions and patient outcomes after lumbar TFESI found more favorable outcomes for disc herniations over fixed lesions and single lesions more than tandem lesions [155]. In a small prospective study of 34 patients with degenerative lumbar stenosis confirmed by MRI who received fluoroscopically guided lumbar TFESI at the presumed symptomatic nerve root, 75% had > 50% reduction in pain scores between pre- and postinjection at 1-year follow-up [26]. In patients with radiculopathy that is due to multilevel stenosis, MRI may steer one toward surgery or other treatment options rather than ESI. Lastly, MRI reveals features, such as central and foraminal stenosis, disc herniations that compromise canal diameter, ligamentum flavum hypertrophy, epidural fibrosis, and previous surgical scarring that can alter the level of procedural difficulty [156]. Previous surgical and epidural interventions (eg, epidural blood patch) at the targeted level may also alter the epidural space and surrounding tissue. The resulting inflammatory changes can cause connective tissue proliferation and adhesions between the dura mater and the ligamentum flavum and granulation changes in the ligamentum flavum [157].

2. Procedural Care
   a. Prior to the initiation of the procedure, a time-out verifying the correct patient, correct procedure and correct site must be performed. The organization should have processes and systems in place for reconciling differences in staff responses during the time-out.
   b. The multispecialty FDA Safe Use Initiative Expert Working Group recommends extension tubing after needle placement in a safe location to avoid dislodging it when syringes are connected [4]. As per guidelines of aseptic technique, face masks and sterile gloves should be worn [158].
c. Vital signs may be obtained at regular intervals during the course of the procedure depending on the preference of the interventionalist, and a record of these measurements should be maintained.

d. Some interventionalists may prefer that patients have intravenous access in place for the administration of fluids and medications as needed.

e. Monitoring of vital signs and pulse oximetry is recommended whether or not sedation is being given for the ESI procedure. Administration of sedation for ESI should be in accordance with the ACR–SIR Practice Parameter for Sedation/Analgesia [159]. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained. For cervical procedures, heavy sedation or unresponsiveness at the time of injection is not recommended [4]. Analysis of closed claims has revealed that cervical procedures under heavy sedation are significantly associated with an increased risk of spinal cord injury [160]. There is agreement by all societies that sedation should be light enough to allow the patient to communicate pain or other adverse sensations or events during the procedure, especially when performed in the cervical region [4].

3. Postprocedural Care

a. A procedural note should be written in the patient’s medical record summarizing the course of the procedure and what was accomplished, any immediate complications, and the patient’s status at the conclusion of the procedure (see complications section below). This information should be communicated to the referring physician in a timely manner.

b. All patients should be monitored after the procedure by skilled nurses or other appropriately trained personnel. The length of this period will depend on the patient’s medical condition and is at the discretion of the performing physician.

c. Initial ambulation of the patient must be carefully supervised.

d. The operating physician or a qualified designee (another physician or a nurse) should evaluate the patient after the initial postprocedural period, and these findings should be summarized in a progress note on the patient’s medical record. The physician or designee must be available for continuing postprocedural care at the facility and after discharge. Follow-up visits should be arranged prior to the patient leaving the facility.

VII. EQUIPMENT QUALITY CONTROL

Each facility should have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of imaging and interventional equipment. The quality control program should be designed to maximize the quality of the diagnostic information. This may be accomplished as part of a routine preventive maintenance program.

VIII. QUALITY IMPROVEMENT AND DOCUMENTATION

A. Documentation

Results of ESI procedures should be monitored on a continuous basis. Records should be kept of both immediate results and complications by the physician performing the procedure. If the patient is seen in follow-up, long-term results should be recorded. The number and type of complications should be documented. A permanent record of ESI procedures should be maintained in a retrievable image storage format.

1. Imaging labeling should include permanent identification containing:

a. Facility name and location

b. Examination date

c. Patient’s first and last names

d. Patient’s identification number and/or date of birth.

659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710
2. Separate preprocedure and postprocedure notes should include:
   a. Procedure undertaken and its purpose
   b. Type of anesthesia used (local or moderate)
   c. Listing of level(s) treated and amount of medication (contrast, steroid, and local anesthetic) injected at each level
   d. Evaluation of injection site and focused neurologic examination
   e. Immediate complications, if any, including treatment and outcome
   f. Radiation dose estimate (or fluoroscopy time and the number of images obtained on equipment that does not provide direct dosimetry information) [161-163]

3. Follow-up documentation:
   a. Postprocedure evaluation to assess patient response (pain relief, mobility improvement). Standardized assessment tools, such as the Visual Analog Scale, Short Form (36) Health Survey, and the Roland-Morris disability scale, may be useful for both preoperative and postoperative patient evaluation
   b. Evaluation of injection site and focused neurologic examination
   c. Delayed complications, if any, including treatment and outcome
   d. Record of communications with patient and referring physician
   e. Patient disposition

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [164].

B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must comply with the ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures [165].

Risks cited may include, but are not limited to, infection, bleeding (including epidural hematoma), allergic reaction, vessel injury, worsening pain or paralysis, spinal cord or nerve injury, arachnoiditis, or death. The potential need for immediate surgical intervention should be discussed. The possibility that the patient may or may not experience significant pain relief should also be discussed.

C. Success and Complication Thresholds

Procedure thresholds or overall thresholds, for example, major complications, may be used as part of ongoing quality assurance programs. 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 infection is one measure of the quality of ESI, values in excess of the defined threshold (1% to 2%) [126] 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. Patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality assurance program needs.

Complications can be 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 but may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix A). Routine tracking and periodic review of all cases having less than perfect outcomes is strongly encouraged. Although serious complications of ESIs are infrequent, a review for all instances of infection, significant bleeding, symptomatic nerve injury, or death, is recommended.
Success
When an ESI is performed, success is defined as achievement of significant pain relief, reduced disability, and/or improved quality of life. These should be measured by at least one of the relevant and validated measurement tools, such as the ten-point numerical pain rating scale score or a visual analogue scale score (Roland-Morris Back Pain score, Oswestry Disability Index, The Short Form (36) Health Survey, or similar outcome tool to measure pain, disability, and/or quality of life). It is generally accepted that a minimum of 20% change in pain scores is clinically meaningful, based upon previous trials and FDA requirements [166,167]. However, interventional pain management trials have adopted robust outcome measures defined as significant improvement with at least 50% improvement in pain and functional status rather than 10% or 20% improvement [101,168-186].

Complications
Despite its acceptance as a relatively safe procedure, an ESI is not without risk [187,188]. ESIs can be associated with a number of minor, temporary complications and side effects, such as exacerbation of pain, vasovagal reaction, headache, and unintentional dural puncture, [29,189-193]. Vasovagal syncope occurs in 1% to 2% of lumbar ESI and 8% with cervical ESI [194]. Flushing can occur in 2.6% to 11% of patients undergoing ESIs [195-198]. Transient weakness and numbness may be related to the local anesthetic (e.g., lidocaine).

Arachnoiditis
Although arachnoiditis has frequently been cited as a potential complication of ESI, there is actually no direct evidence to support this premise. The arachnoid villi allow microscopic communication between the subarachnoid and epidural spaces. In addition, macroscopic communications may pre-exist or be created by prior surgery. Inadvertent subarachnoid drug injection may occur via these routes or by improper needle placement. Thus, it has been postulated that subarachnoid injection of glucocorticoids may occur during ESI and thereby lead to the development of arachnoiditis. Published references to the potential development of arachnoiditis after ESI are based upon historic reports of patients developing arachnoiditis after receiving intrathecal methylprednisolone injections for the treatment of multiple sclerosis [199,200]. Arachnoiditis was not, however, reported in a large and more recent series of patients treated for herpetic neuralgia by intrathecal methylprednisolone injection [201]. Multiple large series of patients treated with ESI have not reported arachnoiditis as a complication [55,202]. Preservatives in the glucocorticoid solution, such as polyethylene glycol and benzyl alcohol [135,203,204], have also been questioned as potential cause of arachnoiditis, but direct causation has never been proven.

In contrast to intrathecal glucocorticoids, spinal surgery and subarachnoid hemorrhage are well documented as potential causes of arachnoiditis [205,206]. Arachnoiditis developing after a single lumbar puncture without any other known cause has also been reported [207]. Some of the patients treated for multiple sclerosis with intrathecal methylprednisolone received in excess of fifty such injections, and these injections were performed long before image guidance became widely used. It seems reasonable to conclude that iatrogenic subarachnoid hemorrhage occurred in at least some of these patients and that such hemorrhage might have caused arachnoiditis [199,200]. Notable by its absence is “arachnoiditis” among the multiple specific warnings for ESI mandated by the FDA [208]. The FDA does acknowledge 41 submitted reports of arachnoiditis allegedly occurring after ESI [209] but concluded that these reports “did not provide sufficient clinical detail to make a reasonable assessment regarding causality.” We were unable to identify any published report of arachnoiditis occurring after ESI in the absence of contemporaneous spinal surgery or subarachnoid hemorrhage.

Bleeding
Spinal hematoma is a rare but serious complication following epidural puncture (incidence less than 1:150,000) [210,211]. The pressure effects of epidural hematoma can lead to compression and/or ischemia of the spinal cord and/or nerve roots [212]. Particular care is needed in individuals with coagulopathy either from intrinsic medical problems or due to medication. There is a risk of 0.0% to 0.4% for hemorrhagic complications when continuing anticoagulants and 0.0% to 0.6% when continuing antiplatelet medications [213,214]. The risk of hemorrhagic complications in anticoagulated patients undergoing ILESIs [215-221] may not be the same for lumbar TFESI. As there may actually be more risk in discontinuing anticoagulants, thus increasing the risk for vascular or
cerebrovascular events, the benefits and risks of an ESI should be considered on an individual patient basis and after discussion with the clinician prescribing the anticoagulant [188,222].

Infection

Even with the use of proper sterile technique, infection can occur with spine interventions. Goodman et al noted an infection rate of 1% to 2%, with severe infections noted in 0.01% of all spinal injections, varying among meningitis, epidural abscess, osteomyelitis, and discitis [126].

Vascular Injury

The penetrating needle may cause vascular dissection. Embolic occlusion of a vessel with steroid aggregates, the majority of which are the particulate type, may occur. A rare, devastating complication of cervical and lumbar ESIs is spinal cord infarction, which is hypothesized to be due to embolization of particulate steroids, needle-induced vasospasm, compression from an epidural hematoma or abscess, and mechanical disruption of radiculomedullary arteries [56,223-225]. Preservatives, such as benzyl alcohol, in commercial preparations may be neurotoxic with reports of paraplegia, neural degeneration, and demyelination [226-229].

Nerve Injury

A theoretical risk of ESIs is nerve injury by the procedural needle. Intraneural hematoma may occur from puncture of the nerve root with the needle. Intraneural injection of the medication can be neurotoxic. An awake patient will be able to notify the interventionalist if the needle tip is too close to the nerve.

Dural Puncture

Dural puncture may occur, particularly with ILESI, and can lead to positional spinal headache. The incidence of dural puncture in a prospective, observational study of 10,000 procedures was 0.5%, with 1% in the cervical region [202]. Intrathecal injection of local anesthetic may result in variable levels of spinal block. Intrathecal injection in the cervical region may lead to respiratory depression; therefore, appropriate equipment should be readily available to treat the patient. As stated previously, the effects of intrathecal injection of corticosteroid remain of uncertain significance.

Systemic Effects

Corticosteroid therapy can have systemic effects, such as bone loss and osteoporosis [230]. This steroid effect on bone health is particularly concerning in patients with predisposition to osteoporosis, such as postmenopausal women, receiving ESIs. Retrospective evaluation of postmenopausal women with LBP who were treated with or without ESI showed decreased bone mineral density (BMD) in patients treated with ESI. However, there was no significant difference between or within the groups in terms of mean percentage change from baseline BMD [231]. These authors concluded that a maximum cumulative triamcinolone dose of 200 mg in one year would be a safe treatment method with no significant impact on BMD. Kim and Hwang showed that multiple ESIs with a cumulative triamcinolone dose of approximately 400 mg can reduce BMD in postmenopausal women treated for LBP [232]. Underlying patient characteristics may be an important factor in developing osteoporotic fracture or lower BMD post-ESI. Yi et al found that older age and lower BMD were associated with osteoporotic fracture in postmenopausal women treated for LBP with ESI [233].

The effect of steroids used in spine procedures remains controversial, with some studies showing that patients treated with high-dose glucocorticoid therapy are at risk for lower BMD [230,234,235], whereas others find no change with low-dose administration of neuraxial steroids [33]. A retrospective cohort study comparing patients receiving lumbar ESIs with a control group showed that an increasing number of injections was associated with an increasing likelihood of fractures. Each successive injection increased the risk of fracture by 21% [236]. A recent analysis of the Medicare data revealed that although acute exposure to exogenous steroids via the interlaminar or transforminal epidural space does not seem to increase the risk of an osteoporotic fracture (spine, hip, or wrist), the prolonged steroid exposure was found to increase the risk of spine fracture for ESI patients [237].
The steroids in ESIs can have endocrinological effects. They can increase blood glucose levels in diabetic patients for 2 to 3 days after an ESI [238-240]. Similarly, ESIs can suppress the hypothalamic-pituitary-adrenal (HPA) axis for up to 3 weeks [241,242]. Maillefert et al found decreased serum cortisol, Adrenocorticotropic hormone (ACTH), and urinary cortisol after the single epidural injection of 15 mg of dexamethasone acetate [243]. The levels returned to normal at day 21. This effect may be dose dependent. Hsu et al found that a single epidural injection of 40 mg of triamcinolone markedly decreased plasma cortisol for only 24 hours, whereas 80 mg resulted in a decrease for up to 14 days posttreatment; HPA axis function returned to normal within 35 days in both groups [244]. A recent article demonstrated fewer systemic effects (i.e., suppression of the pituitary axis for up to 3 weeks) with dexamethasone compared with particulate steroids [138].

Less common side effects have included elevated temperature, euphoria, depression, mood swings, transient changes in sleep pattern, local fat atrophy, depigmentation of the skin, and pain flare [187]. Several authors have reported cases of symptomatic epidural lipomatosis following epidural injections of corticosteroids [245-250]. Insomnia (39%), facial erythema (20%), nausea (20%), and rash and pruritus (8%) have been observed following betamethasone injection [187]. Finally, ESIs do not induce weight gain [251].

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) at 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).
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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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

ACR
Lubdha M. Shah, MD, Chair
Wende N. Gibbs, MD
John E. Jordan, MD, MPP, FACR

ASNR
Bassem A. Georgy, MD
A. Orlando Ortiz, MD, MBA, FACR
Kent B. Remley, MD

ASSR
John D. Barr, MD, FACR
Daniel T.D. Nguyen, MD
Jeffrey A. Stone, MD, FACR

SNIS
Kristine A. Blackham, MD
Allan L. Brook, MD, FACR
Joshua A. Hirsch, MD, FACR

Committee on Practice Parameters – Neuroradiology
(ACR Committee responsible for sponsoring the draft through the process)

Raymond K. Tu, MD, FACR, Chair
Kristine A. Blackham, MD
Brian A. Conley, MD
Kavita K. Ericksson, MD
Adam E. Flanders, MD
H. Simms Hardin, IV, MD
Steven W. Hetts, MD
John E. Jordan, MD, MPP, FACR

Jacqueline C. Junn, MD
Robert J. McDonald, MD
Alexander M. McKinney, IV, MD
David M. Mirsky, MD
Robin J. Mitnick, MD, FACR
Lubdha M. Shah, MD
Max Wintermark, MD

Alexander M. Norbash, MD, FACR, Chair, Commission on Neuroradiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Catherine J. Everett, MD, MBA, FACR, Chair
John E. Jordan, MD, MPP, FACR


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**Appendix A**

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

For further information see the *Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee*.

*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
BE IT RESOLVED, that the American College of Radiology adopt the ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology

Sponsored By: ACR Council Steering Committee

ACR–SIR–SNIS–SPR PRACTICE PARAMETER FOR THE CLINICAL PRACTICE OF INTERVENTIONAL RADIOLOGY

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.

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

This practice parameter has been developed, written, and revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), the Society of NeuroInterventional Surgery (SNIS), and the Society for Pediatric Radiology (SPR).

Interventional radiology is a medical specialty that focuses on diagnosis, treatment, and clinical management of patients using minimally invasive procedures guided by medical imaging. These clinical subspecialties of radiology are focused on minimally invasive, image-guided therapy for numerous diseases. This document identifies the common elements that define the clinical practice of “interventional radiologists,” inclusive of related subspecialties, such as pediatric interventional radiology, interventional oncology, and interventional neuroradiology.

An interventional radiologist or interventional neuroradiologist interacts directly with patients, and counsels evaluating and counseling them regarding their diseases and therapeutic options. Interventional therapy includes initial consultation, patient assessment, image-guided therapeutic interventions when appropriate and continues through time to eventual resolution of the clinical problem or establishment of an alternative care plan. To achieve these ends, it is necessary for the interventional radiologist or interventional neuroradiologist to see patients in a clinical practice setting and often in order to formulate and execute management plans. Traditional A clinical office space and privileges to manage patients in the hospital are essential.

In addition to the mandatory infrastructure requirements, there are benchmarks that define an interventional clinical practice. These benchmarks should be used as goals for developing the practice. Clinical An interventional radiologists and interventional neuroradiologists should be able to:

- Accept referrals for evaluation and therapeutic interventions as the sole or primary consultant for the disease process.
- Perform consultations prior to and following elective, urgent, or emergent interventions with a system to communicate these consultations back to the referring providers. referrers.
- Submit accurate claims and have the necessary billing support system.
- Inform patients referred for diagnostic imaging services and their referring providers about the spectrum of therapeutic options that might benefit them and provide interventional treatment if the patient desires.
- Establish, document, and implement treatment plans as medically indicated, without requiring the participation of another specialist.
- Admit patients as needed, who require inpatient care following therapeutic interventions. The interventional physician should have admitting privileges as required. Clinical coverage is required 24 hours a day, 7 days a week.
- Provide longitudinal patient care as appropriate.
- Submit accurate claims and have the necessary billing support system.
The following practice parameters should be used to develop an interventional clinical practice for both inpatient and outpatient clinical services [1-3]. Recommendations will include requirements concerning processes for handling referrals, physician-patient relationship, scheduling of invasive procedures, staffing, clinic space, time dedicated to clinical duties, equipment needs, clerical services, and continuous quality improvement programs.

II. THE CLINICAL TEAM

A. Interventional Radiologist or Interventional Neuroradiologist

The interventional radiologist or interventional neuroradiologist should be dedicated to the clinical management of patients and the performance of interventional procedures. The number of interventional radiologists and interventional neuroradiologists is based primarily on the volume of procedures performed and clinical care delivered. The interventional radiologist/neuroradiologist has the primary clinical responsibility as head of the team. He/she should be dedicated to the clinical management of patients and the performance of interventional procedures. Nonphysician practitioners can help improve the efficiency of the clinical practice, especially with regard to routine perioperative and follow-up care in the hospital or in the office.

B. Advanced Practice Provider Nonphysician Practitioner

Nonphysician practitioners Advanced practice providers (APPs) can help improve the efficiency of the clinical practice, and their training makes them valuable members of the interventional clinical team [4-7]. Include nurse practitioners (NPs), physician assistants (PAs), and radiologist assistants (RAs). These medical professionals can obtain medical histories, perform physical examinations, and participate with the interventional radiologist or interventional neuroradiologist in forming a clinical assessment and plan. Their clinical training makes them valuable members of the interventional clinical team.

A nonphysician practitioner employed by a radiology group may function as a member of the interventional team, delivering clinical care to the patient. Medicare and most other third-party payers allow them APPs to bill under their own identification numbers for the clinical services they provide. The nonphysician practitioner APPs can perform minor various interventional procedures, thereby increasing the productivity of the interventional clinical team. They should be trained and credentialed for the procedures they perform and their clinical activities.

Although physician assistants (PAs) and nurse practitioners (NPs) can function in a similar, if not identical manner, there are clear differences in the way they can practice as viewed or determined by the Centers for Medicare & Medicaid Services (CMS), regulatory agencies, and local hospitals. Interventional radiologists and interventional neuroradiologists are advised to consult with their local regulatory agencies and hospitals regarding the modes of practice that are acceptable in their regions.

C. Nursing

Registered nurses (RNs) play a critical role during providing clinical evaluation interventional procedures and can be used to augment clinical services. RNs can obtain vital signs, perform routine screening, review medications and allergies, and obtain “review of systems” during clinical evaluation. They can provide education to patients about procedures, management of catheters at home, and postprocedure instructions. RNs are also involved in administering medications during procedural sedation and interventional procedures. They are often the independent observers for monitoring patients during procedural sedation. For further information on sedation, see the ACR–SIR Practice Parameter for Sedation/Analgesia [8]. are not trained and/or may not be authorized to provide the types of clinical duties that the nonphysician practitioner provides.

The addition of a nurse coordinator to a clinical interventional team should be considered when there is a need to provide care adjunctive to that provided by the practitioner. Examples include, but are not limited to, obtaining portions of the history, gathering laboratory values, and speaking with family members, and organizing referrals to other clinical services. In the outpatient setting, adjunctive care might include obtaining vital signs, drawing blood, providing patient education, assisting with scheduling, and telephone consultation and follow-up with...
D. 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/ASRT (American Society of Radiologic Technologists) 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)

E. Radiologic Technologist

A radiologic technologist plays a critical role during interventional procedures. The radiologic technologist should be certified by the ARRT or have an unrestricted state license by the relevant authorities in their jurisdiction or country, with documented training and experience in interventional procedures. It is desirable for the technologist to have special certification in cardiac-interventional (CI) and/or vascular interventional (VI) radiography procedures (eg, RT [R] [CV]).

Radiologic technologists are not trained and are not authorized to perform the clinical duties of the nonphysician practitioner. However, the addition of a technologist to the interventional team is essential for patient care; they are skilled in the operation of equipment and instrumentation, image/data management, selected procedures, and quality assurance per hospital policy.

F. Certified Medical Assistant

The medical assistant plays a valuable role in a robust clinical practice. Within an outpatient clinic setting, the medical assistant facilitates patient flow and operational efficiency. A medical assistant can be tasked to prepare an examination room, chaperone patients throughout a large physical area (moving to and from rooms, blood draw areas, and imaging centers), acquire vital signs, and perform basic charting. The medical assistant contributes to efficient use of resources, performing activities that do not require higher levels of training possessed by the nurse, nonphysician practitioner APP, or physician, medical doctor.

III. ADMINISTRATIVE SERVICES

The required administrative personnel needed to run an office-based clinical practice ideally include a receptionist, an office manager, a scheduler, an individual to perform insurance precertification, personnel with knowledge of coding guidelines with experience and expertise in interventional coding and claims submission, and a compliance officer. In addition, personnel to perform data management and quality improvement are important. Individual staff members may perform more than one function.

The following elements are necessary to implement an effective quality program:

- A computer with a database such as the SIR HI-IQ™ for tracking outcomes (Other databases are available.)
- Resources to track procedures, outcome and quality data, and long-term follow-up
- Regular analysis of the quality of data and implementation of quality improvement actions

The following elements are highly desirable and contribute to quality control/continuous quality improvement:

- Participation in national databases or registries (which may become necessary for reimbursement and facility accreditation for some services)
Participation in structured reporting for quality assurance purposes

An individual may fulfill the responsibilities of more than one position. Many of these administrative services are already available in a clinic and could be expanded or modified to meet the additional needs.

IV. THE OUTPATIENT PRACTICE

The outpatient interventional clinic should be the cornerstone of any interventional clinical practice and serves as the “front door” through which most patients enter the practice. The outpatient clinic is essential in providing for provision of longitudinal care, including monitoring and surveillance of disease progression or recurrence. Many patients may require follow-up interventional or diagnostic studies. Longitudinal care is vital to the growth and future success of interventional practices and to the patient’s well-being.

In the outpatient clinic setting, the interventional radiologist or interventional neuroradiologist and support staff can perform the following duties while providing evaluation and management (E&M) services:

- Determining appropriate diagnostic workup
- Determining the need for and arranging consultation with other physicians
- Scheduling interventional procedures
- Obtaining insurance authorization for care
- Providing follow-up care, including postprocedure testing
- Providing counseling to patients and families visits

A. Space and Equipment

A successful interventional clinic practice requires quality a dedicated clinic space. Although placing the interventional clinic within the radiology department is certainly economical and convenient for the physician, it can be confusing to the outpatient who is expecting to see the interventional radiologist or interventional neuroradiologist in a traditional physician office setting. The interventional clinic is best designed as a conventional doctor’s office, with a waiting room, a receptionist, and a private and confidential examination room setting. This can be achieved using an office-sharing arrangement within a hospital-owned clinic or within another specialty clinic (eg, a surgical or internal medicine clinic).

There are many advantages to establishing an office practice outside the hospital (such as in a medical office building) or in a dedicated outpatient center within the hospital. They include patient comfort and privacy and an increased profile for the clinical practice among other doctors in the building, an increased understanding by the referring doctors of the practice’s level of commitment to longitudinal patient care, and an improved status with the hospital administration. Specifically, trying to perform routine clinical consultation in a holding/recovery area or in an interventional suite is not appropriate.

The examination room(s) should be large enough to accommodate an examination table, a sink, and chairs, and be wheelchair accessible if needed. Equipment requirements for the examination room(s)/clinic should include the following:

- Examination table
- Sphygmomanometer
- Stethoscope
- Educational material
- Desk
- Phone/intercom access for communication
- Emergency access bell/pull/alarm available at floor level
- Other devices as required by different subspecialties

Other office requirements should include the following:

- Space for storing medical equipment and medical records storage space

PRACTICE PARAMETER Intervventional Clinical Practice Resolution No. 15
Consultation space
Dictation/transcription capabilities
Facilities for viewing imaging and clinical information
Restroom facilities availability

A patient education room is an optional feature.

Additional equipment (such as a vein light, portable ultrasound machine, or portable Doppler) may be required for the interventional neuroradiology clinic in order to perform thorough neurological examinations.

B. Personnel

Whether in an office-sharing arrangement or in a freestanding interventional clinic, certain personnel may be required:

- Receptionist
- Scheduler
- Clerical support
- Nonphysician practitioner APPs, RN, or both
- Practice manager
- Coding and billing personnel
- Interventional radiologist physician

A single individual may fulfill the responsibilities of more than one position. A receptionist, for example, may provide typing/dictation service, and also manage medical records.

C. Time

Interventional clinics should ideally be staffed with doctors providers dedicated to seeing patients and not scheduled to perform procedures concurrently. The physician time recommended for evaluating new patients and providing adequate follow-up care for interventional patients is expected to be in the range of 5 to 15 hours per week. The exact time required will vary depending on the size of the practice. The weekly provider time recommended for new patient evaluations and established patient follow-up visits is at least 10% to 30% of the total weekly time dedicated to the interventional radiology practice. The exact percentage of time required will vary depending on the size and case mix of the practice. Practice parameters for time (including both physician and ancillary personnel time) allotted per clinic patient are can vary widely depending on the complexity of medical problem, but are usually in the range of 30 to 60 minutes for each a new patient visit and 15 to 30 minutes for each a follow-up patient visit.

D. Communication of Clinical Care

A written consultation report describing the preoperative clinical interaction with the patient detailing each patient’s clinical evaluation and treatment plan must be sent to the referring physician (and the clinical care team if necessary) in a timely fashion. It should be in the form of a letter, not an imaging report. The consultation should be filed and electronically signed within the patient’s electronic medical record (EMR). In addition, documentation of any postoperative care should be forwarded to the referring physician as well as to any other physician who may have an interest in the ongoing care of the patient.

V. THE INPATIENT PRACTICE

A. Inpatient Service Admitting Privileges

The ability to obtain hospital admitting privileges are is critical for a successful clinical interventional practice. It demonstrates that the interventional radiologist or interventional neuroradiologist is willing and able to take the lead
primary responsibility while the patient is in the hospital. This will also facilitate direct referrals to the interventional radiologist or interventional neuroradiologist. In circumstances wherein hospital-based physicians, hospitalists or specific physicians (such as pediatricians or critical care physicians) are available, the interventional radiologist interventionist or neurointerventionist might choose to work in conjunction with these providers.

The interventional radiology practice is often the best place to address periprocedure inpatient service allows management of patients during and after an interventional procedure, and complications that may arise, as well as the appropriate timing of hospital discharge and outpatient follow-up. Patients are admitted at the discretion of the interventional radiologist. IR physician. Examples include the following:

- Painful procedures that will require prolonged analgesia (e.g., uterine artery embolization)
- Procedures requiring prolonged monitoring (e.g., carotid stent)
- Procedures known to have greater than minimal risk (e.g., neuroendovascular procedures, new biliary tube, percutaneous nephrostomy, cancer therapy)
- Significant unexpected procedural complications
- Other considerations (e.g., advanced age, no home caregiver, home distant from hospital facility)

The number of physicians in the group who provide interventional services and have admitting privileges should be sufficient to provide 24-hour interventional call coverage. This includes managing the clinical problems that fall within the interventional radiologist’s or interventional neuroradiologist scope of practice as well as consulting other specialties as necessary.

Part of the duties of the inpatient service should be include daily clinical rounds, discharging inpatients admitted to the interventional radiology inpatient service, and arranging follow-up. Patients. The inpatients to be seen should include the following:

- Any patient who is admitted by the interventional practice
- Patients with a significant portion of his or her inpatient care managed by the interventional service, including patients with abscess drainage
- Any patient with a clinical problem that is being managed by the interventional practice in consultation

The physician inpatient visits can be performed in concert with the nonphysician practitioner visit. This strategy will ensure the most efficient use of physician time and help reduce costs while maintaining the personal contact provided to the patient by the interventional radiologist or interventional neuroradiologist.

B. Time Allocation

The time allocation for inpatient clinical duties includes the total time spent by the physician, nonphysician practitioner APP, and any other ancillary staff that the interventional radiologist or interventional neuroradiologist and hospital deems appropriate. The exact amount of time required for daily rounds and admissions will depend on the size of the practice and case mix.

The amount of time required will also depend on case mix. Practices performing large volumes of procedures such as arterial interventions, neurointerventions, chemoembolization, tumor ablation, uterine fibroid embolization, and abscess/drain management require more time for admissions and inpatient care.

C. Scheduling of Intervventional Procedures

It may be acceptable to schedule some invasive diagnostic radiology procedures, such as superficial biopsy or arthrography, based on a direct request from a physician’s office. Booking of invasive diagnostic most interventional procedures entailing therapeutic options or posing some degree of risk to the patient should be referred to the clinic for patient consultation with the interventional radiologist or interventional neuroradiologist prior to the procedure. The interventional radiologist or interventional neuroradiologist will examine the patient; formulate a care plan; determine the appropriateness of a requested procedure (if specifically requested); discuss
the risks, benefits, and alternatives to the procedure; obtain informed consent; and arrange for scheduling of the procedure.

VI. IMAGING REQUIREMENTS

Radiology departments must continue to take the lead in providing state-of-the-art imaging. Patients who may benefit from an interventional procedure are often seen first in the radiology department for imaging studies. These patients should be identified and the information promptly conveyed to the referring physician(s). This will help to optimize the use of interventional procedures in clinical practice. If the diagnostic radiologist interpreting the study is not familiar with the indications for a specific interventional procedure, he or she may consult with an interventional radiologist or interventional neuroradiologist.

Quality control mechanisms that track the imaging of potential interventional patients to guarantee that the imaging is performed with high quality and with a high level of service may be helpful in promoting interventional procedures. These goals are best accomplished in most radiology departments using a team approach. The critical points in the program include the following:

- Maintaining high-quality image interpretation. In many departments, this may require involvement of the interventional radiologist or interventional neuroradiologist in either a primary reading role or a support role.
- Identifying patients who may benefit from interventional procedures.
- Communicating knowledgeably about potential interventions to the referring physician.
- Educating potential referring physicians on the role of the interventional radiologist or interventional neuroradiologist in the evaluation and management (E&M) of those patients who are found to have treatable disease at the time of imaging. At times, this will be best accomplished by having the interventional radiologist or interventional neuroradiologist directly communicate with the referring physician.
- Providing the time necessary for the interventional radiologist or interventional neuroradiologist to participate in such a program.

These collaborative measures are in the interest of patient care and in the interest of the future growth of interventional radiology and interventional neuroradiology.

VII. INTERVENTIONAL SUITE REQUIREMENTS

This section summarizes the equipment required to operate a clinical interventional practice. This equipment needs to be located in a setting that provides the electrical service, air conditioning, air exchange, sterile conditions, room and task lighting, telephone, computer, and patient amenities required for these types of procedures. The setting may be within a hospital or in a sophisticated outpatient facility. The interventional suite must be of sufficient size to hold the imaging and nonradiographic equipment, provide easy access to the patient from multiple approaches, and accommodate the necessary life-support equipment. Interventional procedures may be performed in other parts of the Radiology Department, such as computed tomography (CT), ultrasound (US), and magnetic resonance imaging (MRI).

A. Radiographic Equipment

Fixed-installation fluoroscopy equipment designed and specified for interventional procedures is preferable [9,10]. The equipment parameters should be sufficient to perform interventional procedures. Some of these parameters include the following:

- Appropriately sized image receptor
- Permanent recording modes (eg, digital subtraction angiography (DSA), cine)
- Fluoroscopic tube focal spot(s), output, heat load, and cooling capacity
- Generator capacity
- Software packages
- Local modality image storage capacity
DICOM capability—ability to integrate with PACS

- Procedure-appropriate radiation dose-management tools
- Patient table weight limits

Biplane imaging and 3-D angiography are strongly recommended for the interventional neuroradiology practice. Cone-beam CT capability is very useful for interventional radiology and interventional neuroradiology procedures. Depending on patient size and user preference, large-bore CT scanners with CT fluoroscopy may be recommended for CT-guided interventions. Ultrasound equipment with high-quality near-field imaging and penetration is a critical component of most interventional practices.

Mobile fluoroscopy equipment may be adequate for some interventional procedures.

B. Patient Preparation Area and Recovery Room

Dedicated space should be allocated to hold inpatients and outpatients while awaiting procedures or transport, to observe patients prior to transfer to the wards, and for recovery of outpatients. The amount of space should be appropriate to the clinical practice and may require up to four beds per interventional suite. This could include space in a dedicated recovery area, not necessarily in the radiology department. This space requires oxygen, suction, physiologic monitoring capability, a telephone, computer (or mobile device), and ready access to resuscitation equipment, as well as call button/emergency access/alarm capability at floor level. An efficient preprocedure and recovery area is important for a high-volume practice.

C. Medical/Surgical Supply Inventory

The dedicated interventional suite must have sufficient storage for commonly used equipment, as well as an inventory control system. This space should be located close to the suite.

The following items relevant to inventory should be considered when developing an interventional practice suite:

- Sufficient facility budgetary commitment to sustain the supply and disposable equipment needs of the suite
- Dedicated personnel responsible for inventory management
- An inventory control system, ideally with barcode-reading capability

D. Nonradiographic Equipment

The modern interventional suite often requires other invasive and noninvasive equipment for nonradiographic imaging and interventions. The following list of such essential equipment is intended to serve as a guide:

- Oxygen and suction
- Physiologic monitors
- Resuscitation equipment
- Image-viewing facilities
- Readily accessible secure storage for drugs, including those that require refrigerated storage
- Communication equipment (eg, telephone, mobile devices)
- Ceiling-mounted or mobile operating room light
- For programs that provide pediatric interventions, equipment and supplies appropriately sized and configured for procedures in children [2]

E. Staffing

Nurse staffing levels should be sufficient to provide at least one qualified individual to monitor each patient for the patient in each procedure. This nurse provides patient care and monitoring and may perform other departmental activities such as quality assurance. Nurses providing sedation should be appropriately trained and credentialed for sedation needs. In addition, the recovery room area should be appropriately staffed with RNs, nurses, or APPs so as to care for patients recovering from moderate sedation, as well as patients that may require higher nurse-to-patient ratios, such as critically ill patients and pediatric patients.
Radiologic technologist staffing levels should be sufficient to provide a one to two technologists per procedure room. The technologist will assist with the case, perform imaging functions, inventory, cleanup, room preparation, image or digital image processing, and data entry.

To achieve consistent coverage, the above staffing recommendations should be considered in light of local staffing factors. This will require greater than one full-time equivalent (FTE) per procedure room to cover vacations, sick time, and educational leave and can vary from 1.2 to approximately 1.8 FTEs per staff position depending on the benefit levels and number of shifts per day.

F. Physiological Monitoring Equipment

The interventional suite must be capable of monitoring critically ill patients and patients under moderate sedation and/or general anesthesia. The ability to monitor blood pressure, heart rate, electrocardiogram (ECG), and pulse oximetry and to perform invasive pressure measurements must be available at a minimum. Capnography is desirable.

A paper printer connected to the physiological monitor device is desirable to produce a permanent hardcopy of any selected physiological parameter. Direct transmittal of intra-procedural physiological monitoring data to the EMR is ideal. Alternatively, a paper printer should be available to produce a permanent hardcopy of any selected physiological parameter. In addition, point-of-care testing facilities to obtain desirable laboratory tests (such as activated clotting time, serum creatinine, serum potassium, etc) improve efficiency of patient care.

VIII. PRACTICE DEVELOPMENT

The preservation and development of an interventional radiology–based clinical office practice has unique challenges and requires regular attention with a multifaceted approach. The goal is to inform referring physicians and the public of the services offered and to provide reliable service with a reputation for availability and consistency [11,12].

A. Communications

Written communication is the primary means by which a clinical practice interacts with its referring community. Letters should have a letterhead that reflects the practice’s interventional radiology focus. Letters should not resemble imaging reports. Copies of letters should be sent to all doctors important in the care of the patient and should always include the primary care doctor when he or she is not the referring doctor. In practices that use electronic communications, this correspondence can be provided electronically.

B. Website

The letterhead and any brochure of the interventional practice should ideally provide a website address through which referring physicians and the public can find details about the interventional physicians and the services provided by the practice as well as reliable location and contact information. Social media has taken on increasing importance in marketing directly both to connecting patients and referring physicians, and this avenue starts with a robust website. Search engine optimization (SEO) has developed as a useful tool to ensure high visibility of an interventional practice on a local, regional, and national level. With a visually appealing and highly informative website as a base, interventionists can generate direct outreach to promote visibility in the community.

C. Personal Contact

An analysis of key imaging referrals through the larger radiology practice can lead to identification of physicians or physician groups to whom direct contact should be targeted with personal phone calls, visits, and educational
D. Education

Active attendance and participation in multidisciplinary conferences within the hospital are important signals of commitment and availability. Ongoing interaction with potential referring doctors can also be accomplished through grand rounds on topics for which interventional services are available and sponsorship or cosponsorship of educational symposia or dinners with presentations by local, regional, or national interventionists. Availability should be made of patient-oriented educational brochures covering routinely treated diseases for referring physicians to distribute to their patients. These brochures should be informative and present interventional services in a balanced way and should also be available in the interventional waiting room.

E. Practice Promotion

Public education through radio, television, local newspapers, and magazines with announcements of new physicians, new procedures, and new research is an important supplement to mailing such notification directly to physicians and nonphysician practitioners APPs, medical directors of practices, and practice managers. Emphasizing board certifications, specialty training, and other unique achievements is also important. In larger practices, having individual interventional radiologists and interventional neuroradiologists subspecialize along broad disease categories or service lines may enhance promotion. For example, an interventional radiologist that specializes in uterine fibroid embolization can serve as the primary contact person in that practice for the referring gynecologists. Such an interventionist benefits from increased familiarity with referring physicians and individual patient groups. Similarly, scheduling clinic days around the specific disease entities or service lines will provide continuity for referring physicians.

F. Other Considerations

Whenever possible, a physician’s presence and connection solidifies relationships with the referring physician community. In larger hospital settings, this may entail direct contact with a referring physician’s office. Best practice outpatient interventional clinics often have physical proximity to a referrer’s clinic.

IX. QUALITY IMPROVEMENT AND PRACTICE EVALUATION

Maintaining and improving quality is a cornerstone of all of the practice parameter and technical standard programs of the ACR. This optimizes patient care and is required by The Joint Commission in the hospital setting. Established programs of continual practice evaluation and quality improvement are a requirement of all current interventional practices [13]. Participation in ongoing practice assessment, including ongoing professional practice evaluation (OPPE) and focused ongoing practice evaluation (FPPE) as warranted, is required by The Joint Commission. Practice Quality Improvement (PQI) has also become a is an important core competency of the American Board of Radiology (ABR) and Maintenance of Certification (MOC) for successful interventional radiology clinical programs. The PQI initiative is a framework to facilitate improvement of medical care and/or its delivery as an individual, group, or institution. Participating in mortality and morbidity conferences, with review of practice complications or adverse outcomes, are also beneficial to continual practice improvement. In addition, the interventional radiology clinical practice should participate in the ongoing quality metrics as required by the institution, CMS, and other government agencies.

Quality parameters should be set according to the published data and relevant national societal guidelines. This pertains to both the clinical aspects of an interventional practice as well as the technical outcomes of the procedures. Areas of concern or improvement should be identified and addressed. If a problem or area of improvement is identified, actions designed to improve quality should be made, and the actions should be monitored and documented to ensure improvement.
Individual physician outcomes data are also necessary for granting and maintaining physician privileges. Outcomes data are an important means to inform referring physicians of the benefits of referring patients to interventional radiology and interventional neuroradiology practices.

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment.

X. RADIATION SAFETY 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).

Two personal dosimeters, one worn under the protective apron and a second worn at neck level above protective garments, are preferred and should be used in the fluoroscopically guided-procedure environment. Alternatively, a single personal dosimeter worn at neck level, above protective garments, may be used if it complies with state or local regulations.
These dosimeters should be monitored by the Radiation Safety Officer.

XI. EVALUATION AND MANAGEMENT

An intelligent framework for documenting and reporting E&M interactions is a requirement for any successful clinical interventional practice. For all clinical interactions, a robust system of documentation and coding is the first step toward ensuring the clinic is compliant with coding guidelines. Critical aspects of E&M coding include, but are not limited to, the following elements [14]:

- Reimbursement for E&M services require appropriate selection of Current Procedural Terminology® (CPT®) codes that best capture patient type, setting of service, and level of service performed;
- The patient type can be either new or established patients;
- The setting of the E&M service typically falls into the categories of outpatient visits, hospital inpatients, or consultations;
- The level of E&M service is determined by three key components: history, physical examination, and medical decision making;
- Documentation of history and physical examination can be categorized as problem-focused, expanded problem-focused, detailed, or comprehensive services;
- Documentation of medical decision making can be categorized into one of four levels of increasing complexity of care;
- New patients require documentation of all three components, whereas established patient encounters only require two components;
- Documentation of these components can be waived if greater than 50% of the visit was utilized to provide counseling and coordination of care. The total visit time then needs to be documented;
- Federal and state policies guide E&M reimbursement for nurse practitioners and physician assistants.

A facile comprehension of documentation and coding increases the likelihood of being in compliance with coding guidelines and prompt and accurate payor reimbursement for individual visits. By following proper practice parameters, downstream benefits accrue to an interventional clinical practice with an organized system [15].

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Collaborative Committee – members represent their societies in the initial and final revision of this technical standard

ACR
Sanjeeva P. Kalva, MD, Chair
Timothy J. Carmody, MD, FACP
Kevin W. Dickey, MD, FSIR
Suvarnu Ganguli, MD
Joshua A. Hirsch, MD, FACP
Matthew Lungren, MD

SNIS
Guilherme Dabus, MD

SIR
Aparna Annam, DO
Kevin M. Baskin, MD
Waleska M. Pabon-Ramos, MD

SPR
Jared R. Green, MD

PRACTICE PARAMETER

Interventional Clinical Practice
Resolution No. 15
PRACTICE PARAMETER

Interventional Clinical Practice

Resolution No. 15

NOT FOR PUBLICATION, QUOTATION, OR CITATION

Mahesh V. Jayaraman, MD
Richard P. Klucznik, MD, FACR

Craig M. Johnson, DO

616

Committee on Practice Parameters – Interventional and Cardiovascular Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Clayton K. Trimmer, DO, FACR, FAOCR, FSIR, Chair
Chaitanya Ahuja, MBBS
Drew M. Caplin, MD
Douglas M. Coldwell, MD, PhD
Mandeep S. Dagli, MD
Kevin W. Dickey, MD
Joshua A. Hirsh, MD, FACR, FSIR
Kelvin Hong, MD, FSIR

Elizabeth A. Ignacio, MD, FSIR
Sanjeeva P. Kalva, MD, FSIR
Claire Kaufman, MD
Kenneth F. Layton, MD, FACR
Margaret Hsin-Shung Lee, MD, FACR
John D. Prologo, MD
Sanjit Tewari, MD

617

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACR

618

Alan H. Matsumoto, MD, FACR, Chair, Commission on Interventional and Cardiovascular Radiology
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

620

Comments Reconciliation Committee

Samir B. Patel, MD, FACR, Chair
Daniel Ortiz, MD, Co-Chair
Aparna Annam, DO
Richard A. Barsh, MD, FACR
Kevin M. Baskin, MD
Jacqueline A. Bello, MD, FACR
Lynn A. Brody, MD
Timothy J. Carmody, MD, FACR
Bairbre Connolly, MD
Harry R. Cramer, MD
John Crowley, MD
Guilherme Dabus, MD
Kevin W. Dicke, MD, FSIR
Richard Duszak, Jr., MD, FACR
Laura K. Findeiss, MD
Suvranu Ganguli, MD
Jared R. Green, MD
Atul K. Gupta, MD

Manraj K.S. Heran, MD
Joshua A. Hirsh, MD, FACR
Mahesh V. Jayaraman, MD
Craig M. Johnson, DO
Sanjeeva P. Kalva, MD
Clair Kaufman, MD
Richard P. Klucznik, MD
Paul A. Larson, MD, FACR
Matthew Lungren, MD
Alan H. Matsumoto, MD, FACR
Jason W. Mitchell, MD
Mary S. Newell, MD, FACR
Waleska M. Pabon-Ramos, MD
Matthew S. Pollack, MD, FACR
Michael S. Stecker, MD
Timothy L. Swan, MD, FACR
Clayton K. Trimmer, DO, FACR
REFERENCES


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**PRACTICE PARAMETER**

**Interventional Clinical Practice**

**Resolution No. 15**

**Development Chronology for this Practice Parameter**

- 2004 (Resolution 24)
- Amended 2006 (Resolution 34)
- Revised 2009 (Resolution 24)
- Revised 2014 (Resolution 18)
BE IT RESOLVED,
    that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Spectroscopy of the Central Nervous System

Sponsored By:       ACR Council Steering Committee

ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF MAGNETIC RESONANCE SPECTROSCOPY OF THE CENTRAL NERVOUS SYSTEM

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, ___ N.W.2d ___ (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), the American Society of Neuroradiology (ASNR), and the Society for Pediatric Radiology (SPR).

Magnetic resonance spectroscopy (MRS) is a proven and useful method for the evaluation, assessment of severity, therapeutic planning, posttherapeutic monitoring, and follow-up of diseases of the brain and other regions of the body [1-4]. It should be performed only for a valid medical reason. While MRS can be useful in the diagnosis and management of patients, its findings may be misleading if not closely correlated with clinical history, physical examination, laboratory results, and diagnostic imaging studies. Adherence to these practice parameters optimizes the benefit of MRS for patients.

II. INDICATIONS

When conventional imaging by magnetic resonance imaging (MRI) or computed tomography (CT) provides limited information regarding specific clinical questions, indications for MRS in adults and children include, but are not limited to, the following:

1. Evidence or suspicion of primary or secondary neoplasm (pretreatment and posttreatment)
2. Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma [5,6]
3. Evidence or suspicion of brain infection, especially cerebral abscess (pretreatment and posttreatment) and HIV-related infections
4. Seizures, especially temporal lobe epilepsy
5. Evidence or suspicion of neurodegenerative disease, especially Alzheimer’s disease, Parkinson’s disease, and Huntington’s disease [7-9]
6. Evidence or suspicion of subclinical or clinical hepatic encephalopathy
7. Evidence or suspicion of an inherited metabolic disorder, such as Canavan disease, mitochondrial encephalopathies, and other leukodystrophies [10,11]
8. Suspicion of acute brain ischemia or infarction, including birth asphyxia [12]
9. Evidence or suspicion of a demyelination or dysmyelination disorder [13-16]
10. Evidence or suspicion of traumatic brain injury
11. Evidence or suspicion of brain developmental abnormality and cerebral palsy
12. Evidence or suspicion of other neurodegenerative diseases, such as amyotrophic lateral sclerosis
13. Evidence or suspicion of chronic pain syndromes
14. Evidence or suspicion of chromosomal and inherited neurocutaneous disorders, such as neurofibromatosis and tuberous sclerosis
15. Evidence or suspicion of neurotoxicity, such as misuse of medications, and exposure to environmental hazards, such as carbon monoxide and inhalants
16. Evidence or suspicion of hypoxic ischemic encephalopathy
17. Evidence or suspicion of spinal cord disorders, such as tumors, demyelination, infection, and trauma
18. Evidence of neuropsychiatric disorders, such as depression, posttraumatic stress syndrome, and schizophrenia [17-26]

19. Differentiation between recurrent tumor and treatment-related changes or radiation injury

20. Differentiation of cystic lesions (eg, abscess versus cystic metastasis or cystic primary neoplasm)

21. Evidence or suspicion of cerebral vasculitis, systemic lupus erythematosus (SLE), and neuropsychiatric systemic lupus erythematosus (NPSLE)

22. Evaluation of response to treatment of neurological disorders (eg, tumor evaluation)

23. **Detection of 2-hydroxyglutarate (2-HG) in suspected IDH1 mutant gliomas**

24. **Developmental delay**

25. **Evaluation of response to treatment of metabolic disorders**

### III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [27].

The physician supervising and interpreting MRS must understand the specific questions to be answered before the procedure in order to plan and perform the study safely and effectively.

### IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI), the ACR Manual on Contrast Media, and the ACR Guidance Document on MR Safe Practices [27-29].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis.

### V. SPECIFICATIONS OF THE EXAMINATION

#### A. Written Request for the Examination

The written or electronic request for MRS of the central nervous system (CNS) 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)

Reasonable efforts should be made to ensure that all **pertinent** prior imaging of the region in question is available to the interpreting physician/spectroscopist at the time of the study.

#### B. 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 and all other persons entering the MRI safety zone must be screened
and interviewed (if their condition permits) before 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 [30].)

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of sedation may be needed to achieve a successful examination. If sedation is necessary, it should be administered by appropriately certified personnel (see the ACR–SIR Practice Parameter for Sedation/Analgesia [31]).

C. 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.

D. Examination Technique

Physicians and/or spectroscopists using MRS should understand the artifacts and limitations of the MR pulse sequences. MRS involves the application of various MR pulse sequences that are designed to provide a range of capabilities. These include the following:

1. STEAM (stimulated echo acquisition mode) that uses three 90° radiofrequency (RF) pulses for volume selection.
2. PRESS (point-resolved spectroscopy) that uses a 90° excitation pulse plus two 180° refocusing RF pulses for volume selection.

The physician and/or spectroscopist should understand the differences between the PRESS and STEAM techniques.

Other basic pulse sequences for spectral data acquisition are available commercially.

The physician and/or spectroscopist performing the study should understand how the history and physical examination affect the choice of technique (including location of voxel placement), repetition time (TR), and echo time (TE) for the examination and how the metabolite peaks are affected by changes in the TE. The physician and/or spectroscopist performing and the physician interpreting the examination should be knowledgeable about the normal metabolites and their relative concentrations, as well as the spectra that could be anticipated for the diagnostic entities being considered in the patient. All examinations are interpreted by physicians.

E. Guidelines for Performing MRS, Including the Choice of Echo Time

1. Short echo time (eg, 20–40 ms)

   Short TE is useful in demonstrating myoinositol (MI), glutamine/glutamate (Glx), amino acids, lactate, and lipids. These metabolites are useful in characterizing most neurological diseases, such as tumors, metabolic and neurodegenerative disorders, seizures, chronic pain syndrome, and disorders of myelination. They are also useful in monitoring therapy for these diseases. This is the recommended TE if only one MRS sequence is considered for the examination; however, the choice of TE would also depend on the clinical indication. For example, in the characterization of neurodegenerative disorders such as Alzheimer’s disease, short TE MRS is recommended to ensure that information on metabolites is only detected with short TE MRS, such as MI and the Glx complexes, is obtained.
2. Intermediate echo (eg, 288-144 ms)
Intermediate TE has a number of advantages over short TE MRS but provides information on fewer metabolites. Intermediate TE can be performed for the following reasons:

a. In differentiating lactate and alanine from lipids around 1.3 to 1.4 ppm by J-modulation/inversion of the lactate and alanine doublet peaks. However, it should be noted that J-modulation is field-strength dependent. While lactate peak inversion is a reasonably consistent phenomenon at 1.5T field strength, it is variable at 3T, which could cause a false-negative results [32].

b. Better-defined baseline and less baseline distortion compared with short TE.

c. No artifactual n-acetylaspartate (NAA). Peak in the 2.0 to 2.05 range can only be attributed to NAA rather than superimposed Glx complex peaks in the 2.05 to 2.5 ppm range.

d. Presence of lipids may imply more significance than when observed at short TE.

e. More reproducibility and accuracy, particularly for quantifying Cho and NAA peaks.

f. Provide optimal identification of 2-HG in IDH1 mutant glioma imaged at 3T.

3. Long echo time (eg, 270-288 ms)
At longer TE (longer than 144 ms), there is less signal from NAA, Cho, and Cr relative to the baseline noise; hence, the signal-to-noise ratio (SNR) is lower than that at short and intermediate TE measurements because of the T2 decay of metabolites. The recommendation is to acquire MRS data at short TE and, time permitting, to include an intermediate echo time acquisition for the reasons stated above. Long TE can be used if the user has experience and normative data for comparison. However, a long TE MRS may be primarily performed on 3T scanners for a more accurate depiction of lactate levels [32].

4. Chemical shift imaging (CSI) or MRS imaging (MRSI)
MRSI or CSI, either 2-D or 3-D, obtain spectroscopic information from multiple adjacent volumes over a large volume of interest in a single measurement. They have better resolution and sample metabolites over a larger region of interest than other techniques, facilitating evaluation for focal as well as global neurological processes. CSI can be combined with conventional MRI because spectral patterns and metabolite concentrations can be overlaid on grayscale conventional imaging to compare voxels containing normal parenchyma and voxels containing pathology and also to obtain distributional patterns of specific metabolites. It also allows for comparison and normalization of pathologic spectra to spectra in normal tissue. However, caution must be exercised regarding artifacts, such as chemical-shift artifact, voxel bleeding, and voxel contamination, when using commercially available CSI sequences.

The physician, technologist, and/or spectroscopist performing the examination must understand how voxel placement and regional variation can impact the distribution and relative concentration of the metabolites in different parts of the brain. The placement of voxels over the ventricles and near the bony calvarium can also affect the water suppression and cause susceptibility, affecting the shim and quality of the spectra. affects diagnostic accuracy.

When investigating focal disease, it is recommended that multivoxel MRSI be used, as this will provide MRS samples from heterogeneous areas within a focal lesion as well as some normal tissue voxels for a comparison. If multivoxel is not available, single voxel can be used; having a second voxel in normal tissue for comparison would also be recommended.

When investigating diffuse brain or spinal cord disease, single-voxel MRS can be used, as the MRS changes should be found diffusely.

The voxel size, thickness, and matrix should be determined by the disease process, the extent of disease, its location, and a compromise between obtaining sufficient SNR and reducing volume averaging through normal tissue.
The physician and/or spectroscopist performing and the physician interpreting MRS should recognize artifacts that are due to poor shimming, improper water suppression, lipid contamination, chemical shift artifact/misregistration, and/or poor voxel placement.

MRS can be used in the setting of contrast without significant detriment to the quality of the spectra.

5. Technical consideration in MRS
Adequate shimming narrows peak widths, increases SNR, and improves water suppression. Single-voxel spectra are easier to shim than multivoxel spectra, and higher shimming is needed with voxels placed at the periphery compared to the center of the brain.

Single-voxel PRESS MRS is used most often in routine clinical practice for pediatrics. Appropriate placement of voxel requires knowledge of the clinical indications for the MRS and region of the brain potentially affected by the disease process. An incorrect voxel placement may result in nondiagnostic MRS. Inclusion of the ventricle in a voxel should be avoided. The MRS should be reviewed by the radiologist in conjunction with the routine MR image and preferably before the patient has been removed from the scanner.

Pediatric MRS can be acquired at 1.5T and 3T; the higher SNR of 3T potentially allows for decreases in image acquisition time and/or smaller voxel size with the marginal compromise of somewhat wider metabolite peaks using short TEs at 3T [33].

MRS is routinely performed with short TE (35 ms versus 20-40 ms), intermediate TE (144 ms versus 97-144 ms), and/or long TE (288 ms versus 270-288 ms); short TE technique provides for higher SNR and depiction of all metabolites. Preferred voxel size is 2 × 2 × 2 cm or 2 cm cubed (8 cc). Smaller voxels may be needed to avoid partial volume effects; voxel size should be at least 4 cc.

6. Detection of specific metabolites
Glycine and MI resonate at 3.5 ppm and 3.56 ppm, respectively, and pathologic evaluations of glycine in nonketotic hyperglycinemia may be masked by myo-inositol at short TE. At intermediate TE values, myo-inositol normally decreases while glycine does not, and intermediate or long TE, in addition to short TE, should be acquired in neonates with clinical suspicion of nonketotic hyperglycinemia [34].

The 2016 World Health Organization (WHO) CNS classification presents major restructuring of the diffuse gliomas, medulloblastomas, and other embryonal tumors and incorporates new entities that are defined by both histology and molecular features, including glioblastoma, IDH-wildtype, and glioblastoma, IDH-mutant. The reclassification of glioblastoma and gliomas based on IDH mutation acknowledges significant differences in glioma biology, therapeutic triage, and outcome. As a result, the application of MRS in characterizing the molecular subtypes of glioma is important [35].

The physician should be familiar with MRS in normal neonates and young infants. Age-related differences in metabolites in normal neonates include high myo-inositol levels. The NAA levels are also lower in neonates up until 24 months. In these early years, macromolecules/lipids at 0.8 and 1.3 ppm may also be present as the brain myelinates.

7. Multinuclear MRS
Besides proton hydrogen-1 (\(^1\)H) MRS, other nuclei for MRS that can be used include helium-3 (\(^3\)He), lithium-7 (\(^7\)Li), carbon-13 (\(^13\)C), oxygen-17 (\(^17\)O), fluorine-19 (\(^19\)F), sodium-23 (\(^23\)Na), phosphorus-31 (\(^31\)P), and xenon-129 (\(^129\)Xe). It is recommended that multinuclear MRS be performed using a field strength of at least 3T. Some of the reasons for the recommendation to use higher field strength are:

a. Lower gyromagnetic ratio compared with \(^1\)H.
b. Lower sensitivity that will be mitigated by the higher SNR provided by higher B0 at 1.5T resulting in poorer signal to noise ratio (SNR) at 1.5T.
c. Longer measurement times at 1.5T.
d. Low spatial resolution at 1.5T.
e. Multiplets – needed to decouple to demonstrate the metabolites adequately.

a. Lower abundance of the nuclei compared with 1H.
b. Lower spectral resolution at 1.5T.

c. In poorer signal-to-noise ratio (SNR) at 1.5T resulting in longer measurement times at 1.5T.  
d. Low spatial resolution at 1.5T.

e. Multiplets – needed to decouple to demonstrate the metabolites adequately.

Phosphorus-31, 19F, and 13C have demonstrated some utility in neuro-oncologic evaluations [36]. Phosphorus-31 MRS provides information on cellular energy metabolism, membrane phosphates, and intracellular pH. Compared with proton spectroscopy (1H MRS), the clinical utility of 31P MRS has been limited, which is due in part to the necessity for hardware modifications (coils), the relatively large volumes of tissue required (resulting in partial volume effects through necrotic regions), and the sometimes subtle metabolite changes when the spectra are reviewed visually. Cellular energy metabolism is represented by adenosine triphosphate (ATP), phosphocreatine (PCr), and inorganic phosphate (Pi). The phosphodiester (PDE) and phosphor monoester (PME) compounds are from membrane phospholipids. In high-grade glial tumors (HGGT), such as glioblastoma multiforme, there is alkalization (pH: 7.12), an increase in PME, and a decrease in PDE/α-ATP with no significant changes in PCr/α-ATP or PCr/Pi ratios. The metabolite resonances in HGGT may sometimes be reduced by the presence of necrosis. As expected, HGGT will express higher levels of phosphatidylcholine compared with low-grade glial tumors. Meningiomas are characterized by an alkalinity (pH: 7.16), a decrease in phosphocreatine, and decreased PDEs. Proton-decoupled 31P (31P-[1H]) and 1H MRS may eventually be used in a multinuclear, multi-TE approach to neurologic diseases.

8. Ultra-high-field MRS (beyond 3T) is FDA approved and can be performed clinically at field strengths up to 7T for neurological and extremity applications and up to 3T for other sites. The safety and clinical application efficacy of MRS for ultra-high field spectroscopy beyond 3T are still under investigation. There are technical challenges however, the ability to resolve metabolites not usually demonstrated at lower field strengths and only when using proton MRS suggests that ultra-high field spectroscopy is likely to have a place in the near future.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [37].

The report should describe the peaks visualized in the spectrum, the relative heights of the peaks, or relative concentrations of the metabolites. It should attempt to address the potential etiologies suggested by any abnormalities found.

VII. EQUIPMENT SPECIFICATIONS

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 magnetic field strength, maximum RFpower 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Specific policies and procedures related to MR safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MR physician. Guidelines should be provided that deal with potential hazards associated with the MR 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 MR examination.

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of MRI Equipment [38].

Follow-up pathology and laboratory results and diagnoses are needed to correlate radiology and pathology findings and should be actively sought whenever possible as part of any quality control or quality improvement program.

ACKNOWLEDGEMENTS

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

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

ACR
Meng Law, MD, Chair
David A. Joyner, MD
Whitney B. Pope, MD
Nancy K. Rollins, MD

ASNR
Kavita K. Erickson, MD
Raymond K. Tu, MD, FACP

SPR
S. Srinivas Ganapathy, MD
Saurabh Guleria, MD

Committee on Practice Parameters – Neuroradiology
(ACR Committee responsible for sponsoring the draft through the process)

Raymond K. Tu, MD, FACP, Chair
Kristine A. Blackham, MD
Brian A. Conley, MD
Kavita K. Erickson, MD
Adam E. Flanders, MD
H. Simms Hardin, IV, MD
Steven W. Hetts, MD
John E. Jordan, MD, MPP, FACP

Jacqueline C. Junn, MD
Robert J. McDonald, MD
Alexander M. McKinney, IV, MD
David M. Mirsky, MD
Robin J. Mitnick, MD, FACP
Lubdha M. Shah, MD
Max Wintermark, MD

PRACTICE PARAMETER

MR Spectroscopy

2019 Resolution No. 16
Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair           Kerri A. Highmore, MD
Timothy J. Carmody, MD, FACR                       Sue C. Kaste, DO
Tara M. Catanzano, MB, BCh                             Terry L. Levin, MD, FACR
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Matthew S Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Colin M. Segovis, MD, PhD, Chair                  Paul A. Larson, MD, FACR
Kevin L. Smith, MD, FACR, Co-Chair                  Meng Law, MD
Richard A. Barth, MD, FACR                        Mary S. Newell, MD, FACR
Jacqueline A. Bello, MD, FACR                        Beverley Newman, MB, BCh, BSc, FACR
Richard Duszak, Jr., MD, FACR                        Alexander M. Norbash, MD, FACR
Kavita K. Erickson, MD                                Matthew S. Pollack, MD, FACR
S. Srinivas Ganapathy, MD                          Whitney B. Pope, MD
Saurabh Guleria, MD                                   Nancy K. Rollins, MD
Steven W. Hetts, MD                                    Timothy L. Swan, MD, FACR
David A. Joyner, MD                                  Matthew Whitehead, MD

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*Practice 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 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 9)
Amended 2006 (Resolution 35)
Revised 2008 (Resolution 19)
Revised 2013 (Resolution 7)
Amended 2014 (Resolution 39)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the 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 2013 (Resolution 6)*

ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF MAGNETIC RESONANCE IMAGING (MRI) OF THE 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.

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

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

Magnetic resonance imaging (MRI) of the brain is a proven and well-established imaging modality in the evaluation and assessment of normal and abnormal conditions of the brain. MRI of the brain is the most sensitive technique available because of its high sensitivity in exploiting inherent contrast differences of tissues as a result of variable magnetic relaxation properties and magnetic susceptibilities. MRI is a rapidly changing evolving technology, and ongoing technical improvements advancements will continue to improve MRI the diagnosis of brain disorders. This practice parameter outlines the principles for performing high-quality MRI of the brain.

II. INDICATIONS

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

1. Neoplastic conditions or other mass or mass-like conditions of the brain parenchyma, meninges, or cranium, either primary or secondary [1-8] [9]

2. Vascular
   a. Acute ischemia and infarction [9-15]
   b. Chronic vascular disease [16-19]
   c. Vascular malformations, such as developmental venous anomaly, capillary telangiectasia, cavernous angioma, arteriovenous malformation, arteriovenous fistulas and aneurysm [20-22]
   d. Arterial or venous/dural venous sinus abnormalities, including congenital and acquired disorders and thrombosis [23,24]
   e. Additionally, MR angiography/arteriography (MRA) and MR venography (MRV) may provide more detailed noninvasive vascular information. (See the ACR–ASNR–SNIS–SPR Practice Parameter for the Performance of Cervicocerebral Magnetic Resonance Angiography [MRA] [25].)

3. Congenital disorders and anatomical abnormalities, including the evaluation of brain maturation [26-29]

4. Congenital or acquired neurodegenerative disorders [16,30-34]

5. Congenital or acquired hydrocephalus [35,36]

6. Metabolic, nutritional, and dysmyelinating disorders [37-39]

7. Trauma [40-43]
   a. Certain benefits over computed tomography (CT), such as detection of diffuse axonal injury
   b. Assessment of unexplained posttraumatic neurological deficits
   c. Posttraumatic brain injury
   d. Nonaccidental trauma

8. Hemorrhage
   a. Certain benefits over CT, such as determining the age of hemorrhage, evaluation of chronic hemorrhage, and detection of microhemorrhages [44,45]
   b. MRI with gradient echo/susceptibility weighted axial imaging has sensitivity comparable to or higher to that of CT in specific settings, such as detection of hemorrhagic transformation in the rapid evaluation of acute ischemic stroke [46].
9. Inflammatory and autoimmune disorders, including disorders of demyelination [47-50]
10. Infectious disorders: encephalitis, meningitis, empyema, abscess [51-53]
11. Endocrine disorders [54,55]

   a. High-resolution assessment of hypothalamic/pituitary axis

12. Evaluation of the cranial nerve anatomy or pathology nerves [56]
13. Epilepsy and movement disorders [33,57-61]
14. Organic psychiatric disorders [62]
15. Follow-up of treatment, including iatrogenic sequelae such as radiation necrosis [63-66]
16. Image guidance for treatment planning, surgery, or interventional [67-71] (see the ACR–ASNR Practice Parameter for the Performance of Non-Breast MRI-Guided Procedures [72])
17. Evaluation of headaches with associated neurological findings or suspected brain structural abnormality [73,74]
18. Elevated or decreased intracranial pressure
19. For further characterization of abnormalities (or suspected abnormalities) detected on other imaging tests (eg, CT or sonography)

Extended indications for brain MRI include techniques that provide additional real-time, dynamic, or quantitative information that assists in therapeutic guidance or clinical decision making.

1. Cerebral spinal fluid (CSF) flow, blood flow, and brain perfusion [13,35,36,75-79]
2. Spectroscopy [10,38,76,80-83]
3. Functional imaging [67,84-87]
4. Volumetry [16,31,88]
5. Morphometry [61,62,89]
6. Diffusion tensor imaging/diffusion kurtosis/tractography [29,90-95]
7. Combination with positron emission tomography [96-98]
8. Radiogenomics [99]
9. Radiomics [100]

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [101].

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI), the ACR Manual on Contrast Media, and the ACR Guidance Document on MR Safe Practices [101].

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis.

V. 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 [102-105]. The physician must be familiar with potential hazards associated with MRI including conditional, legacy, or unsafe implants; foreign bodies; 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 [106].)

The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.
The clinical request form should be initiated by the referring physician or any appropriate allied health care professional acting within his or her scope of practice. It should contain pertinent information regarding the clinical indication for the procedure.

The written or electronic request for MRI of the brain 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)

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 and all other persons entering the MRI safety zone (employees and nonemployees) must be screened and interviewed (when their condition permits) prior to the examination to exclude individuals who may be at risk by exposure to the MRI 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. Patients receiving IV gadolinium chelates should be evaluated for risk factors or contraindications to IV MRI contrast media, especially the potential risk of nephrogenic systemic fibrosis (NSF) [107]. (See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media, the ACR Manual on Contrast Media, the ACR Guidance Document on MR Safe Practices, and the ACR website.)

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Sedation of pediatric patients (and in some cases nonsedated patients) may benefit from child life support staff. Administration of anxiolytics or 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 [108].

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

MRI examination of the brain can be performed on closed and open MRI systems of various field strengths using a local surface coil (head coil) and a wide array of pulse sequences [7, 10, 12, 26, 28, 32, 33, 36, 49, 50, 53, 54, 76, 85, 86, 109-131]. This is a rapidly evolving field, and the appropriate pulse sequences and plane of imaging must be individualized and tailored to the clinical question at hand under the supervision of the MRI physician. The most commonly accepted basic imaging protocols. A typical imaging protocol for MRI of the brain currently includes a sagittal T1-weighted sequence in the sagittal plane (or a T1-weighted volumetric acquisition), and axial T2-weighted and axial T2-weighted fluid-attenuated inversion recovery (FLAIR), and fast spin-echo or turbo-spin-echo (or equivalent) sequences in the axial plane. If T2-weighted FLAIR is not available or used in children under the age of 2 years, proton density–weighted sequences may be performed helpful. Under certain clinical circumstances (uncooperative or pediatric patients), very rapid acquisitions, such as echo planar imaging or single-shot fast spin-echo imaging, can be performed to obtain T2 information. Diffusion imaging is essential for if available, is helpful in many indications, particularly in the assessment of infarction, abscess, epidermoid lesion, active demyelination, and hypercellular neoplasm. Inclusion of gradient recall echo (GRE) or susceptibility weighted imaging (SWI) markedly improves the detection/assessment of calcifications, microhemorrhages, and intravascular thrombosis. The entire brain should be covered in the respective axial and/or coronal and/or sagittal imaging planes multiple imaging planes. (See the Clinical Image Quality Guide section of the ACR MR Accreditation Program Testing Instructions.)

The recovery time (TR) and echo time (TE) required to optimize image quality depends on the field strength of the magnet. These parameters must therefore be adjusted by the supervising physician for image optimization. For example, lower-field-strength magnets may require lower TRs, whereas higher-field-strength magnets may require longer TRs for image optimization.

Slice thickness, spatial resolution, signal-to-noise ratio, acquisition time, and contrast are all interrelated. To optimize spatial resolution, imaging of the brain should be performed with a slice thickness of no greater than 5 mm and an interslice gap of no greater than 2.5 mm. Thinner slices (less than 5 mm) and smaller interslice gaps (less than 2.5 mm) may or interleaved images without a slice gap provide superior image detail if clinical circumstances warrant.

Gadolinium chelates may be administered by IV when there is suspicion of breakdown of the blood-brain barrier [6, 132-135]. Recently, controversy has arisen regarding reports of gadolinium deposition in tissues, and questions have been raised about the safety of these chelates [136, 137]. The clinical significance of tissue deposition remains unknown, but most experts believe that gadolinium chelates are safe. However, any contrast agent should only be administered under the supervision of a physician when clinically indicated [136]. Alternatives to gadolinium chelates might also be contemplated in the appropriate setting [138]. Postcontrast images, when indicated, should be obtained in at least one plane but preferably in two or more perpendicular planes. With one plane being the same as the precontrast series, with short TR and TE sequences (T1-weighted) (Alternatively, one postcontrast series could be obtained using a T1-weighted volumetric acquisition.) Postcontrast FLAIR images may add value in the assessment of leptomeningeal disease [139]. (Please see the ACR Manual on Contrast Media [140].)

With the advent of high-performance gradient coil assemblies, and amplifiers, and other technical enhancements, advanced imaging applications are also an option when with the appropriate hardware and software exist. Improvements in the receiver and data acquisition systems also allow for more rapid imaging. Higher-field-strength MR (eg. 3T and 7T) may provide added utility in some clinical situations [57, 141-147].

While a detailed discussion of all the evolving advanced imaging techniques is beyond the scope of this practice parameter, it should be noted that rapid pulse sequences and other advanced imaging techniques may provide added value for MRI of the brain [148]. These can include, but are not limited to, echo planar imaging [149], parallel imaging [32, 110, 119, 150, 151], diffusion-weighted imaging [50, 109, 112, 152-158], diffusion-tensor imaging [28, 29, 91, 92, 94, 110, 123, 156, 159-162], rapid gradient echo pulse sequences (capable of providing T1 or T2
information and enabling 3-D acquisitions) [163], SWI [164-170], functional imaging [159,171-186], perfusion imaging [187-194], volumetric [36,195-199], morphometric [200-210], magnetic source imaging [211], and other quantitative applications [156,212-222]. When considering T1- and/or T2-weighted 3D image acquisitions, it is essential to weigh benefits of efficiency against levels of diagnostic confidence. The latter may vary widely across imaging providers and may require extensive testing and consensus before implementing 3D sequences into diagnostic imaging protocols.

Certain clinical circumstances may warrant the use of proton MR spectroscopy [80-82,223-229] as an adjunct to routine MR brain imaging. (See the ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Spectroscopy of the Central Nervous System [230].) Additional techniques that may be useful under the appropriate clinical circumstances include 3-D imaging techniques [231-234], neuronavigation, and intraoperative MRI [68,115,124,235], magnetization transfer imaging [236-240], CSF flow study using phase-contrast pulse sequences [241], and variations of single-shot fast spin-echo or turbo spin-echo imaging.

It is the responsibility of the supervising physician to determine whether additional pulse sequences or nonconventional pulse sequences and imaging techniques confer added benefit for the diagnosis and management of the patient. Generally, MRI examination of the brain should be performed within parameters approved by the Food and Drug Administration (FDA). Examinations that use techniques not approved by the FDA can be considered when they are judged to be medically appropriate.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [106].

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 magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels [242,243].

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Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [244].
ACKNOWLEDGEMENT

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<tbody>
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<td>Mariaem M. Andres, MD</td>
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<tr>
<td>Timothy J. Carmody, MD, FACR</td>
<td>Adam E. Flanders, MD</td>
<td>Carolina V Guimaraes, MD</td>
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<tr>
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Committee on Practice Parameters – Neuroradiology
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Brian A. Conley, MD | David M. Mirsky, MD |
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H. Simms Hardin, IV, MD | Raymond K. Tu, MD, FACR, Chair |
John E. Jordan, MD, MPP, FACR | Max Wintermark, MD |
Jacqueline C. Junn, MD |

Committee on Practice Parameters – Pediatric Radiology
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Comments Reconciliation Committee

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Mariaem M. Andres, MD
Colin M. Segovis, MD, PhD, Co-Chair
Johnson B. Lightfoote, MD, FACR, Chair

REFERENCES


PRACTICE PARAMETER

MRI of the Brain

2019 Resolution No. 17


PRACTICE PARAMETER

MRI of the Brain

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Revised 2013 (Resolution 8)*

ACR–ASNR PRACTICE PARAMETER FOR THE PERFORMANCE OF NON-BREAST MAGNETIC RESONANCE IMAGING (MRI) GUIDED 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 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

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Recent hardware and software improvements in magnetic resonance imaging (MRI) have resulted in an expanding and evolving role for image guidance during interventional or surgical procedures in multiple organ systems. Pulse sequence improvements have allowed for the development of rapid imaging methods as well as advances in MRI-compatible equipment.

The major benefits of using MRI for procedure guidance and monitoring are [1,2]:

1. The ability to continuously visualize vascular structures during the entire procedure. The high vascular conspicuity is due to flow-related enhancement effects inherent in the gradient-echo sequences used for procedure guidance.
2. The multiplanar imaging capabilities that ensure precise accurate targeted placement of the interventional device, eg, biopsy needle along the axial as well as the craniocaudal dimensions in the anatomy of interest. In addition, imaging in any arbitrary plane allows the device trajectory to be tailored according to the individual case.
3. The ability to guide device navigation with continuous, near real-time imaging so the device can be redirected in a timely manner in order to avoid critical structures.
4. The ability to shift between T1-weighted, and T2-weighted, and other contrasts during the procedure to maximize the anatomic/pathologic conspicuity. For example, T2-weighted techniques allow sampling of the non-necrotic regions of complex masses, thus increasing the diagnostic tissue yield. In addition, physiologic functional information from procedural dynamic contrast-enhancement, chemical shift, and diffusion-weighted MR imaging allow for targeting of specific areas.
5. The ability to perform advanced physiologic imaging intraprocedurally, thus monitoring the effects of intervention. For example, diffusion-weighted imaging can monitor tissue infarction, perfusion-weighted imaging can assess tissue blood flow, and thermometry can assess tissue temperature.

II. DEFINITION

The term “procedural MRI” describes the use of MRI techniques for guidance and/or monitoring or control of noninvasive or minimally invasive diagnosis or and therapy with the entire procedure performed in the procedural MRI suite. MRI-guided procedures encompass multiple approaches, including endoscopic, endovascular, percutaneous, transcutaneous-focused ultrasound, and open techniques.

This practice parameter specifically excludes breast biopsy and localization procedures that can be safely and appropriately performed according to the ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedures [3].
III. INDICATIONS

A. Indications

Current indications for the use of MRI to guide/monitor procedures in near real-time can be classified under the following major categories:

1. Biopsy and aspiration

   The general indications for image-guided percutaneous tissue sampling can be reviewed in the ACR–SIR–SPR Practice Parameter for the Performance of Image-Guided Percutaneous Needle Biopsy (PNB) and the ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Percutaneous Drainage/Aspiration of Abscesses and Fluid Collections (PDAFC) [4,5].

   Since MRI guidance is not intended to substitute for other less expensive modes of biopsy/aspiration guidance, MRI-guided procedures will assume a role when the patient would otherwise be subjected to a blind (nontargeted) biopsy, surgical exploration, or open biopsy performed solely for the purpose of tissue diagnosis. Therefore, MRI-guided biopsy/aspiration will be most suited for patients who have 1 or more of the following conditions [2,6-12]:

   a. Lesions in areas of complex anatomy (eg, suprathyroid neck, base of the neck adjacent to the brachial plexus or lung apex, adrenal glands, and liver dome lesions) needing greater contrast than available on computed tomography (CT) between tissues to delineate abnormalities
   b. Lesions close to vascular structures needing continuous real-time monitoring
   c. Transiently enhancing lesions that are visible using MR
   d. Skeletal muscle or soft-tissue lesions lacking sufficient tissue contrast on computed tomography (CT) and ultrasound
   e. Bone marrow infiltrative processes
   f. Tumors with heterogenous functional activity, necessitating the need for targeted MRI biopsies to the functionally active portions
   g. Lesions seen only by MRI and not on other imaging modalities under which biopsy could be performed (eg, prostate biopsy)
   h. At-risk populations in whom ionizing radiation exposure should be limited.
   i. Particular attention should be made for these patients who are receiving serial procedures.
   j. Previously unsuccessful procedure with other imaging modalities.

   MRI guidance may also be used for joint fluid aspirations and/or injections for additional procedural safety compared to conventional fluoroscopically guided joint interventions [13].

2. Minimally invasive percutaneous procedures

   Whenever feasible, minimally invasive approaches are preferred over other surgical procedures because of the following advantages:

   • Decreased morbidity and mortality.
   • Decreased length of hospitalization and expense.
   • The potential for treatment or cure for patients who are not open surgical candidates.

   These procedures may include, but are not limited to, the following:

   a. Thermal tumor ablation

      The core contribution of MRI to interstitial thermotherapy is its ability to monitor the zone of thermal tissue destruction during the procedure, thereby providing real-time guidance for the deposition of thermal energy (MR thermometry). Through MRI monitoring, ablation zone size/volume and configuration can be directly controlled by the operator and adjusted during the procedure in order to
compensate for deviations from the preoperative predictions and to define the treatment endpoint without moving the patient from the operative or MRI suite. This is an attribute of MRI imaging that cannot be reliably duplicated by any other currently used imaging modality [14,15]. It not only permits accurate tumor destruction, including the margins, but also extends the application of radiofrequency (RF), cryoablation, focused ultrasound, and other ablation techniques to the safe destruction of tumor within the visceral organs and adjacent to vital neurovascular structures.

Interactive MRI can be used to guide and monitor tumor ablation with various sources of thermal energy such as:

- Radiofrequency (RF) [6,16-21]
- Laser [22-27]
- Cryotherapy [28-30]
- Focused ultrasound [31-37]
- Microwave [38,39]
- MRI guidance can also be used to ablate peripheral sensory nerves for pain therapy [40]

Primary and metastatic liver tumors and primary renal malignancies are the tumors most commonly treated by MRI-guided percutaneous thermoablation. Less common targets include, but are not limited to, breast, prostate or liver tumors, uterine fibroids, and osteoid osteomas of bone. MR-guided focused ultrasound have also been used in nonneoplastic conditions, such as essential tremor and Parkinson’s disease.

b. Direct intralesional, intracompartmental, and perineural diagnostic and therapeutic drug injection

Mixing the drug of interest with diluted gadolinium chelate enables interactive MRI guidance of the injection process and monitoring of drug distribution within the target tissue. Alternatively, injectants can be visualized and monitored based on their long T2 constants without or with subtraction techniques. Indications include, but are not limited to [41-45]:

- Chemical tumor ablation (eg, via direct ethanol injection)
- Injection sclerotherapy of low-flow vascular malformations
- Percutaneous Injection of local anesthetics and steroids into a muscle or joint
- Perineural and epidural injections [46-49]

3. Open surgical MRI

The integration of MRI systems into the traditional surgical arena is currently implemented in some of the following procedures [50-60]:

a. Image guidance or monitoring

- Neurobiopsy or cranial cyst aspiration
- Deep brain stimulation/electrode placement
- Thermal ablation of brain tumors
- Trans-sphenoidal pituitary resection

b. Procedure monitoring

- Craniotomy for brain and spine tumor resection, epileptogenic focus resection, or hematoma evacuation.

4. Catheter-based procedures

Using passive or active tracking techniques, catheter and/or guidewire navigation can be performed in the cardiovascular system in near-real-time to achieve better soft-tissue visualization and to obtain more pertinent physiological information compared to conventional X-ray fluoroscopic techniques. Preliminary clinical data demonstrate the safety and feasibility of MRI guidance for diagnostic cardiac catheterization.
in patients with congenital heart disease and for interventional cardiac catheterization and radiofrequency ablation [61-63].

Vessel wall imaging using intravascular coils is an emerging application of MRI-guided procedures that has strong potential for clinical application in the near future because of its ability to map out vulnerable plaques that may not be identified with the “lumen-only” information obtained by conventional angiography [64,65].

Transcatheter intra-arterial perfusion (TRIP) MRI can be used as a first-pass intraprocedural perfusion technique to a) verify anticipated distribution of injected contrast media, b) monitor changes in tumor perfusion during transcatheter embolic therapies, and c) exclude potential unexpected collateral supply when used in conjunction with intravenous (IV) dynamic contrast enhancement (DCE) [66-69].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physicians

MRI-guided procedures must be performed by, or under the supervision of, a physician who has the qualifications specified in sections 1 or 2 below. In addition to these qualifications, a physician must also have the training specified in section 3.

1. a. Certification in Radiology, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada or the Collège des Médecins du Québec. Also, the physician must have demonstrated competency as primary operator in MRI-guided procedures under the supervision of an on-site qualified physician, during which a minimum of 5 MRI-guided procedures were performed with acceptable success and completions rates documented by a case log.

or

b. Completion of a diagnostic radiology residency or fellowship program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) that included 6 months of training in cross-sectional imaging, including CT and MRI, and 3 months of training in image-guided interventional radiological techniques that included percutaneous biopsy and drainage procedures and vascular catheterization. This must include performance (under the supervision of a qualified physician) of at least 5 MRI-guided procedures with acceptable success and complication rates documented by a case log.

or

2. In the absence of the above requirements or other postgraduate certification and training that included comparable instruction and experience, physicians may meet the requirements for performing MRI-guided procedures by adhering to ALL of the following recommendations:
   a. Documentation of hands-on training in the performance of MRI-guided procedures.
   b. Performance and completion of at least 5 successful and uncomplicated MRI-guided procedures as primary operator under the supervision of an on-site qualified physician with acceptable success and complication rates.
   c. Substantiation in writing by the chair of the department of the institution in which the physician will be providing these services.

3. In addition, physicians involved in MRI-guided procedures are expected to demonstrate competence in the following fields of knowledge and skills:
   a. General medical background in order to be able to communicate appropriately with referring physicians from various specialties and to be able to discuss the appropriateness of the specific procedures in light of the patient’s integrated individual history, physical findings, comorbid conditions, and preoperative imaging findings.
b. Basic anatomy (including congenital and developmental variants), physiology, and pathophysiology of
the specific organ or tissue targeted for intervention.

c. Fundamental MRI physics with particular emphasis on the technical parameters that influence device
visualization and navigation. The ability to operate the scanner is strongly recommended for all
physicians involved in MRI-guided procedures. A thorough understanding of MRI safety related to
ferromagnetic attraction of instruments and equipment (eg, oxygen tanks), instrument-related artifacts,
and the generation of heat or current by magnetic induction of either permanently or temporarily
implanted devices is mandatory.

d. Initial management of clinical emergencies that may arise during surgical MRI, including, but not
limited to, the administration of basic life support and the recognition and treatment of adverse reactions
to administered sedatives and analgesics.

Maintenance of Competence

Physicians must perform a sufficient number of MRI-guided 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, as well as participation in postgraduate
continuing medical education (CME) courses on diagnostic and technical advances in MRI-guided procedures.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing
Medical Education (CME) [70].

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team but should
not perform MRI-guided procedures independent of supervision by physicians with training, experience, and
privileges to perform the relevant procedures. See the ACR–SIR–SNIS–SPR Practice Parameter for Interventional
Clinical Practice and Management [71].

C. Qualified Medical Physicist

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [72].

D. Radiologic Technologist

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [72].

E. Nursing Services

Nursing services are an integral part of the team for preprocedural and postprocedural patient management and
education and may assist the physician in monitoring the patient during MRI-guided procedures.

V. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

For contraindications to MRI scanning, see the ACR Practice Parameter for Performing and Interpreting Magnetic
Resonance Imaging (MRI), the ACR Manual on Contrast Media, and the ACR Guidance Document on MR Safe
Practices [72].
For relative contraindications to percutaneous needle procedures, see the ACR–SIR–SPR Practice Parameter for the Performance of Image-Guided Percutaneous Needle Biopsy (PNB) and the ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Percutaneous Drainage/Aspiration of Abscesses and Fluid Collections (PDAFC) [4,5].

Relative contraindications to percutaneous thermal tumor ablation include, but are not limited to:

1. Large size of the targeted tumor. There is no universal cut-off diameter for eligibility for percutaneous thermal ablation. However, the larger the tumor the greater the likelihood of incomplete necrosis and development of postablation syndrome. Tumors smaller than 3 to 4 cm in diameter are generally suitable for percutaneous ablation.

2. Proximity to vital structures, such as the gallbladder, renal pelvis, or bowel wall, or nontarget nerves if protective measures are not possible

3. Proximity to large blood vessels. The presence of flowing blood in the vicinity of the tumor being ablated compromises the efficacy of treatment because of the heat sink effect.

4. Amenability to surgical resection with respect to both technical feasibility and patient fitness.

VI. SPECIFICATIONS OF THE EXAMINATION

A. Request for the Examination or Interventional Consultation

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

Documentations 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)

In practice settings in which the interventional radiologist or interventional neuroradiologist performs procedures on the basis of physician referrals or direct patient referrals, an appropriate radiology clinic or consultation note should document preprocedure patient evaluation, procedure indication, and procedure medical necessity.

B. Facility Requirements

The basic requirements for setting up a procedural MRI suite are [73-79]:

1. Hardware requirements

   a. An appropriate MRI system should be available to facilitate the patient access necessary for performing the procedures. Many different MRI system designs have been used to interactively guide procedures. Each of them has advantages and disadvantages, with a constant tradeoff between signal-to-noise ratio, patient access, useable field of view, and expense.

   b. When performing MRI-guided procedures on low-field MRI systems, sufficiently high signal-to-noise ratios and image quality are important prerequisites to guide interactive procedures.
scans performed with low-field MRI systems, low-noise receiver chains should be available to provide
relatively high signal-to-noise ratios and sufficient image quality to guide interactive procedures. Image
acquisition times should be tailored to the indication to provide appropriate temporal resolution.

c. Facilities should be have the ability to operate the scanner and view images in the operative suite within
the magnetic field through an in-room, high-resolution, RF-shielded monitor, if applicable. Combined
with the patient access allowed by an appropriate MRI system, this capability allows the entire
procedure to be performed with the operator maintaining constant device or instrument control while
simultaneously viewing the images.

d. Facilities should have the availability of MRI-conditional needles, probes, catheters, guidewires, etc.
that are undeflected by the magnetic field and that create little or no field distortions or image
degradation except as desired for passive device localization. The potential for specific devices,
particularly catheters and guidewires, to be heated by imaging gradients should be understood before
clinical use [80].

e. A surgical or MRI table capable of safely transferring a patient from the operating position into the
imager in case of intraoperative MRI should be present and available for rapid removal of the patient
outside the MR suite in case of emergency.

f. The 5-gauss line should be clearly defined.

g. MRI-compatible patient monitoring equipment should be available and used as appropriate during the
procedure [81].

2. Software requirements

Appropriate pulse sequences to permit adequate tissue contrast imaging device visualization and
process monitoring should be available. The application of fast gradient echo pulse sequences that allow
a wide range of tissue contrast in a time frame sufficient for device tracking even at the low field strengths
of open magnets and with the suboptimal coil position sometimes required to access the puncture site [76-81].

C. Performance Guidelines

1. Minimally invasive procedures

   a. Biopsy and aspiration

      The MRI-compatible biopsy needle is advanced into the targeted lesion under MRI guidance using
optimized short recovery time (TR)/short echo time (TE) gradient-echo or fast and turbo spin-echo
(TSE) sequences. The process uses a continuous imaging mode that allows consisting of automated
sequential acquisition, reconstruction, and in-room display of multiple sets of images to permit real-
time or near real-time to guided needle insertion with respect to the 3-D geometry of the lesion. This
may be performed through acquisition of a set of contiguous, parallel thin (eg, 5 mm) slices centered on
the needle position, or through the acquisition of image sets in multiple scan planes oriented along the
shaft of the needle. Depending on the operator’s preference, the procedure can be performed using free-
hand methods, needle holders, MR-compatible robotically controlled arms or real-time guidance from
optically linked systems [82-87]. At higher field strength, fast and TSE-based pulse sequence can
be acquired fast enough for near-real-time MRI and also provide advanced metal artifact
reduction with specialized pulse sequences [88].

   b. MR-guided focused ultrasound

      A noninvasive technique that uses ultrasound energy as a thermos-coagulative method to ablate
tissue under MR guidance and monitoring. The ultrasound waves are emitted from a transducer
placed close to the organ of interest (e.g., in the table of the MRI system for uterine fibroid treatments, in a skull “helmet”-like transducer array for essential tremor treatments, or in a transrectal probe for prostate cancer treatment). The MRI sequences for targeting are similar as in other procedures described. MR thermometry sequences often use phase contrast for proton resonance frequency (PRF) measurements and are fundamental for monitoring of MR-guided focus ultrasound. All individual sonications are imaged using the phase contrast sequence with thermometry measures obtained each time. In these procedures, the MR data are integral to the ablation determining the success/failure of the tissue necrosis at every level. After all individual sonications are delivered, thermometry is deemed satisfactory. Gadolinium contrast-enhanced MR images of the treated volume of tissue are obtained to determine interval changes in perfusion. The nonperfused volume (NPV) is a critical outcome measurement.

c. Percutaneous thermal ablation

The needle, thermal electrode, cryotherapy probe, or laser fiber is introduced into the abnormal structure or to the targeted area of pathology anatomic structure using the basic technique of MRI guidance described above for biopsy and aspiration.

For thermal tumor ablation, real-time monitoring of the evolving ablation zone can be achieved using a rapid gradient-echo or fast and TSE pulse sequence. In cases of MRI-guided radiofrequency tumor ablation, imaging interference caused by the RF source can be overcome by software and hardware modifications that allow RF energy to be deposited during imaging [89]. Alternatively, TSE T2-weighted and/or TSE Short tau inversion recovery (STIR) TSE MR images can be simply acquired intermittently between the RF deposition cycles. During cryoablation, the growing ice ball can be continuously or intermittently monitored with fast T1, intermediate, and T2-weighted TSE pulse sequences. Regardless of the source of thermal energy used, the size and shape of the developing ablation zone are directly observed as an enlarging low-signal area surrounded by high-signal tissue reaction. Electrode repositioning into persistent foci of high-signal tumor as detected on the T2 and/or STIR fluid-sensitive MR images is performed in the scanner under continuous MRI guidance in an interactive manner similar to that used for initial electrode placement, or with intermittent MRI guidance. The “guide-ablate-monitor” sequence of events is repeated until the induced ablation zone is noted to encompass the entire tumor and a small cuff of normal adjacent tissue or the developing ablation zone approaches adjacent vital structures [90].

d. Lesion injection and chemical ablation

If MRI is used to guide intralesional drug injection rather than thermal ablation, the injected drug (alcohol, sclerosing agent, botulinum toxin, or anesthetic/steroid) may be mixed with an MRI contrast agent to facilitate interactive monitoring of drug distribution during injection or may be visualized based on the long T2 constant of the injectants without the addition of Gadolinium-based contrast [91-93].

2. Open surgical MRI

The performance of open surgical procedures that require interactive image guidance of devices—such as biopsy needles, aspiration devices, thermal electrodes, laser fibers, or curettes with continuous or intermittent monitoring of the result—should follow the previously described guidelines for “minimally invasive procedures,” as appropriate.

The status of tumor resection, hematoma evacuation, or other invasive procedures may be intermittently imaged so that a satisfactory result can be documented. This requires only relatively minor modification to standard imaging systems because patient access is not necessary during the monitoring process. These types of procedures may not require an open operating room MRI scanner but may be performed on conventional cylindrical superconducting systems provided that patient transfer between the surgical position and the imager is secured as discussed above in “hardware requirements.” Integration with a
frameless stereotactic localization system may be added in these procedures to facilitate guidance to areas of residual pathology [94-102].

3. Catheter-based procedures

After vascular access is performed, a coronal 2-D steady-state free-precession sequence is used to localize the abdominal aorta and to interactively guide the advancement of catheters and guidewires in real time from the introducer sheath to the heart or the vascular anatomy of interest. The imaging plane can subsequently be modified to best fit the route of catheter manipulation within the vascular system [103].

Visualization of catheters and guidewires is usually achieved via “passive tracking” techniques by incorporating a metal ring within the dilator tip [104] and by using catheters and guidewires modified with a ferrite mixture to induce susceptibility artifacts [105]. Another simple technique that may be used to render a catheter MRI-visible using the same theory of passive tracking is to fill the balloon of a standard angiographic catheter with a small amount of carbon dioxide gas [61].

Other methods to track catheters within the vascular system are achieved by creating “controlled locally induced field inhomogeneities.” One way is to generate current in a thin copper wire wrapped around the catheter shaft. Another is to use “active tracking” techniques achieved by mounting a single or multiple microcoils connected to the receive channel of the MRI system to the tip of the catheter [106-116]. Augmented steering of catheters can currently be achieved by mechanical tip-deflecting catheters [116-119].

D. Patient Care

1. Preprocedural care

   a. The clinical history and relevant physical findings, including the vital signs and all relevant imaging, must be reviewed and recorded in a patient’s medical record by the physician performing the procedure. Specific inquiry should be made with respect to relevant Details regarding current medications, prior allergic reactions, and bleeding/clotting status must be recorded.

   b. The indication(s) for the procedure, including (if applicable) documentation of prior therapy, must be recorded. Any relevant prior studies should be reviewed.

   c. Explanation of the procedure along with its benefits, risks, and alternatives should be discussed with the patient by an appropriate member of the procedural team in accordance with the ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures [120].

   d. The patient should be screened for contraindications for MRI and for MRI contrast media.

   e. Preprocedure plan formulated.

2. Procedural care

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

   Anesthesia equipment, surgical scalpels, and electrocautery systems should be made of MRI-compatible materials. Physiologic monitors must be either nonferromagnetic or kept outside the fringe field of the magnet.
b. **When appropriate**, patients undergoing MRI-guided procedures **must** have IV access in place for the administration of any required fluids and medications.

c. **When appropriate**, vital signs should be obtained at regular intervals during the procedure, and a record of these measurements should be maintained.

d. If the patient is to receive conscious sedation, pulse oximetry must be used. Administration of sedation for MRI-guided procedures should be in accordance with the ACR–SIR Practice Parameter for Sedation/Analgesia as appropriate [121]. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained.

e. 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 [122].)

f. 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 size in the patient population.

3. Postprocedural care

a. A postprocedural MRI scan (typically after injection of IV contrast) should be obtained prior to transferring the patient from the procedural MRI suite in order to document the procedural result and the presence and extent of any complications and to provide a baseline for future comparison imaging.

b. A procedural or operative note should be documented in the patient’s medical record, detailing the procedure, any immediate complications, and the patient’s status at the conclusion of the procedure and a brief description of the postprocedure imaging to serve as reference for future imaging.

c. During the initial postprocedural period, patients will usually require bed rest, and appropriately trained personnel should monitor the patient’s vital signs and observe for bleeding.

d. **Following a postprocedural physical examination and response assessment including the interventional site and neuromuscular function**, postprocedural pain should be treated as deemed appropriate by the physicians performing the procedure, nonphysician practitioners or, in certain practice settings, by the patient’s referring physician or surgeon.

e. Patient discharge

Group I - Patients undergoing uneventful MRI-guided biopsy or aspiration, sclerotherapy, drug injection, catheter-based procedures, **thermal nerve ablation**, and other minor procedures may be discharged after an observation period of 1 to 6 hours **based on institution guidelines**.

Group II - Patients subjected to percutaneous thermal or chemical tumor ablation may be admitted to the hospital for overnight observation and to be examined by the treating physician before discharge. In selected cases, when the percutaneous approach to the tumor is straightforward and the ablation is uneventful, the patient may be discharged after careful physical examination following an initial observation period of 6 hours.
Group III - The disposition (transfer or discharge) of patients undergoing open surgical MRI will be managed by the primary surgical team.

In all cases, the physician, surgeon, or health care surrogate must be available for continuing care both during hospitalization and after discharge. The patient’s status at discharge must be documented in the patient’s medical record. The patient should be educated about possible delayed complications.

E. Surgical and Emergency Support

When MRI-guided procedures are performed in a freestanding diagnostic center, detailed protocols for prompt transport or admission of the patient to an emergency department with a surgical facility should be formalized in writing.

VII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [123].

VIII. SUCCESS AND COMPLICATION RATES AND THRESHOLDS

Indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these practice parameters, a threshold is a specific level of an indicator, eg, a complication rate that should prompt a review. MRI techniques are used to guide and monitor an increasing array of diverse percutaneous and open surgical procedures. The success and complication rates and thresholds are therefore expected to demonstrate significant variations depending on the nature of the procedure and on the targeted organ. Because the primary aim of using MRI to guide and monitor procedures is to increase patient safety by improving the visualization of vascular and other vital structures and by enhancing the intraprocedural or intraoperative detectability of residual abnormalities, pathology complication thresholds should never exceed those used for equivalent procedures performed under the guidance of other imaging modalities or for open surgery performed without MRI monitoring.

Routine periodic review with audits and documentation in electronic databases is strongly encouraged for all cases, with particular attention to unexpected or unsatisfactory outcomes, and can serve as peer-reviewed learning. When complication rates exceed a threshold value, a review should be performed to determine the causes and to implement any necessary changes.

Similarly, success rates and thresholds should be viewed in light of each specific procedure, and institutional results should be compared to the published data for standard equivalent procedures and surgeries.

The only exception would involve the technical success rate. The ability to use appropriate MRI techniques to adequately visualize the target lesion and procedural device, to navigate it safely into the tissue of interest, and to unequivocally discriminate pathological tissue from adjacent structures is essential, so the technical success rate should be 100%.

At the time these practice parameters were written, there were no published reports of comprehensive success or complication rates of institutional procedural MRI programs.

IX. EQUIPMENT SPECIFICATIONS

The MRI 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 magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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.

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [124].

ACKNOWLEDGEMENTS

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

ACR

Steven W. Hetts, MD, Chair
Daniel L. Cooke, MD
Jan Fritz, MD
Ritu R. Gill, MBBS, MPH
Clare M.C. Tempany-Afdhal, MB, BAO, BCh, FISMRM
Clifford R. Weiss, MD, FSIR

ASNR

Raymond K. Tu, MD, FACR

Committee on Practice Parameters – Neuroradiology

(ACR Committee responsible for sponsoring the draft through the process)

Steven W. Hetts, MD, Chair
Kristine A. Blackham, MD
Brian A. Conley, MD
Kavita K. Erickson, MD
Adam E. Flanders, MD

Robert J. McDonald, MD
Alexander M. McKinney, IV, MD
David M. Mirsky, MD
Robin J. Mitnick, MD, FACR
Lubdha M. Shah, MD

PRACTICE PARAMETER

Non-Breast MRI-Guided Procedures
2019 Resolution No. 18
Committee on Practice Parameters – Neuroradiology
(ACR Committee responsible for sponsoring the draft through the process)

H. Simms Hardin, IV, MD  Raymond K. Tu, MD, FACR, Chair
John E. Jordan, MD, MPP, FACR Max Wintermark, MD
Jacqueline C. Junn, MD

Committee on Practice Parameters – Interventional and Cardiovascular Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Clayton K. Trimmer, DO, FACR, FAOCR, FSIR, Chair Elizabeth A. Ignacio, MD, FSIR
Chaitanya Ahuja, MBBS Sanjeeva P. Kalva, MD, FSIR
Drew M. Caplin, MD Claire Kaufman, MD
Douglas M. Coldwell, MD, PhD Kenneth F. Layton, MD, FACR
Mandeep S. Dagli, MD Margaret Hsin-Shung Lee, MD, FACR
Kevin W. Dickey, MD John D. Prologo, MD
Joshua A. Hirsch, MD, FACR, FSIR Sanjit Tewari, MD
Kelvin Hong, MD, FSIR

Alexander M. Norbash, MD, FACR, Chair, Commission on Neuroradiology
Alan H Matsumoto, MD, FACR, Chair, Commission on Interventional and Cardiovascular Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Aradhana M. Venkatesan, MD, Chair  Alan H. Matsumoto, MD, FACR
Timothy A. Crummy, MD, FACR, Co-Chair Mary S. Newell, MD, FACR
Jacqueline A. Bello, MD, FACR Alexander M. Norbash, MD, FACR
Daniel L. Cooke, MD Matthew S. Pollack, MD, FACR
Richard Duszak, Jr., MD, FACR Timothy L. Swan, MD, FACR
Jan Fritz, MD Clare M.C. Tempany-Afdhal, MB, BAO, BCh, FISMRM
Ritu R. Gill, MBBS, MPH Clayton K. Trimmer, DO, FACR, FAOCR, FSIR
Steven W. Hetts, MD Raymond K. Tu, MD, FACR
Paul A. Larson, MD, FACR Clifford R. Weiss, MD, FSIR

REFERENCES


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Development Chronology for this Practice Parameter
2008 (Resolution 18)
Revised 2013 (Resolution 8)
Amended 2014 (Resolution 39)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ASNR–SPR Practice Parameter for the Performance of Myelography and Cisternography

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 2013 (Resolution 9)*

ACR–ASNR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MYELOGRAPHY AND CISTERNOGRAPHY

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, ___ N.W.2d ___ (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).

Myelography has been an important diagnostic modality for a wide range of spinal disease processes for more than 80 years. Cisternography using intrathecal contrast media has also been used for many years in the diagnostic evaluation of disease processes involving the basal cisterns and skull base.

These procedures typically involve performance of a lumbar puncture under fluoroscopic guidance followed by the fluoroscopically monitored introduction into the subarachnoid space of a nonionic water-soluble iodinated contrast medium that is appropriate for intrathecal administration. Alternatively, when the lumbar approach is contraindicated, previously unsuccessfully attempted, or less advantageous, the contrast medium may be introduced into the thecal sac via a lateral C1-C2 puncture, which is described in section V.C.9. In certain clinical situations, water-soluble magnetic resonance imaging (MRI) contrast and MR imaging techniques may be used in a similar fashion for similar indications; however, such media are not presently the Food and Drug Administration (FDA) approved for this purpose. Following the introduction of a sufficient quantity of intrathecal contrast medium, the needle is withdrawn.

With the aid of a tilting table, the opacified cerebrospinal fluid (CSF) is positioned in the desired region of the spinal subarachnoid space (lumbar, thoracic, or cervical) or in the intracranial basal cisterns, and appropriate radiographic/fluoroscopic (conventional myelogram) and/or computed tomographic (CT) myelogram or cisternogram images are obtained.

Institutions offering myelography should insist on documentation of appropriate training, demonstrated competence, and maintenance of skills for all physicians who receive privileges to perform these procedures.

II. INDICATIONS

Although myelography and cisternography have largely been superseded by the development of high-resolution CT and MRI, there remain numerous indications for these procedures, including but not limited to:

1. Demonstration of the site of a CSF leak (postlumbar puncture headache, postspinal surgery headache, orthostatic headache, rhinorrhea or otorrhea, or cerebrospinal-venous fistula) [1,2].
2. Symptoms or signs of spontaneous intracranial hypotension [3-7].
3. Surgical planning, especially in regard to the nerve roots.

4. Evaluation of suspected brachial plexus or nerve root injury in the neonate [8-10].
5. Evaluation of intraspinal arachnoid webs or cysts [11-14].
6. Evaluation of the bony and soft-tissue components of spinal degenerative changes [3,15,16].
7. Radiation therapy planning.
8. Diagnostic evaluation of spinal or basal cisternal disease.
9. Nondiagnostic MRI studies of the spine or skull base.
10. Poor correlation of physical findings with MRI studies.
11. Use of MRI precluded because of:
   a. Claustrophobia
b. Technical issues, eg, patient size
c. Safety reasons, eg, pacemaker
d. Surgical hardware

12. Delineation of congenital anomalies (eg, diastematomyelia) when MRI is insufficient.

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 [17].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Certification in Radiology, Diagnostic Radiology, Interventional Radiology/Diagnostic Radiology (IR/DR), Nuclear Radiology, or Nuclear Medicine by one of the following organizations: the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and the performance of myelography with acceptable success and complication rates.

or

Completion of a residency or fellowship training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include evidence of training and competency in myelography. Adequate training should include the performance of a sufficient number of myelographic procedures to become facile in the technique.

and

Instruction in all of the following areas should be substantiated by the director of the training program:

1. Anatomy, physiology, and pathophysiology of the central and peripheral nervous systems.
2. Physics of ionizing radiation, including an understanding of its production, detection, and risks and of techniques to minimize radiation exposure.
3. Pharmacology and dosage of contrast media used in myelography. (Use of only those agents approved for intrathecal use should be emphasized.)
4. Indications for myelography and cisternography, and indications for alternative imaging studies, including MRI.
5. Preprocedural assessment of the patient.
6. Conduct of the myelographic examination. This includes spinal puncture, patient positioning, and fluoroscopic and filming techniques.
7. Conduct of the postmyelogram CT examination. This includes timing, patient positioning, and technical factors.
8. Postprocedural patient management, especially the recognition and initial management of complications.
9. Interpretation of lumbar, thoracic, and cervical myelograms and cisternograms, as well as interpretation of postmyelogram CT scans.
10. Contraindications to myelography.
11. Knowledge of the drugs that can increase the risk of myelographic adverse events.

Maintenance of Competence

To maintain privileges, physicians must perform a sufficient number of myelographic procedures to maintain their skills with acceptable success and complication rates.
Continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [18].

B. Registered Radiologist Assistant [19]

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/ASRT (American Society of Radiologic Technologists) 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)

C. Radiologic Technologist

Certification by the American Registry of Radiologic Technologists or unrestricted state licensure is required. In addition, the radiologic technologist should have training in and be skilled in performing fluoroscopic examinations on patients with intrathecal contrast media, including patient positioning, fluoroscopic beam limitation, and methods of applying safe physical restraint during table tilting. Continuing education programs and on-the-job training under the supervision of qualified physicians should be available.

IV. EQUIPMENT SPECIFICATIONS

A. Myelographic Facility

The suggested specifications for the facility are:

1. High-quality radiographic/fluoroscopic imaging equipment with a capability for film or digital recording of selected portions of the examination. A tilt table and a proper support device for securing the patient on it should be available.

2. An adequate selection of spinal needles and appropriate nonionic contrast media approved for intrathecal use.

3. Appropriate facilities and equipment for treating adverse reactions (eg, seizure, vasovagal reaction, and/or cardiorespiratory collapse).

4. Appropriately trained personnel to provide proper patient care and operation of the equipment.

5. A multidetector CT scanner to perform postmyelogram CT myelographic and/or cisternographic studies. A multiplanar reconstruction capability for CT is highly desirable.

B. Surgical and Emergency Support

Although serious complications of myelography are infrequent, there should be prompt access to surgical and interventional management of complications.
V. SPECIFICATIONS OF THE EXAMINATION

A. Preprocedural Patient Care

The written or electronic request for myelography 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)

The clinical history and findings are to be reviewed by the performing physician.

1. Prior to myelography, any prior pertinent imaging studies, including spinal images, CT, and/or MRI, should be reviewed. The review should include evaluation for the position of the conus as well as for the presence of cervical stenosis, cisternal narrowing or lumbar stenosis, operative hardware, or any other potential hazard prior to choosing the level for lumbar, cervical, or cisternal puncture for myelography.

2. Appropriate prior medical history should include questions about relevant medications, especially those that can increase risk of adverse events; prior seizures; prior allergic reactions; and clotting ability.

3. Patients who are on anticoagulant therapy (eg, warfarin [Coumadin], heparin, clopidogrel [Plavix], ticlopidine [Ticlid]) should discontinue these drugs for a period of time indicated in the consensus guideline of the American Society of Regional Anesthesia and Pain Medicine (see Table 1) [20,21] prior to undergoing myelography. However, as there are now many marketed anticoagulation medications, each agent has a recommended period for which it should be continued, and if possible, this decision should be made after discussion with the physician who prescribed such medication. If the risks of discontinuing the anticoagulation are deemed greater than the risk of myelography, consideration should be given to bridging with intravenous heparin (if appropriate for the specific therapy) or delaying the myelogram until such time as it is reasonably safe to hold the anticoagulation (eg, patient who has recently undergone coronary artery stenting and is on clopidogrel).

4. For patients with hematologic disorders or other conditions affecting blood coagulation, a platelet count and international normalized ratio (INR), prothrombin time (PT), and partial thromboplastin time (PTT) values within one week of the procedure should be available.

5. Medications known to decrease the seizure threshold should be carefully evaluated. While the contributory role of these medications has not been established, physicians may withhold some of these medications for 48 hours pre- and 24 hours postmyelography, based on consideration of the potential risks and benefits. Of note, medications that lower the antiseizure threshold (such as monoamine oxidase inhibitors) and certain antidepressant medications could in theory precipitate a seizure, per the medication’s manufacturers, and should be considered carefully if not withheld for an appropriate time to allow adequate clearance (typically at least 24 to 48 hours premyelography). Antiseizure medications should not be withheld, as, in theory, they may prevent a seizure or their nontapered absence may make the patient more susceptible to having a seizure secondary to the myelography contrast instillation.

6. Informed consent should be obtained and documented. The risks and benefits of the procedure and of possible alternative procedures that may provide the needed information should be addressed.

7. The patient should be appropriately hydrated both prior to and after the procedure.
8. If sedation is used, it should be administered in accordance with the ACR–SIR Practice Parameter for Sedation/Analgesia [22].

Table 1:

<table>
<thead>
<tr>
<th>Recommended guidelines for performing spinal procedures in anticoagulated patients</th>
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<tr>
<td><strong>Warfarin</strong></td>
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<td><strong>Antiplaeter medications</strong></td>
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<td><strong>Thrombolytics/fibrinolytics</strong></td>
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<td><strong>LMWH</strong></td>
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<td><strong>Unfractionated SQ heparin</strong></td>
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<td><strong>Unfractionated IV heparin</strong></td>
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B. Relative Contraindications to Myelography

1. Known space-occupying intracranial process with increased intracranial pressure
2. Historical or laboratory evidence of bleeding disorder or coagulopathy
3. Recent myelography performed within 1 week
4. Previous surgical procedure in anticipated puncture site (can choose alternative puncture site)
5. Generalized septicemia
6. History of adverse reaction to iodinated contrast media and/or gadolinium-based MR contrast agents
7. History of seizures (patient may be premedicated)
8. Grossly bloody spinal tap (may proceed when benefit outweighs risk)
9. Hematoma or localized infection at region of puncture site
10. Pregnancy

C. Procedure [3]

1. The patient is placed prone or lateral decubitus on the tabletop, and the skin of the midsagittal back is prepped and draped in standard sterile technique.
2. Using the lumbar approach, typically, the L2-L3 or L3-L4 interlaminar or interspinous space is localized. Subcutaneous and intramuscular local anesthetic is administered. Generally, diagnostic myelography is performed with a styletted small bore (22 to 25 gauge) spinal needle introduced through the anesthetized region and directed toward the midline. Smaller needles are associated with lower risk of bleeding and posttap headache. Occasionally, because of body habitus or specific pathology, larger-gauge needles may be required. The needle is advanced under intermittent image guidance. If a beveled needle is used, the bevel may be utilized to control the direction of the needle. If possible, the bevel of the needle should be parallel to the vertical plane of the dura in order to minimize transverse cutting of dural fibers. When the dura is traversed, a change in resistance is often, but not always, perceived. The stylet is then slowly removed to check for CSF return. At this point, opening pressure can be measured, and/or CSF sampling can be performed prior to contrast injection.
3. A nonionic iodinated contrast medium is slowly administered intrathecally through the lumbar needle under intermittent imaging. An appropriate amount of contrast is injected, not to exceed the manufacturer’s recommendations [3,23-26].

4. Prior to removing the needle, imaging may be obtained to document the needle position.

5. The needle is then removed from the back, and the patient is secured to the tabletop by a support device prior to being tilted into Trendelenburg or reverse Trendelenburg positions.

6. Transforaminal puncture for myelography: recent preliminary reports suggest that a transformaminal puncture (rather than interspinous, interlaminar, or lateral C1-C2 approach) may be utilized in patients with extremely difficult access, complete posterior fusion, or spinomuscular disorders preventing access. Further experience is needed to evaluate the utility and indications for this technique in a wider array of disorders [27].

7. Using intermittent imaging, table tilting, and patient rotation, anteroposterior, oblique, and cross-table lateral images of the region in question are documented on film or digital media. For lumbar myelography, if the conus medullaris has not been recently visualized by other means, evaluation of that area should be included in the study.

8. For cervical myelography, and, in some instances, thoracic myelography with the patient prone, the head is hyperextended on the neck, thus creating a lordotic “trough,” and the table is then gradually and slowly tilted head downward until the opacified CSF “column” flows through the area of interest. The myelographic table must have adequate and secure shoulder support for the patient’s safety. The patient’s chin is supported in a chin rest to prevent rapid ascent of the contrast into the intracranial basal cisterns. The lead-gloved hands of the technologist may also support the positioning of the patient’s head and neck. As in the lumbar region, anteroposterior, oblique, and cross-table lateral images can be documented on film or digital media.

9. If cisternography is requested, with the opacified CSF “column” in the cervical spine canal, the table is restored to the horizontal position, and then the hyperextended head is gradually and slowly lowered (flexed) into a neutral position under image guidance. Imaging for cisternography is typically obtained with CT; conventional radiographic images are not usually obtained [4,5].

10. In the lateral C1-C2 approach [28], the patient is ideally positioned prone on the table top, and the head is secured in a neutral position. The supine position may be used in situations where the prone position is not feasible, such as cases involving general anesthesia, sedation, or hardware [29]. Using image guidance, the head and neck are positioned in the true lateral projection, and local anesthesia is administered subcutaneously and intramuscularly in the side of the neck at a point overlying the posterior aspect of the C1-C2 interlamina space slightly anterior to the spinolaminar junction line and inferior to the arch of C1. If C-arm fluoroscopy is not available or if the patient is unable to remain in a prone position on the tabletop but can lie quietly and comfortably in a nonrotated lateral decubitus position, lateral C1-C2 puncture can be performed using vertical beam fluoroscopy. Under intermittent image guidance, the spinal needle is advanced incrementally into the subarachnoid space at the posterior margin of the thecal sac behind the posterior margin of the upper cervical spinal cord. Great caution with frequent image monitoring should always be used during needle advancement, as the dura is punctured and as the iodinated contrast medium is cautiously and slowly injected into the posterior cervical subarachnoid space. When this is completed, an image should be documented and permanently retained, and the needle is then withdrawn from the neck. The desired area of the opacified subarachnoid space is then examined and documented.

11. Following completion of the examination as described above, the patient may be transferred to the CT scanner for CT myelographic or cisternographic imaging, when appropriate.

12. For CT myelography, the patient is rolled from side to side to promote uniform diffusion of contrast to completely opacify the region of interest. Imaging is obtained using a multidetector CT scanner with the patient prone and/or supine as needed within the scanner. Image data are acquired helically with thin collimation. Images are reconstructed in the axial, coronal, and sagittal planes and reviewed in soft-tissue and bone windows.

13. For CT cisternography, CT imaging is obtained as soon as possible after positioning of the opacified CSF in the basal cisterns. Thin-section image data are obtained helically through the area of interest with thin collimation with the patient in both prone and supine positions. Images are reconstructed in the axial, coronal, and sagittal planes and reviewed in soft-tissue and bone windows. For detection of CSF leakage at
14. Pediatric myelography is most often performed under conscious sedation or general anesthesia. Pediatric patients are often kept NPO for 6 to 8 hours prior to anesthesia or sedation and may be dehydrated. Patients should be appropriately hydrated before and for several hours after the sedation. Pediatric patients may be at higher risk of adverse events during contrast medium administration, including patients with asthma, sensitivity to medication and/or allergens, congestive heart failure, serum creatinine level greater than 1.5 mg/dL, or those younger than 12 months of age. However, the incidence of headache, vomiting, and back pain appears to be lower in the pediatric population.

Prior to performing myelography in a child, the radiologist should review imaging studies of the brain and spine to determine if the patient has undergone repair of a posterior dysraphic defect, a low-lying tethered cord, or a lipomeningocele, all of which preclude lumbar puncture. Low-lying cerebellar tonsils and Chiari II malformations with caudal displacement of the hindbrain into the cervical canal are contraindications to lateral C1-C2 puncture. The position of the conus in infants and young children is lower than in older children and adults, and lumbar puncture should be performed at the L3-L4 or L4-L5 level in children younger than 3 years of age using a 25-gauge needle. Penetration of the dura may be inapparent. When CSF sampling is needed, collection should be limited to 1 to 2 cc per vial, especially in infants with small-capacity thecal sacs. Instillation of the contrast medium under intermittent imaging control is recommended. The minimum volume and dose to produce adequate visualization should be used; dosage should be calculated per kg of body weight.

15. Delayed CT through the region of interest can be useful in certain situations (eg, to demonstrate opacification of suspected arachnoid cysts that do not opacify on the initial CT).

16. In particular situations, recent reports of modifications of fluoroscopic and CT myelography techniques, including digital subtraction, dual energy, and ultrafast myelography, suggest their utility but report only preliminary results with limited data. Inclusion of these techniques herein will await greater experience and definition of specific indications.

D. Postprocedural Care [24-26,30]

1. The patient should be adequately hydrated.

2. The patient should be observed following the examination for sufficient time to observe for potential complications.

3. If the myelogram is performed on an outpatient basis, the patient should be properly instructed regarding limitations following the procedure (eg, no driving).

4. Instructions regarding postprocedural care, including warning signs of adverse reactions, symptoms, and signs of infection at the puncture site and the possibility of persistent headaches, should be given to the patient by a trained professional. The instructions should include a recommendation that the patient be in the company of a responsible adult for 12 hours following the procedure.

5. A physician should be available to answer questions and provide patient management following the procedure.

VI. MR MYELOGRAPHY AND MR CISTERNOGRAPHY

A. Indications for MR Myelography (MRM)

Similar to conventional myelography and cisternography, MRM has the following indications, including but not limited to:

1. Demonstrating the location and size of a CSF leak in posttrauma and postsurgical patients and in spontaneous intracranial hypotension.

2. Defining target volume for craniospinal irradiation.

3. Determining the cause of cervical or thoracic myelopathy.

5. Assessing brachial plexus or nerve root injuries, particularly in neonates [9,10,31].
7. Determining the presence of, or flow obstruction by, spinal arachnoid cysts or webs [11]

B. Indications for MR Cisternography

Similar to conventional cisternography, both without or with intrathecal gadolinium contrast, MR cisternography (MRC) has the following indications, including but not limited to:

1. Localization and measurement of skull-base CSF fistulae or leaks. In patients with negative CT myelography or MRM, MRC with gadolinium can be utilized as a subsequent technique to detect leaks and may employ the use of delayed postcontrast imaging [32,33].
2. Preoperative evaluation of intracranial arachnoid cysts [14].
3. Evaluation of inner ear structures.
5. Evaluation of the cranial nerves and lesions within the basilar cisterns and intracranial subarachnoid spaces.

C. Equipment Specifications


D. Myelography Facility (for intrathecal injection of gadolinium contrast)

Please see section IV.A.1-4.

E. Specifications of the Examination (for intrathecal injection of gadolinium)

Please see section V.

F. MRM Technique [7,36,37]

1. MRM without intrathecal contrast is best accomplished using a heavily T2-weighted pulse sequence (eg, constructive interference in the steady state [CISS] or fast imaging employing steady state acquisition [FIESTA]). These images provide a high degree of contrast resolution, enabling sharp definition between the spinal cord and intrathecal nerve roots and the surrounding CSF. These images are acquired in 3-D, which allow reconstructions in multiple planes. Images are typically obtained in the sagittal and axial planes, although coronal plane images may be specified in particular situations. Leakage of fluid outside the thecal sac, as through a dural tear, can be recognized on noncontrast MRM, although extradural fluid collections that are not derived from an intradural source (eg, a postoperative seroma or a congenital cyst) cannot be distinguished from intradural leakage. Please refer to the ACR–ASNR–SCBT-MR–SSR Practice Parameter for the Performance of Magnetic Resonance Imaging (MRI) of the Adult Spine [34].

2. MRM with intrathecal contrast is an off-label use of gadolinium-based contrast agents [37] (ie, these agents are not approved by the FDA for intrathecal injection. If this procedure is contemplated, the examining physician must obtain informed consent from the patient. To date, this procedure has mainly been performed to establish the site of CSF leakage and to measure the size of the dural tear. The quantity of contrast agent injected into the subarachnoid space via lumber puncture is very small (typically 1 mL of 0.05 mM gadolinium-based contrast); nevertheless, reflecting the much greater contrast resolution of MRI, the contrast between the opacified CSF and the spinal cord and nerve roots is marked.

MRM with intrathecal contrast is conducted in an entirely analogous manner to the technique used in conventional myelography followed by CT. Pulsing sequences for examining the cervical, thoracic, or
lumbar spine typically include sagittal and axial T1- and T2-weighted fast spin echo with fat saturation and short tau inversion recovery (STIR). In particular situations, coronal T1- and T2-weighted images may also be of important diagnostic value. Extradural fluid collections that are derived from dural tears will demonstrate contrast enhancement, whereas such collections that are not of intraspinal origin would not.

G. MRC Technique [38,39]

1. MRC without intrathecal contrast is also achieved using pulsing sequences as described above for MRM that are heavily T2-weighted with thin-section images acquired in the axial and coronal planes. This technique has mainly been used to date for evaluating suspected dural tears in the skull base causing CSF rhinorrhea or otorrhea. MRI examinations in such cases typically also include T1- and conventional T2-weighted images in the same planes. Reported results indicate a high sensitivity for detecting sites of CSF leakage, comparable to those achieved with CT myelography. As compared with CT cisternography, MRC has the advantages of being noninvasive and having no ionizing radiation exposure. However, definition of thin cortical bony margins (as in the cribriform plate and ethmoid air cell walls) is usually better on CT than on MRI.

2. As with MRM, intrathecal administration of gadolinium contrast via lumbar puncture is not FDA approved, and the patient must be so informed. Dosage and method of administration are the same as for MRM with intrathecal gadolinium-based contrast agent (see section VI.F above). Thin-section T1-weighted axial and coronal images with fat saturation allow localization of the site of leakage and measurement of its size. Not infrequently, more than one site of leakage is delineated. Although the number of reported studies is still small, the reported results demonstrate good correlation with endoscopic transnasal operative findings.

VII. DOCUMENTATION

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

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).

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).

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards).

ACKNOWLEDGEMENTS

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

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

ACR
Stephen A. Kieffer, MD, FACR, Co-Chair
Alexander M. McKinney, IV, MD, Co-Chair
Frederick W. Ott, MD
Richard B. Towbin, MD, FACR

ASNR
Kavita K. Erickson, MD
Adam E. Flanders, MD
Amit M. Saindane, MD
Raymond K. Tu, MD, FACR

SPR
Charles R. Fitz, MD
Dennis W. Shaw, MD

Committee on Practice Parameters – Neuroradiology
(ACR Committee responsible for sponsoring the draft through the process)

Steven W. Hetts, MD, Chair
Kristine A. Blackham, MD
Brian A. Conley, MD
Kavita K. Erickson, MD
Adam E. Flanders, MD
H. Simms Hardin, IV, MD
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Jacqueline C. Junn, MD

Robert J. McDonald, MD
Alexander M. McKinney, IV, MD
David M. Mirsky, MD
Robin J. Mitnick, MD, FACR
Lubdha M. Shah, MD
Raymond K. Tu, MD, FACR, Chair
Max Wintermark, MD
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Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

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Sue C. Kaste, DO
Terry L. Levin, MD, FACR
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Charles R. Fitz, MD
Adam E. Flanders, MD
Steven W. Hetts, MD
Stephen A. Kieffer, MD, FACR
Paul A. Larson, MD, FACR

Alexander M. Norbash, MD, FACR, Chair
Richard A. Barth, MD, FACR, Chair
Jacqueline Anne Bello, MD, FACR, Chair
Mary Newell, MD, Vice Chair

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

1994 (Resolution 3)
Amended 1995 (Resolution 24, 53)
Revised 1998 (Resolution 6)
Revised 2003 (Resolution 20)
Amended 2006 (Resolution 17, 34, 35, 36)
Revised 2008 (Resolution 20)
Amended 2009 (Resolution 11)
Revised 2013 (Resolution 9)
Amended 2014 (Resolution 39)
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RESOLUTION NO. 20

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology 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 2014 (Resolution 16)*

ACR–SIR–SPR PRACTICE PARAMETER FOR THE REPORTING AND ARCHIVING OF INTERVENTIONAL RADIOLOGY 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 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, ___ N.W.2d ___ (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 2019 Resolution No. 20
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 Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR) [1].

This practice parameter is intended to improve patient care by improving the consistency of medical record content, the written or dictated reports, and image archiving for vascular/interventional radiology procedures (exclusive of breast interventional procedures). For information on breast interventional procedures, see the ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures or the ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures [2,3].

These practice parameters will serve the following specific purposes:

1. To document medical care
2. To be used in quality improvement programs and for credentialing purposes
3. To be used in teaching and research
4. To document procedures for appropriate coding
5. To provide practice parameters for state health codes for image archiving

II. MEDICAL REPORT

A. Medical Record

A medical record consists of a patient’s medical information recorded in either written hard copy or electronic format. This information may be recorded in the patient medical chart, nursing reports, radiology records, inpatient or outpatient medical information storage areas, or electronically. The medical record should include, as appropriate, the following information [4]:

1. Documentation of preprocedural inpatient and/or office consultation
2. Immediate preprocedure note
3. Immediate postprocedure note
4. Final report
5. Documentation of postprocedure patient follow-up, if applicable

B. Documentation of Preprocedural Inpatient and/or Office Consultation

The preprocedural documentation provides a baseline record of patient status and documents the indication for the procedure. It should be entered in the chart before the procedure. Preprocedural documentation should, as appropriate depending on the complexity and/or clinical urgency of the procedure, include the following information:

1. Indication for procedure and brief history
2. Findings of targeted physical examination
3. Relevant laboratory and other diagnostic findings
4. The plan for each procedure to be performed
5. **Plan for sedation/anesthesia and risk stratification**, such as the American Society of Anesthesiologists Physical Status Classification, if it is going to be administered by the performing physician.
6. Documentation of informed consent (consistent with state and federal laws) or, in the case of an emergency, that it was an emergent medical procedure

C. Updated Immediate Preprocedure Note

The updated immediate preprocedure documentation should be an interval note with any new information developed between the preprocedural evaluation/documentation and the presentation of the patient for the procedure. **The physician performing the procedure should provide a note to administration of any sedation.** In situations where the preprocedural documentation is performed/completed immediately preceding the procedure, the updated immediate preprocedure note is not necessary, as per Joint Commission rules, unless otherwise required by local institution policy.

D. Immediate Postprocedure Note

Before a patient is transferred to the next level of care, an immediate postprocedure note or a final report should be completed and available. The immediate postprocedure note should include the following, as appropriate:

1. Preprocedure diagnosis
2. Postprocedure diagnosis
3. Procedure
4. Operator Physician
5. Assistants
6. Anesthesia/Sedation
7. Medications
8. Access
9. Closure
10. Implants
11. Estimated blood loss
12. Specimens
13. Complications
14. Disposition
15. Findings
16. Plan

It is not necessary for the listed items to be recorded in the order given above.

E. Final Report [5,6]

1. A final report is required for the following purposes:
   a. To transmit procedural information to all members of the health care community who may participate in subsequent care of the patient
   b. For legal purposes
   c. For reimbursement
2. Additional functions of the final report include the following:
   a. Quality improvement programs and for credentialing purposes
   b. Data collection for research
3. Specific information to be included in this report depends on the procedure. The following elements are recommended, although not all of them may be applicable:

a. Procedure name

b. Administrative information
   i. Date
   ii. Time
   iii. Facility

c. Patient information
   i. Medical record number (MRN)
   ii. Date of birth (DOB)
   iii. Gender

d. Procedural personnel
   i. Attending(s)
   ii. Fellow(s)
   iii. Resident(s)
   iv. Advanced Practice Provider(s) Mid-level provider(s)
   v. Other assistant(s)

e. Clinical history
   i. Diagnosis
   ii. Indications
   iii. Comparison

f. Procedure performed

g. Procedural cleanliness
   i. Sterile
   ii. Clean
   iii. Clean contaminated
   iv. Contaminated
   v. Dirty

h. Intraprocedural or immediate postprocedural complications, occurrences, or unexpected events

i. Observations

j. Summary/impression

k. Plan

l. Procedure details
   i. Informed consent
   ii. Time out
   iii. Anesthesia
      • Type and provider
      • Local anesthesia dose should be documented in the final report for pediatric patients as per local policy
   iv. Medications and contrast should be documented in the patient’s electronic health record as per local policy
      • Antibiotics and start time
      • Other medications
      • Contrast

m. Technical details of the procedure
   i. Patient position
   ii. Surface antiseptic preparation
   iii. Patient and provider barrier techniques used (eg, cap, gloves, gown, etc)
   iv. Imaging guidance for access
v. Imaging guidance for procedure
vi. Access location/site
vii. Access technique
viii. Equipment utilized
ix. Closure
x. Estimated blood loss
xi. Radiation doses such as: [7]
- Skin dose mapping
- Peak skin dose (PSD)
- Reference air kerma, \((K_{ar})\) Kerma-area product (PKA).
- Fluoroscopy time/number of fluorographic images
- Dose-length product (DLP).
- Volume computed tomography (CT) dose index (CTDIvol).

n. Attestation
   i. Supervision
   ii. Antisepsis
   iii. Barrier technique

o. Supplemental information

It is not necessary for the listed items to be recorded in the order given above.

F. Structured Reporting

Structured reporting has gained popularity within the diagnostic radiology community as it may provide referring physicians with more consistent, definitive information, especially with complex examinations (eg, oncology staging) [8,9].

Structured reporting within interventional radiology has been shown to improve institutional compliance, quality, and reimbursement, as well as to help facilitate data collection for research [10,11]. One study suggested that referring physicians preferred reading structured reports compared to free-text reports [11], whereas another study found that interventional radiologists were more compliant and satisfied with structured reporting when they had input into the initial design of the report template, including a (free-text) executive summary and a detailed procedural narrative [12].

Indeed, the benefits of structured reporting within interventional radiology have been initially established [12]. Implementation has improved as the templates have automated importing of data into the report and as the templates have become increasingly compatible with existing voice dictation software. Additionally, the interventional radiologist has a vested role in the templates’ creation and layout, all of which will help to increase satisfaction and compliance.

III. ARCHIVING OF IMAGES

A. General Principles

All pertinent imaging data should be saved in permanently retrievable digital or hard-copy format. Legal requirements as to the length of time that images should be retained vary from state to state. Examples of pertinent imaging data include the relevant anatomy that will affect patient management, device position, complications, and any transient adverse events (such as emboli) that have been successfully treated during a procedure.
B. Documentation of Device Position

The final position of all devices inserted permanently or long term with imaging guidance (eg, stents, endovascular grafts, central venous catheters, inferior vena cava filters, embolic agents, drainage catheters) should be documented with imaging.

C. Angiography

Archived images are crucial to the overall diagnostic and/or therapeutic treatment plan of the patient. For saved digital subtraction angiography (DSA) runs, the operator should consider whether archiving unsubtracted or partially subtracted images might be useful and, if so, an attempt should be made to record at least one such an image in unsubtracted or partially subtracted format. This image is useful for orientation/localization purposes. It should be understood that, with the use of rapid-sequence imaging and fluoroscopy, some observations that are described in the report may not be adequately documented by the static archived images.

D. Endovascular Interventions

Predeployment and postdeployment intervention images should be obtained and archived. Intermediate stages that are pertinent to the performance of the endovascular procedure may also be documented with archived images. Images should detail the position of the device and, when appropriate, the effect of the device on target or nontarget vessels.

E. Nonvascular Interventions

Images should document the device’s position and its effect on target and nontarget organs. The final position of drainage catheters within fluid collections, the biliary system, the urinary tract, or the gastrointestinal tract should be documented. If contrast material is injected for delineating cavity size, location, or communication with adjacent structures, at least one image should be archived. If imaging is used to mark a position for subsequent needle entry (eg, ultrasound to mark an entry site for later paracentesis performed without imaging guidance), at least one image of this position should be saved. For needle placement (eg, biopsies, drug delivery, pain management interventions) under direct imaging guidance, at least one image should be saved with the needle in final position at each treated targeted site. The operator may choose to document every needle pass and the final condition of the accessed structure.

IV. ARCHIVING OF RADIATION DOSE DATA

If technically possible, all radiation dose data recorded by the fluoroscopy unit or CT scanner should be transferred and archived with the images from the procedure [7]. When possible, this should be performed electronically with automatic transfer of the data from the fluoroscopy unit or CT scanner to a picture archiving and communication system (PACS). Archiving of radiation dose data is of particular importance if the procedure is likely to be repeated or if the patient has received a clinically important radiation dose [4].

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 – Interventional Cardiovascular of the ACR Commission on Interventional and Cardiovascular and the Committee on Practice Parameters - Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the SIR and the SPR.
**Collaborative Committee** – members represent their societies in the initial and final revision of this technical standard

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<tr>
<th>ACR</th>
<th>SIR</th>
<th>SPR</th>
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<tbody>
<tr>
<td>Sean R. Dariushnia, MD, Chair</td>
<td>Lynn A. Brody, MD</td>
<td>Manish N. Patel, DO</td>
</tr>
<tr>
<td>Drew M. Caplin, MD</td>
<td>Mehran Midia, MD</td>
<td>Ranjith Vellody, MD</td>
</tr>
<tr>
<td>Kassa Darge, MD, PhD</td>
<td>Jason W. Mitchell, MD</td>
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<tr>
<td>Matthew Lungren, MD</td>
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**Committee on Practice Parameters – Interventional and Cardiovascular Radiology**
(ACR Committee responsible for sponsoring the draft through the process)

<table>
<thead>
<tr>
<th>Name</th>
<th>Society</th>
</tr>
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<tbody>
<tr>
<td>Clayton K. Trimmer, DO, FACR, FAOCR, FSIR, Chair</td>
<td>ACR</td>
</tr>
<tr>
<td>Chaitanya Ahuja, MBBS</td>
<td>SIR</td>
</tr>
<tr>
<td>Drew M. Caplin, MD</td>
<td>SPR</td>
</tr>
<tr>
<td>Douglas M. Coldwell, MD, PhD</td>
<td>ACR</td>
</tr>
<tr>
<td>Mandeep S. Dagli, MD</td>
<td>SIR</td>
</tr>
<tr>
<td>Kevin W. Dickey, MD</td>
<td>SPR</td>
</tr>
<tr>
<td>Joshua A. Hirsch, MD, FACR, FSIR</td>
<td>ACR</td>
</tr>
<tr>
<td>Kelvin Hong, MD, FSIR</td>
<td>SIR</td>
</tr>
</tbody>
</table>

**Committee on Practice Parameters – Pediatric Radiology**
(ACR Committee responsible for sponsoring the draft through the process)

<table>
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<tr>
<td>Beverley Newman, MB, BCh, BSc, FACR, Chair</td>
<td>ACR</td>
</tr>
<tr>
<td>Timothy J. Carmody, MD, FACR</td>
<td>SIR</td>
</tr>
<tr>
<td>Tara M. Catanzano, MB, BCh</td>
<td>SPR</td>
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<tr>
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<td>Safwan S. Halabi, MD</td>
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**Comments Reconciliation Committee**

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<td>Gregory N. Nicola, MD, FACR, Chair</td>
<td>ACR</td>
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<td>Samir B. Patel, MD, FACR, Co-Chair</td>
<td>SIR</td>
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<td>Richard A. Barth, MD, FACR</td>
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<td>Jacqueline A. Bello, MD, FACR</td>
<td>ACR</td>
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<td>Lynn A. Brody, MD</td>
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<td>Drew M. Caplin, MD</td>
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<td>Mandeep S. Dagli, MD</td>
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<td>Kassa Darge, MD, PhD</td>
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<td>Sean R. Dariushnia, MD</td>
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<td>Richard Duszak, Jr., MD, FACR</td>
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<td>Clair Kaufman, MD</td>
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**PRACTICE PARAMETER**

Reporting and Archiving

2019 Resolution No. 20
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

2004 (Resolution 25)
Revised 2009 (Resolution 23)
Revised 2014 (Resolution 16)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization for Treatment of Liver Malignancies

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 17)*

ACR–ABS–ACNM–ASTRO–SIR–SNMMI PRACTICE PARAMETER FOR SELECTIVE INTERNAL RADIATION THERAPY (SIRT) OR RADIOEMBOLIZATION WITH MICROSPHERE BRACHYTHERAPY DEVICE (RMBD) FOR TREATMENT OF LIVER MALIGNANCIES

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.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, __ N.W.2d __ (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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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 practice parameter was revised collaboratively by the American College of Radiology (ACR), the American Brachytherapy Society (ABS), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), the Society of Interventional Radiology (SIR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

Radioembolization with a microsphere brachytherapy device, (RMBD) also referred to as selective internal radiation therapy (SIRT) and transarterial radioembolization (TARE), are commonly used terms that describe the same procedure, so for the balance of this document, we will use the term radioembolization.

Radioembolization is the embolization of the hepatic arterial supply of hepatic primary tumors or metastases via delivery of radioactive beta emitters approximately 25 to 32 µm in size. Terms relevant to this practice parameter include intra-arterial therapy and SIRT.

Radioembolization with a microsphere brachytherapy device (RMBD), is the embolization of the hepatic arterial supply of hepatic primary tumors or metastases via delivery of radioactive beta emitters approximately 25 to 32 micrometers (µm) in size. Terms relevant to this practice parameter include intra-arterial therapy and selective internal radiation therapy.

Hepatic arterial therapy takes advantage of the liver’s dual blood supply and the fact that tumors larger than 3 mm in diameter receive 80% to 90% of their blood supply from the hepatic artery [1,2]. In contrast, the majority of the normal hepatic parenchyma receives its supply from the portal vein. For over 30 years, this difference has been exploited to deliver chemotherapy via intra-arterial pumps, embolic agents to occlude the tumoral arteries, and various combinations of both chemotherapy and embolic agents (chemoembolization) to blend the effects to more fully treat the tumors with both ischemic and antineoplastic effects.

The newest addition to intra-arterial therapies is the use of radioactive particulates using yttrium-90 to perform intra-arterial brachytherapy. Brachytherapy is the use of radioisotopes as sealed sources to treat malignancies or benign conditions by means of a radioactive source placed close to or into the tumor. Yttrium-90 is a pure beta emitter with a half-life of 64.2 hours (2.67 days). The maximum energy of the emitted beta particles is 2.27 MeV, with an average energy of 0.94 MeV. This corresponds to a maximum penetration range in tissue of 1.1 cm 11 mm, with a mean path of 2.5 mm and an effective path length of 5.3 mm. Yttrium-90 also emits a positron, with a branching ratio of 32 ppm, allowing for positron emission tomography (PET) imaging. Yttrium-90 is produced by neutron bombardment of yttrium-89, and upon beta emission, decays to a stable isotope of Zr (Zr-90). In 1 kg of tissue, 1 GBq of uniformly dispersed yttrium-90 delivers an absorbed radiation dose of approximately 50 Gy.

Currently, two yttrium-90 products are commercially available. Both contain yttrium-90 as the therapeutic radioactive agent.

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Radioembolization

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1. Glass spheres (TheraSphere®) were approved by the Food and Drug Administration (FDA) in 1999 with a humanitarian device exemption (HDE). These products are approved for use in patients with unresectable hepatocellular carcinoma (HCC). These microspheres arrive a few days before the implant procedure, and all of the spheres contained within a predetermined activity vial are implanted. The spheres have a median size of 25 µm (range 20-30 µm) and nominal specific activity of 2,500 Bq/sphere at time of calibration.

2. Resin spheres (SIR-Spheres®) received FDA approval in 2002 for premarket approval (PMA) for unresectable liver metastases from primary colorectal cancer in conjunction with an intrarterial chemoinfusion pump. The spheres have a median size of 32 µm (range 20-60 µm) and nominal specific activity of 50 Bq/sphere at time of calibration. SIR-Spheres are delivered on either the day before or the day of implantation.

Brachytherapy is the use of radioisotopes as sealed sources to treat malignancies or benign conditions by means of a radioactive source placed close to or into the tumor. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer.

The use of brachytherapy requires detailed attention to personnel, equipment, patient, and personnel safety and to continuing staff education. As brachytherapy is performed in a variety of environments, the authorized user (AU), usually an interventional radiologist, radiation oncologist, or nuclear medicine physician, and a Qualified Medical Physicist should apply these practice parameters to individual practices (see section IV.D for the definition of a Qualified Medical Physicist).

The licensing of radioactive sources used in medicine and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states. Medical use of isotopes for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies. Detailed descriptions of NRC licensing and safety issues can be found in the Code of Federal Regulations, Part 20 and Part 35. State requirements for the agreement states are found in the respective state statutes.

The treatment goal of radioembolization should be tailored to the individual patient, whether it is palliative curative or a bridge to surgical resection or liver transplantation. Treatment should be defined and communicated to the patient and treatment team. The goal of radioembolization is to achieve intrahepatic tumor control. Appropriately selected patients with no or minimal extrahepatic metastases may have improved outcomes following treatment with radioembolization. Radioembolization can induce a partial tumor response, allowing for subsequent surgical excision or liver transplantation. Radioembolization therapy has been used for both palliative therapy for hepatic metastases and for treatment of paraneoplastic syndromes. See Appendix A for a literature review. The most common clinical utility of radioembolization is in the treatment of HCC and liver-dominant metastatic CRC and neuroendocrine tumors (NETs) (see appendix A). Response to radioembolization is typically assessed with multidetector triple-phase contrast-enhanced computed tomography (CT) of the liver or with magnetic resonance imaging (MRI) with contrast and, when appropriate, via fluorine-18-2-fluoro-2-deoxy-D-glucose PET/CT (FDG-PET/CT) [3,4].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications for both agents include, but are not limited to, the following:

1. The presence of unresectable or inoperable primary or secondary liver malignancies (particularly CRC and NET metastases). The tumor burden should be liver dominant, not necessarily exclusive to the liver. Patients should also have a performance status that will allow them to benefit from such therapy. IE, an ECOG performance status of 0 to 2 or 1 or KPS of 70 or more.

2. A life expectancy of at least 3 months

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2 An agreement state is any state with which the U.S. Nuclear Regulatory Commission or the U.S. 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).
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B. Absolute contraindications include the following:

1. Inability to catheterize the hepatic artery
2. Fulminant liver failure
3. **Initial mapping angiography** and/or technetium-99m **macroaggregated albumin** (MAA) hepatic arterial perfusion scintigraphy demonstrating **significant reflux** or nontarget deposition to the gastrointestinal organs that cannot be corrected by angiographic techniques
4. Pretreatment hepatic arterial administration with technetium-99m MAA demonstrative of unfavorable (or unacceptable) shunt fraction between the liver and the pulmonary parenchyma. This shunt fraction must not be greater than acceptable limits specific to each brachytherapy device.
5. Active hepatic infection
6. Therapy during pregnancy may possibly be an option in extraordinary circumstances and with multidisciplinary consult and considerations.

C. Relative contraindications include the following:

1. Excessive tumor burden in the liver with greater than 50% to 70% of the parenchyma replaced by tumor. **In the setting of more extensive tumor burden, treatment can be considered if synthetic hepatic function is preserved.** Tumor burden may be even more extensive if synthetic function is preserved.
2. Total bilirubin greater than 2 mg/dL (in the absence of obstructive cause), which indicates severe liver function impairment. Nonobstructive bilirubin elevations generally may indicate that liver metastases have caused liver impairment to the degree that risks outweigh benefits for this therapy. In contrast, patients with HCC and elevated bilirubin may be treated with radioembolization if a segmental or subsegmental infusion can be performed [5].
3. Pretreatment hepatic arterial perfusion embolization with technetium-99m MAA demonstrative of unfavorable (or unacceptable) shunt fraction between the liver and the pulmonary parenchyma. This shunt fraction must not be greater than acceptable limits specific to each brachytherapy device.
4. Prior radiation therapy to the liver or upper abdomen that included a significant volume of the liver (clinical judgment by the AU required).
5. Chemotherapy agents in the preceding 4 weeks known to be unsafe when used with RMBD. Caution is recommended when treating these patients. Care must be employed when patients are on systemic therapies that may potentiate or may alter the impact of radioembolization and should use caution when combining therapies.
6. If the patient is known to be pregnant, the potential radiation risks to the fetus and the clinical benefits of the procedure required before, during, and after RMBD, and any scatter radiation from the hepatic implant should be considered before proceeding with treatment.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Physicians from various medical specialties are involved at different times in the evaluation and management of patients receiving **radioembolization. RMBD** Multidisciplinary expertise is essential and includes interventional radiology, radiation oncology, nuclear medicine, medical physics, radiation safety, hepatology, gastroenterology, medical oncology, and surgical oncology. Interventional radiologists are responsible for performing the screening **mapping angiogram** with or without embolization, planning the **delivery of dose**, and subsequently placing the delivery catheter. AU and the Qualified Medical Physicist (and sometimes with a combination of other specialists responsible for the care of the patient) The AU should provide a written directive for the source administration and is responsible for administering the radiation **radioactive product** once the interventional radiologist (who may also be the AU) has placed the delivery catheter [6]. The nuclear medicine specialist evaluates the technetium-99m MAA scan to quantify the lung shunt fraction and to evaluate for potential unintended deposition in other gastrointestinal organs. The responsibilities of the multidisciplinary team may include the following:
1. Selecting the patient for radioembolization. RMBD This includes history, physical examination, and review of imaging examinations and laboratory reports [7].

2. Obtaining informed consent for radioembolization. RMBD Complete explanations of the entire radioembolization RMBD process, including necessary imaging, laboratory, and treatment procedures, typical side effects, and potential complications. The team member completing this portion should be the physician coordinating the activities of the entire team [8].

3. Reviewing the hepatic angiogram, technetium-99m MAA scan, and laboratory reports to make the final determination of eligibility for radioembolization. RMBD

4. Determining treatment parameters: (a) single or fractionated (staged) treatment, (b) intended activity to be administered, (c) target volume (whole liver, lobar, or segment), and (d) vessel(s) to be used for delivery of activity

5. Delivering radioactivity, including monitoring for stasis and/or reflux of microspheres during treatment and ending the procedure as needed.

6. During treatment, the AU should monitor for stasis and/or reflux of microspheres and end the procedure as needed.

6. Monitoring the patient during the periprocedural period to provide support and clinical management and radiation safety information

7. Following patient after the day of treatment to monitor for side effects, complications, and response to therapy

8. Monitoring radiation safety and spill periprocedural

9. Verification of treatment delivery using nuclear medicine imaging. Posttherapy yttrium-90 single photon-emission CT (SPECT)/CT or yttrium-90 PET/CT is recommended.

10. Follow-up patients and monitor for radioembolization-induced liver disease that includes elevated bilirubin, elevated albumin, and development of ascites.

A. Interventional Radiologist Physician

The interventional radiologists are typically the treating physicians and experts on locoregional therapy and are responsible for placement of the catheter for angiogram, technetium-99m MAA injection, protective embolization of gastric and gastroduodenal artery (GDA) if deemed necessary, and catheter placement for yttrium-90 treatment. He or she may also be the AU at the treating facility. This individual should meet the following qualifications:

1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of radioembolization RMBD procedures to demonstrate competency as attested by the supervising physician(s)

or

2. Completion of a radiology or interventional residency 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, the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and has performed (with supervision) a sufficient number of radioembolization RMBD procedures to demonstrate competency as attested by the supervising physician(s).

or

3. Completion of an ACGME-approved nonradiology residency or fellowship training and a minimum of 12 months of training in a service that is primarily responsible for the performance of percutaneous visceral arteriography and vascular/interventional radiology during which the physician was supervised. Documented formal training in the performance of invasive catheter arteriographic procedures must be included. During this training the physician should have performed 50 radioembolization RMBD
procedures, 25 of them as primary operator, performing (with supervision) a sufficient number of radioembolization RMBD procedures to demonstrate competency as attested by the supervising physician(s).

**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.

Interventional radiologists may become AUs. In order to do so, interventional radiologists must meet all of the necessary training requirements as described by the NRC and by their own radiation safety officer (RSO) and state. This includes training in physics as well as completion of the necessary training and proctoring by the yttrium-90 manufacturers.

B. **Radiation Oncologists**

Radiation oncologists are experts on liver tolerance to radiation therapy and radiation complications in normal tissues. He or she may be the AU at the treating facility. The radiation oncologist should have the following qualifications and certification:

1. Satisfactory completion of a residency program in radiation oncology approved by the ACGME, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the AOA.

or

2. Certification in Radiology by the ABR of a physician who confines his or her professional practice to radiation oncology or certification in Radiation Oncology or Therapeutic Radiology by the ABR, the American Osteopathic Board of Radiology, the RCPSC, or the Collège des Médecins du Québec may be considered proof of adequate physician qualifications.

And, in addition to certification, education, and other credentials

3. Completion of the manufacturer’s training program, which typically includes a certain number of cases performed under supervision of a proctor provided by the company or under the supervision of an AU who is authorized for the type of microsphere for which the individual is seeking authorization.

The continuing education of a radiation oncologist should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [9].

C. **Nuclear Medicine Physician**

The nuclear medicine physician is responsible for the technetium-99m MAA scintigraphy, including calculation of shunt fraction, and may be the AU at the facility, may also be responsible for the technetium-99m MAA injection, may be involved in planning the therapy, including helping to plan where the delivery catheter should be placed, may administer the yttrium-90, may make the final determination of eligibility for radioembolization, may determine treatment parameters, and may monitor for radiation-related complications. He or she also interprets the postradioembolization PET scan and/or the bremsstrahlung scan. (See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [10].)
The physician providing nuclear medicine services must meet all of the following criteria:

1. Qualifications and certification
   a. Certification in either Radiology, Diagnostic Radiology, Nuclear Radiology, or Nuclear Medicine by one of the following organizations: the ABR, the American Osteopathic Board of Radiology, the RCPSC, the Collège des Médecins du Québec, the American Board of Nuclear Medicine, and/or the American Osteopathic Board of Nuclear Medicine.
   
   b. At a minimum, completion of a general nuclear medicine program approved by the ACGME, the RCPSC, the Collège des Médecins du Québec, or the AOA that must include training in radiation physics, instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection, and quality control. In addition, clinical training in general nuclear medicine is required, which must cover technical performance, calculation of administered activity, evaluation of images, correlation with other diagnostic modalities, interpretation, and formal reporting. Physicians trained prior to the availability of formal instruction in nuclear medicine–related sciences may be exempted from this paragraph, provided they have been actively involved in providing nuclear medicine services.

2. Have documented regular participation in continuing medical education (CME) specifically related to diagnostic procedures using radiopharmaceuticals, in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [9].

3. Be listed as an AU on the radioactive materials license of his or her institution. When required by the NRC or by the state, at least one physician member of the facility must be a participating member of the committee that deals with radiation safety.

4. A physician who will administer yttrium-90 must have the credentials described in section IV and must complete the manufacturer’s training program. This program may include (1) on-site proctoring or technical support or (2) a training course.

5. Have a thorough understanding of each procedure with which he or she is involved. The physician is further responsible for ensuring appropriate utilization of services, quality of procedures, and all aspects of patient and facility safety and compliance with applicable government and institutional regulations regarding the use of radiopharmaceuticals.

6. Be responsible for developing and maintaining a program of quality control and continued quality improvement (see sections IV and V) or accept responsibility for adhering to such an established program.

D. Qualified Medical Physicist

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

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME), (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [9]

The appropriate subfields of medical physics for this standard are Nuclear Medical Physics (including medical physics certification categories of Radiological Physics, Medical Nuclear Physics, and Nuclear Medicine Physics).
The Qualified Medical Physicist or other qualified scientist performing services in support of nuclear medicine facilities should meet all of the following criteria:

1. Advanced training directed at the specific area of responsibility (eg, radiopharmacy, medical physics, health physics, or instrumentation)
2. Licensure, if required by state regulations
3. Documented regular participation in continuing education in the area of specific involvement to maintain competency
4. Knowledge of radiation safety and protection and of all rules and regulations applying to the area of practice

E. Radiologic Technologists

1. Interventional technologist
   a. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing and imaging the procedure. They should be able to demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. Technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
   b. If the patient is to undergo moderate sedation, a nurse or other appropriately trained individual should monitor the patient as his or her primary responsibility. 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) [11].
   c. Although complications of arteriography only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly. This could be performed in an acute-care hospital with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a free-standing center, detailed protocols for the rapid transport or admission of patient to an acute-care hospital should be formalized in writing.

2. Nuclear medicine technologist

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [10].

F. Nursing Services

If the patient is to undergo moderate sedation, a nurse or other appropriately trained individual should monitor the patient as his or her primary responsibility. 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) [11].

IV. SPECIFICATIONS OF THE PROCEDURE

A. Preliminary Angiographic Evaluation

The indications for elective arteriographic studies should be documented as described below. A note should be written summarizing the indications for the study, the pertinent history and physical findings, if available, and the proposed procedure, including:
1. Clinically significant history, including indications for the procedure
2. Clinically significant physical examination, including an awareness of clinical or medical conditions that may necessitate specific care
3. Laboratory evaluation if indicated, including liver function tests, appropriate tumor markers (eg, carcinoembryonic antigen [CEA], alpha-fetoprotein [AFP]), hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters
4. Review of appropriate anatomic and/or functional imaging studies, such as cross-sectional CT, MR, and PET scans

B. Establishing Treatment Goals with Patient and Treatment Team

The goal of yttrium-90 radioembolization is to achieve optimal tumor control. It is likely that patients with no or minimal extrahepatic metastases (appropriately selected patients) will have increased disease-free and possibly increased overall survival as a result of improved hepatic control. Multidetector triple-phase contrast-enhanced CT, of the liver MR, and PET-CT are used to evaluate response. Although both Response Evaluation Criteria in Solid Tumors (RECIST) criteria and modified RECIST criteria have been used to evaluate imaging response in HCC. RECIST criteria have also been used to evaluate imaging response in metastatic disease [12-15]. It has been recently reported that FDG-PET response may be more indicative of the actual tumor response.

C. Obtaining Informed Consent

Consent for the interventional procedure should be obtained by the interventional radiologist after discussing the procedure in detail with the patient or designated medical power of attorney. The risks and complications of the procedure, as well as the treatment outcomes, should be completely and frankly discussed in detail. The consent for radiation therapy should be obtained by the AU or his or her designee, which could include the interventional radiologist, the nuclear medicine physician, or the radiation oncologist. (See the ACR Practice Parameter on Informed Consent – Radiation Oncology [8].)

D. Pretreatment Evaluation

Pretreatment planning includes performance of a CT scan CT, MR, or PET scan within 30 days of treatment with determination of tumor volume. PET scanning should be performed for FDG avid tumors. Other functional imaging may be performed as appropriate and the normal liver volumes.

E. Preliminary Angiographic Evaluation

Once a patient has been selected as a candidate for radioembolization, through multidisciplinary collaboration an initial angiographic evaluation is performed. The proper sequence of vessels to be addressed and evaluated has been previously published [16-18]. This evaluation is done primarily to document the delineate visceral anatomy, identify anatomic variants, isolate the hepatic circulation, and for consideration of occlusion or embolization of extrahepatic vessels.

Pretreatment visceral arteriography should, at a minimum, include injection of the celiac, superior mesenteric, left gastric, gastroduodenal common and/or proper hepatic, and right and left hepatic arteries. Embolization of the GDA as well as the right gastric or any other gastric arteries should can be considered to avoid nontarget microsphere deposition to the gastrointestinal tract. Other vessels that may require similar treatment include the falciform artery, supraduodenal, retroduodenal, left inferior phrenic, accessory left gastric and inferior esophageal arteries. Care should be taken when considering embolization of the gastroduodenal artery (GDA) arteries perfusing the bowel, as collateralization can occur with time. The consensus for embolization of the cystic artery is still not established. If the cystic artery arises distal to the site of planned delivery, proximal embolization of the cystic artery of the time of yttrium-90
administration, usually with Gelfoam pledgets or coils, has been described. Given the rarity of radiation-induced cholecystitis (<2%) and most of the cases being managed conservatively, some institutes choose not to embolize the cystic artery [19]. Accessory hepatic vessels feeding tumor may arise from this artery. Vascular anomalies should be identified, and the relationship of these variants with the tumors should be determined so that all tumors may be treated. These vessels should be recognized and accessed, with consideration for embolization left to the discretion of the operator.

Prophylactic embolization of the above-mentioned vessels converts the hepatic blood flow into one that might be found when a surgically placed hepatic arterial port is placed. Usually, in surgical port placement, the common hepatic artery is skeletonized, the GDA and right gastric are ligated, and any other hepatic-mesenteric or extrahepatic vessels are ligated.

This is analogous to what is accomplished with the above-described angiographic technique. It is important that all hepatic vessels be interrogated during the angiographic assessment of the patient. Only direct catheterization and interrogation of all appropriate vessels would demonstrate remote blood supply to the tumor. The lack of recognition of this phenomenon may result in incomplete treatment of the target tumor bed.

Once the anatomy has been established, selective arteriography is performed in the expected location of the yttrium-90 treatment. This may require use of a microcatheter.

At the conclusion of the vascular mapping arteriogram, and after all nontarget vessels have been embolized, technetium-99m MAA arterial injection is performed: 37 to 185 MBq (1.0-5.0 mCi) of technetium-99m MAA should be injected through the microcatheter for follow-up imaging of the liver and lungs to determine the amount degree of shunting to the lungs. Options for MAA injection locations include the (1) site of planned yttrium-90 infusion, (2) lobar artery to the hepatic lobe with greatest risk for elevated lung shunt fraction (eg, vascular invasion or greater tumor burden), or (3) common or proper hepatic artery [20,21]. In cases of metastases, injection can often be performed in the proper hepatic artery, given the low incidence of lung shunting in patients with metastatic disease to the liver. The approach to the technetium-99m MAA injection in patients with HCC is slightly different. If the patient has bilobar HCC, proper hepatic artery injection of technetium-99m MAA can be performed unless gross vascular shunting into the hepatic or portal vein is seen. The shunt fraction obtained is assumed to be representative of the bilobar tumors, and if a lobar injection is performed for bilobar disease, the lung shunt fraction may be a slightly overestimated, which would provide the largest margin of safety with regards to lung dose. In cases of bilobar disease where angiographic shunting is seen, a unilateral injection of technetium-99m MAA is performed, and only one lobe is assessed at a time. A repeat technetium-99m MAA injection is performed at a later date when the second lobe requires treatment. Both lobes can be evaluated during the initial technetium-99m MAA injection if the intent is to treat both lobes in a single treatment.

It is important to note that in cases where variant arterial anatomy exists, the technetium-99m MAA dose should be fractionated in order to cover the entire liver in one sitting mapping angiogram, if possible. To this purpose, the MAA dose can be split into smaller (eg, 1 or 5 mCi) doses. For example, in cases where there is a replaced right hepatic artery, 2 to 3 mCi of technetium-99m MAA is given in that vessel, whereas the remaining 2 to 3 mCi is given in the left hepatic artery. In cases of a gastrohepatic trunk, 1 to 3 mCi of technetium-99m MAA is injected into the left hepatic artery, and the remainder is injected into the right hepatic artery.

F. Variant Mesenteric Anatomy

In 55% to 65% of cases, the celiac artery gives rise to the splenic artery, the left gastric artery, and the common hepatic artery (CHA). The dorsal pancreatic artery commonly arises from the celiac origin, although it may also arise off the CHA or splenic artery. The CHA then gives rise to the GDA and becomes the proper hepatic artery, which divides into the right and left hepatic arteries. When a distinct vessel arising from the right hepatic artery provides flow to segment IV, it is referred to as the middle hepatic artery. In more than 40% of cases, the origin and course of the hepatic arteries vary, as does the vascular distribution of the vessel irrespective of its anticipated course. Vessels supplying one segment may be recruited to provide flow to other anatomic segments. The most
common variants include a replaced or accessory right hepatic artery arising from the superior mesenteric artery (SMA) and a replaced or accessory left hepatic artery arising from the left gastric artery [22]. Other less common variants include a replaced CHA arising from the SMA or bifurcation of a short CHA into right and left hepatic arteries. The right and left hepatic arteries may arise separately from the celiac trunk or directly from the aorta. The caudate lobe most commonly receives its blood supply from a small branch off the left or right hepatic artery. This caudate artery is normally rather diminutive; however, in the setting of tumor, it can become prominent, thereby allowing selective catheterization and treatment.

G. **Radioembolization** Treatment Plan

1. It is recommended that a written directive be obtained from the AU before the source microsphere dose administration is ordered. The written directive will be in the patient chart and should include the following information:
   a. Before implantation: treatment site, the radionuclide and type of spheres (yttrium-90 glass or resin microspheres), planned dose date and time and/or activity ordered, in gigabequerels [GBq] and medical end point (stasis to determine when to terminate implantation)
   b. After implantation but before completion of the procedure: the radionuclide (yttrium-90 microspheres), treatment site, and the total dose implanted
   c. In addition, the written directive often may include:
      i. Mass or volume of the target
      ii. Location of the target
      iii. Lung shunt fraction
      iv. Dose estimate for lung and gastrointestinal tract
      v. Approximate time of administration
      vi. Upon completion of the procedure, any deviations from the written directive and the action taken

2. **Radioactivity calculation Dosimetry**

Depending on the brachytherapy device being used, results of the studies (CT, technetium-99m MAA hepatic arterial scintigraphy, or angiogram), and the volume of liver to be treated (eg, whole liver versus lobar treatment), various dosimetry models (body surface area (BSA), partition model, single compartment Medical Internal Radiation Dosimetry (MIRD), voxel-based dosimetry) may be used in calculating activity to be administered.

a. Glass sphere Therasphere®

   i. The glass microsphere dosimetry is based on the single-compartment MIRD (MIRD committee of the Society of Nuclear Medicine and Molecular Imaging) model. Although sphere distribution is known to be nonuniform, MIRD dosimetry models assume uniform distribution of activity in mass. Activity calculation requires determination of the patient’s treatment liver mass and the nominal target dose.
   ii. The partition model is based on the MIRD model and involves implanting the highest possible activity to the tumor while maintaining radiation dose to sensitive tissues such as lung and normal liver at an acceptable level. This method can only be used where the tumor mass is localized in a discrete area within the liver and the tumor can be drawn as an “area of interest” on SPECT (single photon-emission CT) camera image.

b. Resin sphere SIR-Spheres®

   There are two methods for calculating the activity as recommended by the manufacturer:

   i. The body surface area (BSA) method uses the manufacturer’s formula to calculate the activity to be implanted. This formula requires the patient’s height, weight, and percentage of the liver that is
replaced by the tumor as calculated from the CT scan.

ii. The partition model is based on the MIRD model and involves implanting the highest possible activity to the tumor while maintaining accepting radiation doses to radiosensitive tissues, such as lung and normal liver. This method can only be used where the tumor mass or masses are localized as a discrete area or areas within the liver and delineated as a “volume or volumes of interest” on a technitium-99 MAA SPECT or SPECT-CT study.

i. The empiric method recommends a standard amount of activity based on estimated percentage of tumor burden in the liver as shown in the table below.

<table>
<thead>
<tr>
<th>Estimated Tumor Involvement of Liver</th>
<th>Recommended Activity for Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50%</td>
<td>3 GBq</td>
</tr>
<tr>
<td>25% to 50%</td>
<td>2.5 GBq</td>
</tr>
<tr>
<td>≤25%</td>
<td>2 GBq</td>
</tr>
</tbody>
</table>

Although all 3 methods have been mentioned in the literature, the BSA method is preferred and is most commonly utilized when a resin-based microsphere device is used.

H. RMBD Radioembolization Treatment Delivery

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

2. All patients should have continuous cardiac monitoring during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.

3. All patients should have intravenous access for the administration of fluids and medications as needed.

4. If the patient is to receive moderate sedation, pulse oximetry should be used in addition to step 2. A registered nurse or other appropriately trained personnel should be present, and his or her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.

5. The diagnostic angiography portion involves assessment of the vascular anatomy, any arterial variants, patency of the portal venous system, and any other vascular anomalies. In particular, therapy with radioembolization involves the identification of vessels that extend outside the anticipated treatment field (examples might include gastric, duodenal, or esophageal vessels). Appropriate precautions for vascular exclusions are undertaken at the time (such as distal catheter placement or coil embolization).

6. Hepatic arterial scintigraphy with technetium-99m MAA is done for treatment planning and for detecting patients who might be at risk for complications from extrahepatic deposition.

a. Perfusion of hepatic tumors

i. Technetium-99m MAA consists of particles of aggregated human serum albumin with a size range of 10 to 90 µm. Given intra-arterially via a hepatic artery perfusion catheter, the MAA particles will localize within the liver in a distribution similar to that of the radioembolization microspheres. The usual adult administered activity is 1.0 to 6.0 mCi (37-222 MBq).

ii. Planar images of the abdomen are obtained immediately in the following projections: anterior and posterior, left anterior oblique, and right anterior oblique, left lateral, and right lateral, followed by planar images of the chest and neck (to include the thyroid) in the anterior and posterior projections. SPECT/CT imaging may should be performed. When using a single-head, large field-of-view SPECT gamma camera, with the following parameters should be used: 64 × 64 matrix, 6° angle of sampling (60 images in a 360° arc), 20 to 30 seconds per stop. For multieheaded gamma cameras, SPECT imaging with a 128 × 128 matrix with a 3° angle of sampling (60 images per head for a dual-head camera or 40 images per head for a three-head camera) can be used. The CT as part of SPECT CT should be of good quality (low noise). There is limited value to using a low-dose
CT scan when the liver will be treated to radiation doses that will be orders of magnitude greater.

b. Identify any extrahepatic radiotracer distribution and calculate the pulmonary shunt fraction by the geometric mean (GM). The GM is performed by drawing a region of interest around the whole lung and the whole liver in the anterior and posterior projections. The square root of the product of the anterior and posterior counts is the GM. To quantitate the percentage of lung shunting, the following formula is used: % lung shunt = \( \frac{(GM \text{ lung} \times GM \text{ liver})}{GM \text{ lung}} \times 100 \). Nontarget dose to lung can be calculated based on the lung shunt fraction, and dose reduction may be required to remain under the recommended lung tolerance doses of 30 Gy per treatment and 50 Gy total lifetime lung dose. Furthermore, the SIR-Spheres package insert states that a lung shunt fraction >20% is a contraindication to therapy. If the lung shunt fraction is >10%, a dose reduction is recommended to prevent radiation pneumonitis. If the lung shunt fraction is >20%, yttrium-90 therapy should not be performed. A dose reduction should also be considered if the patient has received prior chemotherapy [23,24].

7. A physician should be available during the immediate postprocedure period to ensure that there is adequate hemostasis at the puncture site and that the patient is stable prior to transfer to the postprocedure care area.

I. Postprocedure Care

1. The room and staff should be surveyed at the end of the procedure, before they come off the floor pad. The area and all trash containers should also be surveyed for contamination. All contaminated materials must be placed in storage. A dose calibrator, or other system recommended by the manufacturer, should be used to determine residual postprocedure activity in order to verify activity administered to the patient [25].

2. A procedure note must be written entered in the patient’s chart summarizing the major findings of the study and any immediate complications. This note may be brief if an official interpretation3 is available within a few hours. The immediate note should include, at a minimum, the following: indications, operative procedure and imaging findings, date and time, operator(s)/surgeon(s), complications, medications and/or contrast used, and conclusions. However, if the official interpretation is not likely to be on the chart the same day, a more detailed summary of the procedure should be written 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.

3. 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 site and size of the arteriotomy and the patient’s medical condition. Because a small amount of radioactivity maybe excreted in the urine when undergoing radioembolization with resin microspheres, it is advised that for the first 24 hours postprocedure, the patient should use a toilet and not a urinal. The toilet should also be doubled flushed during this time [23].

4. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the distal vascular distribution.

5. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may need to be addressed further.

6. The initial ambulation of the patient must be supervised. Vascular perfusion, puncture-site stability, and independent patient function and mobility must be ensured.

7. 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 moderate sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician, a nurse, or other appropriately qualified and credentialed health care provider.

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3The ACR Medical Legal Committee defines official interpretation as that written report (and any supplements or amendments thereto) that attach to the patient’s permanent record. In a health care facility with a privilege delineation system, such a written report is prepared only by a qualified physician who has been granted specific delineated clinical privileges for that purpose by the facility’s governing body upon the recommendation of the medical staff.
J. Device Implant

Prior to device implantation, all of the above procedures should have been completed, including review of appropriate studies, diagnostic angiography, MAA scanning, dosimetry dose calculations, and ordering of the brachytherapy device. There should be discussion among team members prior to patient treatment to address any unique or unusual characteristics that may affect patient safety or outcome.

The brachytherapy device should be assayed in the dose calibrator to verify the calibration activity of the source. For resin spheres, the appropriate activity should be withdrawn from the source vial and transferred to the treatment vial. Everything that comes in contact with the radioactive source and could cause contamination should be placed in storage. Treatment room preparation should include placement of absorbent pads on the floor where patient/staff contact is anticipated. A “bail out” box should be available. In preparation for implantation, the appropriate hepatic artery is accessed, the catheter is placed in the predetermined position and confirmed by angiography, the administration kit is assembled, and the infusion is initiated. Once treatment delivery starts, everything that comes into contact with the patient should stay on the table.

For glass microspheres, administration involves the injection of sterile saline through the treatment vial in order to suspend the microspheres for transcatheter delivery. Following complete administration, a postradioembolization angiogram from the base catheter is recommended.

For resin microspheres, administration involves the injection of sterile water D5W through the treatment vial in order to suspend the microspheres for transcatheter delivery. Intermittent angiography should be performed to evaluate for antegrade flow. Once slowing or stasis is observed, no further activity should be administered. Following complete administration, a postradioembolization angiogram should be performed. However, to avoid dislodging microspheres, which can reflux into the gastrointestinal tract, contrast injection should be performed gently and with a minimum amount of contrast that will still achieve an adequate image of the final vasculature postimplant. Preferably, the microcatheter should be withdrawn to at least the proper, right or left, hepatic artery prior to the final injection of contrast if super selective placement has been performed.

V. PATIENT AND PERSONNEL SAFETY

Patient protection measures include those related to medical safety and radiation protection.

A. Patient protection measures should include the following:

1. A radiation exposure monitoring program, as required by the Nuclear Regulatory Commission (NRC) and agreement states
2. Charting systems and forms for documenting all aspects of the treatment, including the prescription, definition and delivery of treatment parameters, and summaries of brachytherapy. In addition, any previous interventions, such as chemotherapy, external-beam radiation therapy, and surgeries, should be documented.
3. A physics program for ensuring accurate dose delivery to the patient
4. A check system for the AU and Qualified Medical Physicist to verify independently all brachytherapy parameters to be used in each procedure (source, isotope, and activity calculation, etc) prior to the delivery of radioembolization RMBD
5. Patients should be provided with written descriptions of the radiation protection guidelines, including, but not limited to, discussion of potential limitations of patient contact with minors and pregnant women. This description must be in compliance with state and federal regulations. The AU, Qualified Medical Physicist, and RSO should define the postimplant radiation safety guidelines for patients treated with radioembolization RMBD
6. Personnel in the angiography suite should all be surveyed for possible contamination.
7. The exposure rate from the contaminated waste should be measured to estimate the residual activity. Ninety-degree intervals around the contaminated waste chamber at 25 cm should be used according to the manufacturer’s guidance. These readings should be averaged to determine the final activity.

8. Postprocedure bremsstrahlung planar imaging, SPECT, SPECT/CT, and/or PET/CT, can be used within 24 hours of the conclusion of the procedure to document the placement of the devices and assess for significant extrahepatic shunting.

9. Patients should be seen immediately following the procedure and at intervals consistent with good medical practice.

10. Imaging follow-up should be obtained at 1 to 3 months following the procedure to determine the effectiveness of the procedure.

It is recommended that patients be given a document on discharge stating that they have received a radioactive medical implant. Radiation from the implant can trigger sensitive security alarms in airports and public buildings. Appropriate hospital/clinic contact information for security personnel should be provided on such documents.

B. Personnel safety measures should include the following:

1. A radiation exposure monitoring program, as required by the institution’s radioactive materials license
2. Appropriate safety equipment for storage of the sources

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [7] or the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [26], with the addition of:

1. Specification of the activity of yttrium-90
2. Target volume: whole liver, right or left lobe, or segment
3. Final activity delivered
4. Any evidence of target embolization
5. Any evidence of nontarget embolization
6. Condition of patient on discharge
7. Follow-up clinical visits planned
8. Follow-up laboratory/radiological examinations
9. Final disposition of patient

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)


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).

The manufacturer-provided acrylic shielding effectively blocks the beta radiation and does not generate significant bremsstrahlung. Although the NRC classifies microspheres as sealed sources, in general they should be handled more like unsealed radiopharmaceutical sources. One area where particular care should be exerted is in the prevention and rapid cleanup of any spills. Unlike solutions of unsealed radiopharmaceuticals that dry in place after a spill, the microspheres can roll about and blow around after drying, thereby presenting a somewhat different hazard. Additionally, the microspheres can wedge themselves into tiny cracks and cervices, becoming practically impossible to remove from benchtops and equipment. Appropriate planning and care can reduce this risk.

Facilities, in consultation with the RSO, should have in place, and should adhere to, policies and procedures for the safe handling and administration of radiopharmaceuticals, in accordance with ALARA, and must comply with all applicable radiation safety regulations and conditions of licensure imposed by the NRC, state, and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol. See Appendix B for radiation safety discharge instructions.

VIII. EQUIPMENT SPECIFICATIONS

Several technical requirements are necessary to ensure safe and successful diagnostic arteriogram and radioembolization procedures. These include adequate equipment, institutional facilities, physiologic monitoring equipment (including intravascular pressure measurement systems), and appropriately trained and qualified personnel.

For specific requirements for the arteriographic procedures, see the ACR–SIR–SPR Practice Parameter for the Performance of Arteriography [27].

A gamma camera with a low-energy all-purpose (LEAP) or low-energy high-resolution (LEHR) collimator may be used for the nuclear medicine imaging, of technitum-99 MAA planar or SPECT/CT and medium-energy (ME) or high-energy (HE) collimators for yttrium-90 SPECT/CT as well as PET with time-of-flight (TOF) capabilities.

The activity of yttrium-90 is determined by measurement using an appropriate dose calibrator, such as an ion a pressurized, well-type ionization chamber. The dose calibrator and microsphere manufacturer’s instructions regarding calibration for yttrium-90 microsphere sources should be followed.
Adjustments to the dose calibrator settings or a correction factor may be necessary to bring the measurement from the ion chamber to an acceptable level (±10% of the manufacturer-supplied measurement). These settings or correction factor should then be the standard used for activity measurements of microspheres. Other factors that can influence the activity measurements include the shape and material (glass versus plastic tubing versus polycarbonate) of the container holding the source.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Nuclear medicine equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [28].

The Medical Director of Radiation Oncology, Interventional Radiology, and/or Nuclear Medicine is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the ACR–ASTRO Practice Parameter for Radiation Oncology [29]. It is the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The director will designate appropriate personnel to constitute the CQI committee that will review radioembolization RMBD as part of the CQI meeting agenda. Refer to the ACR–ASTRO Practice Parameter for Radiation Oncology [29] for a detailed description of CQI committee functions.

Medical Event

Medical event must be reported to the regulatory agency (NRC or State), and the AU (or RSO) should follow the published rules and regulations. Common reported events associated with this procedure include, but are not limited to, overdose, wrong site, kinked catheter, defective/cracked catheter, partial obstruction, leaking connection, slow infusion, and reflux to other lobe. Users should be cautious when performing such procedures.

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Collaborative Committee – members represent their societies in the initial and final revision of this technical standard

ACR
Kelvin Kai-Wen Hong, MD, Chair
Don C. Yoo, MD, FACR
Bassem I. Zaki, MD

ABS
Phillip M. Devlin, MD, FACR
Catheryn M. Yashar, MD, FACR

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NOT FOR PUBLICATION, QUOTATION, OR CITATION

ACNM
Murthy RK Chamarthy, MD
Sonya J. Koo, MD

ASTRO
Andrew S. Kennedy, MD
Zoubir Ouhib, MS, FACR

SIR
Olaguoke Akinwande, MD
Suvaranu Ganguli, MD
Siddharth A. Padia, MD
Riad Salem, MD

SNMMI
Lisa Bodei, MD
Shana Elman, MD
Reed G. Selwyn, PhD

Committee on Practice Parameters – Interventional and Cardiovascular Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Clayton K. Trimmer, DO, FACC, FAOCA, FSIR, Chair
Chaitanya Ahuja, MBBS
Drew M. Caplin, MD
Douglas M. Coldwell, MD, PhD
Mandeepl S. Dagli, MD
Kevin W. Dickey, MD
Joshua A. Hirsch, MD, FACR, FSIR
Kelvin Houn, MD, FSIR

Elizabeth A. Ignacio, MD, FSIR
Sanjeeva P. Kalva, MD, FSIR
Claire Kaufman, MD
Kenneth F. Layton, MD, FACR
Margaret Hsin-Shung Lee, MD, FACR
John D. Prologo, MD
Sanjii Tewari, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Richard K. J. Brown, MD, FACR, Co-Chair
Alexandru C. Bageac, MD, MBA
Twyla B. Bartel, DO, MBA
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH
Joanna R. Fair, MD
Erin C. Grady, MD

Edward D. Green, MD
Jeffrey S. Kempf, MD, FACR
Jennifer J. Kwak, MD
Charito Love, MD
Syam P. Reddy, MD
Levi Sokol, MD
Rathan M. Subramaniam, MD, PhD, MPH
Stephanie P. Yen, MD

Committee on Practice Parameters – Radiation Oncology
(ACR Committee responsible for sponsoring the draft through the process)

Alan C. Hartford, MD, PhD, FACR, Chair
Naomi R. Schechter, MD, Vice Chair
Nathan H. J. Bittner, MD
Samuel T. Chao, MD
Chee-Wai Cheng, PhD, FAAPM
Neil B. Desai, MD
Nancy A. Ellerbrock, MD, MBA, FACR
Mark Hurwitz, MD
Lesley A. Jarvis, MD, PhD

Join Y. Luh, MD
Matthew Poggi, MD
Helen A. Shih, MD
Nikhil Thaker, MD
Paul E. Wallner, DO, FACR
Kristina L. Woodhouse, MD
Ying Xiao, PhD
Sue S. Yom, MD, PhD
Bassem I. Zaki, MD

807
808
809
810
Alan H. Matsumoto, MD, FACR, Chair, Commission on Interventional and Cardiovascular Radiology
Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Seth A. Rosenthal, MD, FACR, Chair, Commission on Radiation Oncology

PRACTICE PARAMETER
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REFERENCES


**APPENDIX A**

Literature Review

A. Hepatocellular Carcinoma

Treatment of hepatocellular carcinoma (HCC) is a balance between tumor progression and the treatment’s detrimental effect on liver reserve. Although single lesions can be treated effectively with ablative techniques such as radiofrequency ablation, with an increase in the number and growth of lesions and the failure of other liver directed therapies, eg, transarterial chemoembolization, radioembolization RMBD can be utilized effectively [30]. Patients with early stage HCC and well-compensated cirrhosis (Child-Pugh A) respond well to radioembolization RMBD with an overall survival of 14 to 23 months as seen in both prospective and retrospective studies [31-39] [40-42]. As expected, the more extensive the HCC and the more advanced the cirrhosis, the more survival is impaired. Nevertheless, use of radioembolization RMBD in Child-Pugh B and C patients results in survival rates of 6 to 13 months and 4 to 8 months, respectively [43]. Since this is primarily an outpatient therapy, it is better tolerated than other embolotherapy options for treatment of HCC [43]. The invasion of the portal vein by HCC is a contraindication to the use of embolotherapy, except in radioembolization RMBD in which the survival of these patients shown promising results is approximately 10 months rather than 4 months with standard therapy [44]. RMBD Radioembolization can also be utilized effectively to down stage unresectable HCC, enabling ablative techniques, surgical resection, or transplantation [45].
B. Colorectal Cancer

Colorectal cancer is the third most common cancer diagnosed among both men and women in the United States. The American Cancer Society [46] estimates that approximately 148,810 new cases of colorectal cancer and 49,960 deaths were expected in 2008.

Approximately 72% of new diagnoses are colon cancer and 28% are rectal cancer. The liver is the most frequent site of metastases. An estimated 60% of patients who are diagnosed with colorectal cancer eventually will experience liver disease as a predominant site [47]. Surgical resection is associated with long-term survival in patients with colorectal liver metastases [48]. A median overall survival of 44 months and a 5-year survival rate of 35% [49] are associated with surgical resection of liver confined disease for patients with no evidence of disseminated disease with a resection strategy encompassing all liver disease with adequate remnant liver for recovery and medical fitness for laparotomy. However, patients who have liver metastases amenable to resection account for less than 20% of the population with metastatic liver disease [50]. For the majority of patients without resectable disease, the median overall survival is 22 months and rarely is associated with the survival beyond 5 years [51]. Targeted nonsurgical approaches for liver-confined CRC metastases may offer survival advantages beyond that of systemic therapy alone.

1. Radioembolization for chemorefractory liver metastases:

Radioembolization was evaluated in a cohort of 72 patients with unresectable hepatic colorectal metastases who were treated at a targeted absorbed dose of 120 Gy with a median delivered dose of 118 Gy [52]. The safety and toxicity was assessed using version 3 of the National Cancer Institute Common Terminology Criteria. Response was assessed radiographically and survival was estimated using the Kaplan-Meier method from the diagnosis of hepatic metastases and first treatment. Treatment-related toxicities included fatigue (61%), nausea (21%), and abdominal pain (25%), with grade 3 and 4 bilirubin toxicities observed in 9 of 72 patients (12.6%). The tumor response rate was 40.3%. The median time to hepatic progression was 15.4 months, and the median response duration was 15 months. Overall survival from the first radioembolization treatment was 14.5 months. Based on substratification analyses, tumor replacement (≤25% versus >25%) was associated with significantly greater median survival (18.7 months versus 5.2 months). The presence of extrahepatic disease was associated negatively with overall survival (7.9 months versus 21 months). Overall survival from the date of initial hepatic metastases was 34.6 months. A subset analysis of patients who had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 demonstrated a median survival of 42.8 months and 23.5 months from the time of hepatic metastases and radioembolization treatment, respectively. The data from this study also suggests that patients who have been exposed to fewer than 3 cytotoxic agents may have a better outcome than patients who have received all chemotherapy options prior to radioembolization. Radioembolization RMBD Based on the subset analyses of this study, it appears patients with good performance status, no extrahepatic metastases, liver disease limited to ≤25% of liver volume, who have not received all available lines of chemotherapy may benefit most from treatment of radioembolization. RMBD

Radioembolization [53] was associated with mild to moderate toxicity, except for one grade 4 treatment-associated cholecystitis and 2 grade gastric ulcers, using resin microspheres administered as a single session, whole liver treatment in 41 patients with metastatic colorectal cancer refractory to chemotherapy.

2. Radioembolization with chemotherapy in liver metastases:

In a phase III trial [54], 46 patients with unresectable, chemotherapy-refractory liver-limited metastatic CRC were randomly assigned to fluorouracil protracted intravenous infusion 300 mg/m2 days 1 through 14 every 3 weeks (Arm A) or to radioembolization plus intravenous FU 225 mg/m2 days 1 through 14 and then 300 mg/m2 days 1 through 14 every 3 weeks (Arm B) until hepatic progression. Crossover to radioembolization was permitted after progression in the chemotherapy alone arm. Median follow-up was 24.8 months. Median TTLP was 2.1 and 5.5 months in arms A and B, respectively (P= 0.003). Grade 3 or 4 toxicities were recorded in 6 patients after FU monotherapy and in one patient after radioembolization.
plus FU treatment \((P = 0.10)\). Twenty-five of 44 patients received further treatment after progression, including 10 patients in arm A who received radioembolization. Median overall survival was 7.3 and 10.0 months in arms A and B, respectively \((P = 0.80)\). The conclusion is that radioembolization with 90Y-resin microspheres plus FU is well tolerated and significantly improves TTLP and TTP compared with FU alone for chemotherapy-refractory liver-limited metastatic CRC.

In dose escalation studies reporting use of the resin microspheres in combination with oxaliplatin- [55] based chemotherapy, the maximum-tolerated dose of oxaliplatin was 60 mg/m2 during the first 3 cycles of chemotherapy. In combination with irinotecan-based chemotherapy [56], the authors concluded that the maximum-tolerated dose of irinotecan was not reached. In both trials, radioembolization treatment was administered within a cycle of chemotherapy with the majority of patients experiencing mild to moderate transient toxicities.

3. Response evaluation:

**FDG-PET/CT** appears to be an accurate indicator of treatment response [4]. Studies demonstrated a significant difference between the metabolic and the anatomic response after yttrium-90 glass microsphere treatment for unresectable liver metastases in colorectal cancer. FDG-PET imaging is more sensitive than CT in the assessment of early response to resin microspheres, allowing clinicians to proceed with further therapeutic options [3].

C. Neuroendocrine Tumors

NETs, thought to be uncommon, represent the second highest in incidence of gastrointestinal malignancies. There is mounting evidence that NETs have been increasing in incidence and prevalence over the last 3-4 decades. Gastroentero-pancreatic NETs that arise from cells throughout the gut and pancreas are subclassified based upon the production of hormone-related symptoms (functional versus nonfunctional). The 5-year survival of patients with metastatic disease is less than 40%. The prognosis at presentation for NET is ambiguous, but recent evidence suggests that, along with staging, immunohistochemical and pathological grading are important. Yttrium-90 radioembolotherapy has been demonstrated to retard disease progression in patients with NET liver metastases. Based on sound principles, yttrium-90 microsphere radioembolotherapy offers advantages of low acute and subacute toxicity, and standardized dosing allows interoperator comparison of outcomes. The table below summarizes the peer-reviewed outcomes in NET patients [13,57-65].

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Total Patients</th>
<th>Embolotherapy</th>
<th>Study Design</th>
<th>Median Activity/Treatment</th>
<th>CR + PR</th>
<th>Symptom Response%</th>
<th>Tumor Marker Response%</th>
<th>Median Survival (months)</th>
<th>5-year Survival (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granberg</td>
<td>2007</td>
<td>3</td>
<td>Resin 90Y</td>
<td>Observation</td>
<td>1</td>
<td>100</td>
<td>nr</td>
<td>nr</td>
<td>67</td>
<td>15</td>
</tr>
<tr>
<td>King</td>
<td>2008</td>
<td>34</td>
<td>1V 5FU+90Y Resin</td>
<td>Phase 4</td>
<td>1.99</td>
<td>50</td>
<td>55</td>
<td>nr</td>
<td>nr</td>
<td>nr</td>
</tr>
<tr>
<td>Kennedy</td>
<td>2008</td>
<td>148</td>
<td>Resin 90Y</td>
<td>Observation</td>
<td>1.14</td>
<td>63.2</td>
<td>nr</td>
<td>nr</td>
<td>@36</td>
<td>nr</td>
</tr>
<tr>
<td>Rhee</td>
<td>2008</td>
<td>22</td>
<td>Glass 90Y</td>
<td>Observation</td>
<td>nr</td>
<td>54</td>
<td>nr</td>
<td>nr</td>
<td>70</td>
<td>nr</td>
</tr>
<tr>
<td>Rhee</td>
<td>2008</td>
<td>20</td>
<td>Resin 90Y</td>
<td>Observation</td>
<td>nr</td>
<td>50</td>
<td>nr</td>
<td>nr</td>
<td>22</td>
<td>nr</td>
</tr>
<tr>
<td>Kalinowski</td>
<td>2009</td>
<td>9</td>
<td>Resin 90Y</td>
<td>Phase 4</td>
<td>2.1</td>
<td>66</td>
<td>nr</td>
<td>nr</td>
<td>28</td>
<td>nr</td>
</tr>
</tbody>
</table>
### Author | Year | Total Patients | Embolotherapy | Study Design | Medium Activity Treatment | CR + PR | Symptom Response | Tumor Marker Response | Median Survival (months) | 5-year Survival (months) | CR + PR | Symptom Response | Tumor Marker Response | Median Survival (months) | 5-year Survival (months) |
--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
Cao | 2009 | 58 | Resin 90Y +/- IV 5FU | Observation | 1.8 | 37 | nr | nr | @36 | nr | nr | nr | nr | nr | nr | nr |
Saxena | 2010 | 48 | IV 5FU+90Y Resin | Phase 2 | 1.94 | 54 | nr | nr | 36 | nr | nr | nr | nr | nr | nr | nr |
Memon | 2011 | 40 | Glass 90Y | Observation | 1.98 | 64 | 84 | nr | 35 | nr | nr | nr | nr | nr | nr | nr |
Rajkumar | 2011 | 14 | Resin 90Y +/- IA 5FU | Observation | nr | nr | 100 | 71 | 34.4 | nr | nr | nr | nr | nr | nr | nr | nr |
Paprottka | 2012 | 42 | Resin 90Y | Observation | 1.63 | 22.5 | 95 | 54.8 | 25 | 42% | nr | nr | nr | nr | nr | nr | nr |
Memon | 2012 | 40 | Glass V90 | Observation | 1.98 | 63.9 | 84 | nr | 34.4 | nr | nr | nr | nr | nr | nr | nr | nr |

### APPENDIX B

10 CFR 35.75 authorizes the release of individuals from licensees if the total effective dose equivalent (TEDE) to a member of the public is less than 5 mSv. Written release instructions must be provided if the TEDE to a member of the public is likely to exceed 1 mSv. If the dose to a breast-feeding infant or child could exceed 1 mSv, then breast-feeding interruption guidance and consequences of failure to follow the guidance must be provided. After microsphere administration, dose rates at 1 m have been correlated with administered activity when corrected for by BMI (McCann et al, “Radiation emission from patients treated with selective hepatic radioembolization using yttrium-90 microspheres: Are contact restrictions necessary?”). Patients treated with less than 3 GBq do not require contact restrictions using an occupancy factor of 0.25 (6 hours per day), administered activity, exposure to public at 1 meter, physical half-life, and without considering tissue shielding. Patients who receive greater than 3 GBq may require contact restrictions depending on the...
situation such that the contact is greater than 6 hrs/day or average distance is less than 1 meter (e.g., caregiver for significant care or extensive travel). The following table, modified from McCann et al, provides threshold dose rates measured at 1 m that will allow patients to be released without contact restrictions (1 mSv) for various situations.

<table>
<thead>
<tr>
<th>Contact Situation</th>
<th>Occupancy Factor</th>
<th>Distance (m)</th>
<th>Threshold Dose Rate (mSv/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household member</td>
<td>0.25</td>
<td>1</td>
<td>0.043</td>
</tr>
<tr>
<td>Caregiver, sleeping partner, or extensive travel</td>
<td>0.25</td>
<td>0.3</td>
<td>0.004</td>
</tr>
<tr>
<td>Caregiver for significant care</td>
<td>0.5</td>
<td>0.3</td>
<td>0.0022</td>
</tr>
<tr>
<td>Nursing infant, child or pregnant woman</td>
<td>0.042</td>
<td>0.1</td>
<td>0.0086</td>
</tr>
</tbody>
</table>

It is generally understood that there is very little biological clearance of yttrium-90 and glass microspheres are stable, whereas trace amounts of yttrium can be excreted in urine of patients treated with resin microspheres. Therefore, for the first 24 hours after treatment, patients are instructed to practice good bathroom hygiene by flushing twice and to wash hands very well after the toilet is used [66].

Radiation Safety Discharge Instructions for Patients with Radioactive Yttrium-90 Spheres for Liver Brachytherapy

Yttrium-90 microspheres are radioactive sources that, over time, become inactive. This means that for the next few days there will be a small amount of radioactivity near your liver. This does not represent a significant risk to others. However, to be on the safe side, these precautions and instructions should be followed:

1. Try not to be within 3 feet of others for the next 3 days, especially children (e.g., anyone under 18 years old) or pregnant women.
2. If you have to go to a doctor or emergency room or need surgery within 3 days of this treatment, notify the medical staff that you have a small amount of radiation in your liver. Your physicians should give you any immediate and necessary medical or surgical treatments without concern for the radiation in the liver. They can call Radiation Medicine or Radiation Safety with any questions regarding the details of the treatment.

4. There is NO need to make special arrangements for body fluids (urine, stool, blood, or vomit).

If you have any questions concerning radiation safety, please call the following contacts:

During normal working hours:
- Radiation Oncologist/Interventional Radiologist:
- Radiation Safety Officer:
After hours:
- ______________________

I have read and understand the above radiation safety instructions and agree to abide by them.

_______________________________  ______________________________
Patient Signature    Radiation Safety Officer Signature

DATE       DATE

*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
2008 (Resolution 2)
Amended 2009 (Resolution 11)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AAPM–SIIM Practice Parameter for Electronic Medical Information Privacy and Security

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–SIIM PRACTICE PARAMETER FOR ELECTRONIC MEDICAL INFORMATION PRIVACY AND SECURITY

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, ___ N.W.2d ___ (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

The practice parameter for electronic medical information privacy and security was revised collaboratively by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), and the Society for Imaging Informatics in Medicine (SIIM).

Across most advanced economies, medical imaging and related patient information are increasingly being managed via digital acquisition, transmission, storage, display, and interpretation. The secure management of these data may have an impact on the quality of patient care, on patient’s rights, and on health care professionals and their current practices and legal responsibilities.

The responsibility that physicians all health care employees have to protect their patients from harm extends to protecting patient privacy and patient information. Physicians Health care facilities and other entities engaged with assisting and providing health care should carefully document their privacy and security policies and communicate this information to their patients. The responsibility to protect patient privacy and to secure patient data from loss or corruption is a critical one of a growing set of security requirements for the provision of medical care. Additionally, failing to comply with Electronic Protected Health Information (ePHI) state or federal regulations could result in financial and/or criminal penalties as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequently strengthened by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 regarding civil and criminal enforcement of HIPAA rules. Health care employees also must assess whether they have to comply with the European Union’s General Data Protection Regulation (GDPR). The GDPR strictly limits using and sharing a patient’s personal data, such as his or her health care data. See https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en.

The goal of this practice parameter is to recommend actions for the protection, privacy, security, and integrity of recorded patient information while allowing appropriate access for care and management of patients. Policy and procedure recommendations (sections II and III) are provided, and the tools available to ensure privacy and security are described in section IV. Use cases for specific situations (eg, research use of PHI) are given in Appendix A of this document to elucidate risks and costs for data and applications, as well as the specific legal and practice requirements and the tools used to ensure compliance. Research, educational, and marketing uses of patient information requirements are outlined in section V. The practice parameter concludes in section VI with a list of medical/legal entities and government agencies that may have more restrictive rules and considerations for security and privacy.

An additional resource is a compilation of authoritative report and resource links for a broad scope of cybersecurity issues, which is available from the Congressional Research Service.

2 The United States Congress has been actively involved with cybersecurity issues since 2001. A document with links to selected authoritative reports and resources on cybersecurity law and legislation is periodically updated. As of November, 2013 A report dated October 25, 2013 April 28, 2015, is available at http://www.fas.org/sgp/crs/misc/R42507.pdf.
II. POLICY STATEMENTS

A. In today’s security environment, organizations should assume they have already been breached and enact policies and actions to establish their response rather than focusing primarily on compliance. That being said, policies should include the following topics:

1. Security awareness training for all staff in the organization
2. Security issues for ePHI and personally identifiable information (PII)
3. Designation of responsibility for:
   a. Providing security awareness training
   b. Point of contact position for all access control functions specific to department and enterprise
   c. Developing procedures in support of proper security measures
   d. Providing appropriate computer training
   e. Assuring that policies and procedures are followed
   f. Resolving security problems
   g. Ensuring appropriate mobile device management is enabled and configured for secure access
   h. Responding to a systems breach
4. Initial and subsequent periodic assessment and risk analysis of all processes related to the handling of ePHI; the findings from these audits should be used to guide the development of future policies and procedures.
5. Provision of backup for all systems with means to withstand ransomware attacks
6. Proper storage and retention for all electronic data
7. System downtime and recovery plans for unexpected computer downtime
8. Maintenance of a support manual and how-to guide for computer systems and information
9. Business associate contracts and trust agreements; all current vendors and other entities that have or need access to ePHI must have business associate agreements as required by HIPAA; these agreements should be obtained through the normal purchasing process.

III. PROCEDURES

A. Administrative Safeguards

1. Perform an audit and assessment of existing practices.
   a. The audit will address the following security safeguards:
      i. Physical safeguards
      ii. Technical safeguards
      iii. Administrative safeguards
   b. Share assessment findings and risk analysis with appropriate institutional departments or service providers and vendors.
   c. Establish a policy for risk management for incorporating medical devices [1]
      i. Define the policy for determining acceptable risk, taking into account relevant international standards and national or regional regulations [1]
      ii. Ensure the provision of adequate resources
      iii. Ensure the assignment of qualified personnel for management, performance of work, and assessment activities
      iv. Review the results of risk management activities, including event management at defined intervals, to ensure the continuing suitability and the effectiveness of the IT risk management process
   d. Procurement of medical devices and security verification checklist
      i. Medical device manufacturer disclosure of security-related features [2]
      ii. Review and validate response of manufactures prior to connection of device to medical IT network [2]
2. Security awareness and operational training
   a. Use radiology and specialty-oriented training tools
      i. Provide HIPAA/HITECH security training for all personnel
      ii. Inform staff of departmental policies specific to radiology
   b. Maintain individual documentation of staff training
   c. Conduct annual security training relevant to enterprise and radiology
   d. Provide universal training for all employees and stakeholders encompassing the following:
      i. Operational computer training of all personnel on systems needed to perform their jobs
      ii. Emergency operational and communication procedures for computer downtime
      iii. Operational and communication procedures for planned computer downtime
      iv. Emergency operational and communication procedures to be used during a disaster
      v. Computer Downtime recovery procedures and restoration to normal operation
   e. Require all personnel to sign a responsibility statement for information security and confidentiality.
      This security applies to all information in the department, such as patient data, research, and financial information. Attestation may be obtained through enterprise educational portals

3. Incident reporting and resolution of security issues
   a. Develop procedure for reporting of incidents or vulnerabilities to a department security officer, risk manager, or designee responsible individual
   b. Document and implementing corrective actions for minor problems
   c. Initiating corrective action with the involvement of the appropriate institutional departments, vendors, or service providers
   d. Maintain complete documentation of incidents and actions for Process Quality Improvement (PQI)

4. Accountability and sanctions
   a. Develop, review, and document manager’s responsibilities for overseeing the security plan within his/her areas of responsibility
   b. Develop and confirm personnel responsibility for following the policies and procedures that have been established
   c. Develop, document, and share sanctions and disciplinary actions for violation of policies and procedures

5. Access controls
   a. All systems maintained by the facility or contracted entity must be subject to the facility’s policies and procedures.
   b. Approval of access to all systems is the responsibility of the facility (or local) administration.
   c. Parties responsible for creating, changing, and disabling accounts must be identified and given authority by administration.
   d. Obtaining access privileges requires person’s or entity’s signature on a responsibility and confidentiality statement.
      Require user identification sign-on code:
      i. Limits access to information/systems according to “need to know” as determined by staff member’s manager
      ii. Allows for tracking of user activity
   e. Require separate user-defined password or biometric identification.
   f. Minimum requirement/best practice for password considerations include consideration of:
      i. Syntax
      ii. Expiration cycle
      iii. Reuse rules
   g. Ensure authentication for login process.
   h. Define who monitors all vendor access to radiology departmental equipment and interfaces.
      i. Develop a methodology for comprehensive monitoring of access logs, unauthorized access, and reporting procedures for all IT solutions [3].
   j. Require secure remote application access with current encryption methods with embedded access control a virtual private network (VPN) or secure sockets layer (SSL)
6. Activity review
   a. Define a process to determine who has accessed ePHI.
   b. Define who will review firewall “real-time logs” in a timely and reactive manner to determine if
      inappropriate activity is taking place.
   c. Define who, within radiology, will notify various system entities at the time of employee termination
      and/or status change.
   d. Define the frequency and level of detail for monitoring and reporting.
   e. Define frequency of system privilege audits to ensure proper access level appropriate for current role
   f. Develop a process for data analysis, investigation, verification, reporting, and mitigation.

B. Physical Safeguards

Physical safeguards are physical measure, policies, and procedures enacted to protect a covered entity’s
electronic information systems and related buildings and equipment from natural and environmental
hazards and unauthorized intrusion.

1. Facility Access Controls:
   a. Policies and procedures for contingency operations
      i. Access rules for restoration of lost data under disaster recovery and emergency operations
      ii. Procedures to address major hardware and software recovery following system downtime
      iii. Identification of personnel performing data restoration and physical access to facility
   b. Policies and procedures for facility security plan
      i. Description of safeguards used to protect the facility from unauthorized physical access, tampering, or theft
      ii. Risk analysis data on workforce access to specific facilities and equipment
      iii. Methods to control access (door locks, electronic access, signage, security service/patrol, alarms video monitoring)
      iv. Methods to control property (property control tags, engraving of equipment)
      v. Methods for personnel control (identification badges, visitor badges, escorts)
      vi. Roles and training of staff and employees
   c. Policies for access control and validation procedures
      i. Alignment of person’s access to information necessary for role or function in the organization
      ii. Methods to identify individuals with authorized access
      iii. Methods for visitors: sign-in, visitor badges, escort rules
      iv. Periodic review of employee restricted access list
   d. Policies and procedures for maintenance records
      i. Specification of all physical security components (locks, routine maintenance, new devices)
      ii. Special circumstances for terminated workforce members with access to large amounts of ePHI

2. Workstation (and equipment) use
   a. Policies and procedures to specify proper functions to be performed by computing devices
      i. Identification of workstations that can access ePHI from those that cannot
      ii. Internet accessibility to whitelisted sites, inaccessibility to blacklisted sites
   b. Assessment of physical surroundings to protect ePHI; risk to address possible negative impacts
      i. Sign-on, sign-off procedures, password protection, use of privacy screens, screensavers
   c. Rules for use of workstation devices in remote locations and for access of ePHI

3. Workstation (and equipment) security
   a. Policies and procedures to physically protect workstations that access ePHI
      i. Identification of all workstations that access ePHI (including laptops, personal digital assistants)
      ii. Restriction of physical access to workstations by authorized users only (secure room, area)
4. Device and media controls
   a. Policies and procedures for disposal
      i. Process to ensure unusable and inaccessible ePHI in final disposition of devices/media
      ii. Address data contained on storage devices and media from obsolete computers
   b. Policies and procedures for media reuse
      i. Electronic media reuse – ensuring complete removal of ePHI
      ii. Define how computers that are being repaired and/or stored will be handled
   c. Policies and procedures for accountability
      i. Maintain a record of movements of hardware and electronic media
      ii. Identify individual devices through serial numbers or other tracking mechanisms
      iii. Maintain a record of responsible person(s)
   d. Policies and procedures for data backup and storage
      i. Create a retrievable, exact copy of ePHI, when needed, before movement of equipment
      ii. Develop a policy for backing up data and maintaining copies
      iii. Develop a policy for retention and storage of electronic data

1. Develop a device and hardware disposal and electronic media reuse policy.
   a. Develop a policy to address data contained on storage devices/media from obsolete computers.
   b. Define how computers that are being repaired and/or stored will be handled.
2. Document the process of backing up data and maintaining backup copies of ePHI.
3. Develop an emergency contingency protocol that includes:
   a. Procedures to address major hardware and software recovery following system downtime
   b. A system disaster recovery plan
4. Develop a policy for retention and storage of electronic data.
5. Ensure that workstations and remote printers are physically safeguarded to prevent unauthorized access to data.
6. Define safeguards for laptop computer/tablet/smartphone/flash drive use when connecting to institutional network.

C. Technical Safeguards

1. Firewalls and secure transmission modes for staff communication
   a. Establish secure external firewalls for any network with a connection to the Internet or an outside network. systems that may be vulnerable to security breaches.
   b. Network separation for internal health care systems, which if compromised, could risk patient health. This could be done by air gapping or a second internal firewall.
   c. Establish a VPN or SSL encryption tools to allow secure transmission through the firewall.
   d. Ensure the security of e-mail communication.
      i. If e-mail is provided, make sure it is encrypted or otherwise secure for communication between staff and customers outside of the firewall. VPN or SSL.
      ii. Ensure that communication directly with patients over the Internet is authorized by the patient and that appropriate security precautions are in place.
2. Systems log aggregators to centralize application and server logs and provide automatic monitoring for anomalies.
3. Intrusion detection system to identify breaches earlier
4. Intelligent multifactor authentication to apply different levels of challenges to users as they attempt to access systems from known low-risk zones or high-risk zones
5. Encryption of data storage for mobile devices, desktop devices, and data center storage

IV. SECURITY AND PRIVACY TOOLS USED

The key provisions for handling ePHI on in health care systems are outlined in 21CFR11, Subpart B and C. details controls for medical records, and Subpart C details requirements for electronic signatures. The following tools can
be used to address the privacy and security issues of Subpart B in an electronic medical information system, including The rules require that all electronic record systems have methods for validation, protection, and auditing of records. The control and protection of any electronic record, both in health care and in industry, is termed cybersecurity, and includes methods for the protection of all components in the data stream, ie, computers, networks, programs, as well as control from unintended or unauthorized access, change, or use. Tools that can be used to minimize the risk from loss of control are changing continuously, and so a review of the requirements to address the privacy and security issues is given here to assist in selection of the appropriate one. In general, any tool should include anonymization (elimination of PHI from the electronic files), authentication (digital signing, biometrics, etc), authorization (eg, access controls), auditing (ensuring compliance to HIPAA and other regulations), application availability (fault tolerance and denial of service [DOS] resistance), confidentiality (including encryption when required), data availability, data integrity, and nonrepudiation (digital signing) [4-11]. This section describes these tools. Some tools can be used in more than one role.

Removing patient information is a cornerstone of performing research on clinical information. HIPAA/HITECH requires that only those involved in direct patient care should have access to the patient identity or identifying characteristics. A distinction is made between two levels:

1. **Deidentification**: Defined under HIPAA as being one of two methods: the Safe Harbor method details 18 features that must be removed, and the Statistical Method requires a statistician to document that there is a small likelihood that a given record could be traced back to the patient.

2. **Anonymization**: The process by which medical data are made unlinkable to the original patient.

3. **Pseudonymization**: Retrievably preventing linkage of medical data with an individual, using personal identifiers that have been replaced with artificial identifiers, or pseudonyms [12,13].

**A. Deidentification**

Deidentification requirements apply to images, reports, and other associated image-associated information, though the processes and tools used may be different.

In some situations (eg, research), the removal of patient information from the record can be used to eliminate security risks. The requirements for deidentification are defined by HIPAA/HITECH through CFR§164.514. One means of satisfying the deidentification requirement is to remove all of the following:

1. Names (this includes names of the individual and their relatives, employers, or household members)
2. Geographic subdivisions smaller than a state, with exceptions for the use of part of the zip code
3. All dates, except year, and all ages over 89
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate or license numbers
12. Vehicle identifiers and license plate numbers
13. Device identifiers and serial numbers
14. URLs
15. IP addresses
16. Biometric identifiers
17. Full-face photographs and any comparable images
18. Any other unique, identifying characteristic or code
For some clinical trials and other defined research projects, not all of the 18 elements listed above need to be removed to be considered compliant with deidentification. The requirements for this specialized use of PHI should be defined by the Institutional Review Board (IRB) prior to any use.

Satisfactory image and report deidentification features may or may not be included in the operational clinical infrastructure (e.g., PACS, Radiology Information System (RIS), electronic medical record (EMR)). It may be necessary to use commercial or open-source third-party tools. Whatever tools are used, they should be tested and validated for compliance with standard and national, regional and local (site) policies regarding what information needs to be removed or retained. The manner of their configuration and use shall be addressed at the site’s security risk assessment policies and procedures.

DICOM defines standard data elements with specific values and usage, which can be classified as being at risk for leakage of various categories of identifying information. These are listed in DICOM PS3.15 Annex E, together with the appropriate action to be taken during the deidentification, whether it be to satisfy the 18 elements requirement of the HIPAA Privacy Rule or some other deidentification standard.

As an alternate to performing complete deidentification, PHI can be extracted from the record and used for statistical and scientific analysis without the need for patient identification. This can be used if there is no reasonable mechanism to identify an individual from the data. Protection for this type of data use can be achieved by the application of statistical disclosure limitation procedures. This type of PHI use is considered anonymization.

Removing patient information is a cornerstone of performing research on clinical information. HIPAA/HITECH requires that only those involved in direct patient care should have access to the patient identity or identifying characteristics. A distinction is made between two levels:

1. De-identification: Is defined under HIPAA as being one of 2 methods: the Safe Harbor method details 18 features that must be removed, and the Statistical Method requires a statistician to document that there is a small likelihood that a given record could be traced back to the patient.

2. Anonymization: Is the process by which medical data are made unlinkable to the original patient. De-identified data are still coded to an alias: an agent in possession of the table could link a record back to the real patient. Fully anonymized data is not linkable to the original patient. It is important to realize that not all PHI is always confined to the “digital object” metadata and headers. It is also possible that some PHI resides in the pixel data of the image. At least 2 open-source applications are available to perform both tag and raster anonymization: the RSNA Clinical Trials Processor (http://mircwiki.rsna.org/index.php?title=CTP) and the DICOM Cleaner (http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html). Note: Anonymization of “image pixel data” is ultimately the responsibility of the anonymization site even if “applications” are used to anonymize the data. Anonymization of data burned into the image itself (i.e., image pixel data) is notoriously difficult. Review of all such images for accurate anonymization is strongly recommended when such images are batch anonymized by computer application.

B. Authentication

Authentication is the process of verifying the identity of a user to a computer system. This verification can be accomplished using a variety of approaches, including passwords, digital certificates, smart cards, and biometrics. Authentication only verifies the identity of an individual but does not define his or her access rights (authorization). The term authentication also refers to a confirmation that a message, file, or other data has not been altered or forged. “Challenge response authentication” refers to a family of protocols in which a challenge (question) by the computer is met with a response from a user or computer client.

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3 For further information see the Health Information Privacy – Research 45 CFR 164.501, 164.508, 164.512(i) (See also 45 CFR 164.514(e), 164.528, 164.532): https://www.hhs.gov/hipaa-for-professionals/special-topics/research/index.html
1. The simplest example of challenge response authentication is local management of a combination of user name and passphrase. The traditional user name/password authentication. This involves the use of a unique user name and a password secret passphrase that consists of a secret word or code used as a security measure against unauthorized access to data. Minimal criteria should be met to ensure sufficient resistance against guessing or brute-force attacks, most importantly a length of at least eight characters and vetting against repetitive or easily predictable passphrases (ie, 12345678) and dictionaries of passwords or passphrases that are known to have been breached. Requirements for arbitrary password complexity (ie, numbers, special characters, etc) and regularly scheduled password rotation are no longer considered necessary to ensure security per National Institute of Standards and Technology (NIST) Special Publication 800-63B (https://pages.nist.gov/800-63-3/sp800-63b.html). Central management of authentication is preferred, but if passwords are managed locally, they should not be stored as plaintext as any breach of the system could expose all username and password combinations. Rather, passwords should be stored using modern one-way hash algorithms. This password typically requires a combination of letters, numbers, and/or characters. If it matches the information on the computer’s access control list, login is granted.

2. Management of users and passphrases can, and arguably should, be performed centrally by an institution using Lightweight Directory Access Protocol (LDAP), Microsoft Active Directory (AD), or other similar mechanisms. Advantages are that authentication is managed centrally, more comprehensive institutional oversight is enabled, and the same credentials can be used for multiple applications throughout the institution. Passphrase requirements should be implemented as in Item 1.

3. Users should generally be required to reauthenticate after 30 minutes of inactivity or after 12 hours of use regardless of activity to ensure the user is still present and actively using the system. Some exceptions may be made in particular settings, such as operating or procedure rooms where physical security can be ensured and periodic reauthentication is not feasible.

4. Two-factor authentication, often referred to as strong identification, can strengthen authentication and requires two independent ways to establish user identity and associated privileges. The second factor is often a physical device or application on a personal device, such as a smartphone, but this may more commonly transition to a biometric feature (fingerprint, face, voice recognition) if the agent is a human. Indeed biometric feature authentication is becoming more common in smartphone and other personal devices, which, in some cases, provide access to the second factor. However, biometric features should be limited to the second factor rather than the primary method of authentication as they are probabilistic rather than deterministic and could be potentially fraudulently replicated (ie, photographs or latent fingerprints). Alternately, if the agent is another computer, the second factor is often a cryptographic certificate, which must be preapproved by the authenticating system. Multifactor authentication should be configurable to apply higher and lower degrees of secondary authentication depending on the trust of the device authenticating. For example, a device on a trusted network may only need a second form of authentication once a month, whereas a device coming from a foreign nation known to have an active hacking community may require a second form of authentication for each login.

5. Many other advanced methods of passphrase and authentication security can be found in the NIST publication referenced above, depending on the resources available to the practice.

C. Authorization (access controls)

Restricting access to a system to only authorized users is of primary concern. Sophisticated access controls also define and limit what exact applications and processes a user can reach, how and what hours they can use them, and what hours they can use. Audit their usage. Propagation of access controls to mobile devices, specifically smartphones and tablet computers, must also have methods for restricted database and system access via device identification, encryption, passwords, and auto-logoff, among many controls.
1. Access control lists assign rights and privileges of users to resources. Controls or combinations of controls can be implemented at the institution level using LDAP or AD, operating system or application level. Institutional management of at least broad roles is recommended to centralize control and monitoring but some exceptions can be made depending on the needs and physical security of the space in which the system is used.

2. Auto-logoff is a method of automatically logging off an account after a specified period of inactivity to prevent deter someone besides the valid user from using the session. As above, this should generally be 30 minutes, but exceptions can be made depending on the needs and physical security of the space in which the system is used.

3. Physical access control for critical computers is necessary to prevent console-based attacks, power interruptions, or other threats. Physical controls may vary depending on use case and sensitivity of data.

4. Access control mechanisms should be reviewed regularly to ensure old or inactive accounts have been removed.

D. Auditing (HIPAA, Other Requirements)

Secure, computer-generated, time-stamped audit trails that record activity must be maintained in information systems that contain or use ePHI to stay compliant with HIPAA, HITECH, and other federal regulations [21 C.F.R. § 11.10(e), [45 C.F.R. § 164.312(b)]. Additionally, these audit trails and system activity should be reviewed periodically to assess for any irregular patterns, suspicious activity, or breaches [45 C.F.R. § 164.308(a)(1)(ii)(c)]. This requires fairly detailed logging at a granular level. Subpart B also requires the use of “secure, computer generated, time stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.”

Audit records must be retained for at least as long as the statutory requirement of the medical record itself.

E. Application Availability

System administrator administration must defend against various threats to continuous availability of applications.

1. Virus Malware detection

The need for virulent malicious software defense is widely recognized. Even servers behind firewalls can be attacked by user-infected laptops or other mobile devices if they leave the facility and re-enter the “secure” network, or if a virus gets into a facility before virus protection is in place.

2. Intrusion detection

The system must not be compromised by an unauthorized party. An effective way of preventing this is to compute the hash value of key configuration files on a computer system. Then, the file containing the hash value of the configuration files can itself be encrypted or written to write-only media. Thereafter, periodic retests compare the state of the computer to the original state. Any differences should be cause for concern.

3. Fault tolerance and business continuity considerations

Critical computers must have redundant hardware, data archives, power and networking systems, and the ability to support automatic failover. Such systems should consist of 2 or more nodes (ideally in separate data centers), and they should be capable of supporting software upgrades without system downtime. Solutions such as onsite cloud-based disaster recovery should be identified and described in policies and procedures of the institution.

4. Documentation and staff availability

Redundant human resources are essential for maintaining high system uptime. If only one person knows how to perform a system failover, the enterprise is at risk whenever that person is unavailable. All persons charged with maintaining a critical system must be equipped with full documentation and trained in executing downtime/failover procedures. Documentation should be reviewed periodically to ensure it is up to date and relevant. Reviewed and approved copies of documentation need to be accessible in both online and offline formats. Online formats include internal wiki sites or online notebooks, offline...
formats would include flash media stored physically onsite that contain the latest copy of approved documentation.

5. Physical safety
Servers must be located to protect them from physical damage, intentional or accidental, and from environmental disasters.

6. Mobile devices used to access patient data need to be managed through mobile device management that can enforce password minimums for device access, report device location if lost, and allow for remote wipe capabilities of device if lost and unrecoverable.

7. Encryption controls need to be set for any media storage used in the practice. Storage media containing patient data that is not actively being processed need to be encrypted.

F. Confidentiality

The object of confidentiality is to prevent data from being observed by unauthorized third parties. There are two main strategies for this: prevent third parties from having physical access to the data, and encrypt the data so that even if it is captured by third parties it cannot be read.

Preventing third parties from gaining access

Switched networks

1. Network-based controls
This method attempts to protect confidentiality via the first strategy: denial of data access within the network. One of the most basic tools is the use of switched networks rather than hubs. Additionally, network jacks within publicly accessible areas should not be enabled when not used for a piece of networking equipment. This prevents a malicious attacker from plugging in to an open jack and gaining access to the network. Highly sensitive systems, such as those who could directly harm patients if compromised, should be protected with an inner network tool, such as a firewall, or a separate network without open access to the larger private local area network (LAN). An instantaneous circuit is created between the 2 agents who intend to communicate. This approach makes it more difficult for eavesdropping to occur.

2. Physical-based controls: This method ensures that physical access to data is limited and monitored. This includes controlling physical access to data center rooms or rooms where devices such as personal computers (PC) are accessible from a person passing by.

3. Encryption: public and private key systems
There exist multiple methods of data encryption; however greater amounts of computer processing power have meant that encryption schemes are increasingly vulnerable to various methods of attack. Therefore a static recommendation of an encryption method that provides a reasonable degree of protection cannot be made. However, organizations like NIST do regularly recommend types of encryption. What can be stated is that all health data in motion must be encrypted, all health data at rest on a mobile device should be encrypted, and data at rest on nonmobile devices should strongly be considered a candidate for encryption.

These methods can be used on individual computer storage units (eg, CD-ROM, DVD) or computer networks. They decrease the risk of a security breach, even if a message falls into the wrong hands.

- Private key systems use a single key among all members in an application group to encode/decode information.
- Public key systems have 1 private key that an agent keeps to himself/herself and 1 public key that is shared at large. Agents wishing to send a secure note to the agent use the agent’s public key to encode the note, and the agent decodes it with its private one.

G. Data Availability

The corollary to application availability is data availability. There are two components to data availability: (1) ensuring the systems that deliver the data are always functioning and (2) backing up data to guard against system failure or data loss. Both of these components can be achieved by eliminating single points of failure,
preparing for a disaster and having a mechanism to recover data if a disaster occurs, and monitoring the functioning of all equipment to recognize and reduce potential failure scenarios.

Removing single points of failure and providing disaster recovery can be done through data mirroring, network storage, clustered and distributed file systems, cloud systems, and virtualization.

1. Data mirroring can be used to replicate all computing function and data storage. The mirrored systems can also be used during normal maintenance or during a disaster to improve efficiency.

2. Network storage can be used to reduce a single point of failure for data storage by moving this function to remote locations or locations that have disaster protection (e.g., power backup). Network-attached storage (NAS) refers to dedicated data storage that exists on the same network. A storage area network (SAN) uses a separate network to provide redundant data access.

3. Clustered and distributed file systems make storage and computing available to multiple computers over a network. In general, these systems are a set of client and server services that allow a file to be viewed by multiple servers or workstations at the same time, although none of the client or servers using the data actually store the data.

4. Data stored in the cloud is a form of distributed computing accessed via the Internet. Cloud computing allows access to data from multiple workstations or devices, and there is normally no technical limitations on the amount of data that can be stored. Cloud systems should have similar safeguards to ensure data availability as in-house systems.

5. Virtualization is technology that allows you to create multiple simulated environments on a single physical hardware system. Virtualization can be done for a server, network, or desktop. A virtual system can replicate all functionality and data similar to data mirroring, but because multiple instances are running on a single hardware, it reduces the total hardware needed. Therefore, instead of purchasing multiple redundant hardware for each application, multiple applications run virtually on a single system, and separate systems can be set up to provide automatic failover for redundancy.

Regardless of the computing systems and data storage redundancy used, if the network between systems fails, data availability is lost. Therefore it is essential that the network architecture be robust and have redundancy. There are many methods for ensuring network availability (e.g., multihoming) that can reduce slow data processing, or failure may be corrected by automatically rerouting network traffic. These methods are always changing, and the user should query the network provider to supply the method and assurances of uptime with their technique.

The chief method to maintain data availability is redundancy. Data storage file systems use redundancy in several methods. Within a single storage unit, storage disks make use of several algorithms all named RAID X (where X is a varying number). Sites may also “mirror” entire storage systems on a second storage unit, either in the same data center or “in the cloud.” Popular RAID types are as follows:

1. RAID 1: A simple mirror among 2 disks. System can lose 1 disk without data loss. However, the second disk essentially provides no additional storage.

2. RAID 5: System can support loss of 1 disk, but the system has a higher utilization. For example, 75% of each disk may contain unique data, and 25% of the data are used to reconstruct another disk if it is lost.

3. RAID 6: A system that can survive the loss of 2 disks without data loss; other advantages are similar to RAID 5.

H. Data Integrity

Data integrity refers to the validity, accuracy, consistency, and reliability of data over their entire lifecycle. Integrity is indicated by an absence of any alteration in the data between two or more updates of a data record. Data is recorded exactly as intended, and upon later retrieval, the data is the same as it was when it was originally recorded. It is imposed at the design stage using standard rules and procedures and is maintained using error checking and validation routines. When transferring or storing information, whether textual, numerical, graphical, annotations, medical images, or a combination, it is necessary to verify that
the information has not been modified after the original event (unless an intended change is authorized and documented). Any unintended change to data because of a processing or storage operation, hardware problem, or human error is a failure of data integrity. This change could be benign, potentially harmful, or even catastrophic in the delivery of medical care, resulting in misdiagnosis, mistreatment, or loss of human life. If there is evidence of unauthorized access, there might also be issues of data security.

1. Input validation – quality control checks and corrections to prevent incorrect data entry
2. Access controls, assignment of read/write privileges, auditing
3. Data backup to store a copy of the data in an alternate location
4. Data encryption to lock data by cipher
5. Data validation to certify uncorrupted contents of transmitted or received data
   a. Hash function and hash value

Whether transferring information or storing it, it is necessary to verify that the information has not been modified. The same cryptographic methods outlined under IV.F. Confidentiality have application here.

1. Intrusion detection (tripwire)
   As described in section IV.C.2, an intrusion detection system can inform system administrators if the system has been compromised. Any breach should be cause to view all data on that system with suspicion.

2. Hash function and hash value
   Mathematical operations known as hash functions can be used to compute a unique hash value for given input text or data. Any alteration in the data will alter the hash value. If the sender of a message computes the hash value and encodes it with his or her private key, the recipient can decode the hash with the sender’s public key and compare the value with a new hash computation on the message. If there is a difference, the message has been altered. A third party cannot fake a new hash value after the message alteration because he or she does not have the sender’s private key.

I. Nonrepudiation

Nonrepudiation ensures that a transferred message or data has been sent and received by the parties claiming to have sent and received the message and is a way to guarantee that the sender cannot later deny having sent the message nor can the recipient deny having received the message. Methods of nonrepudiation include:

1. Digital signature
   - With the use of public key infrastructure, the sender signs the message/data with his or her unique private key to encrypt the contents. The contents and signature can only be decoded by the sender’s public key. Denial of sending the information is to claim that the original distributed public key was fake or the private key was stolen.

2. Trusted (digital) timestamping
   - Issued by a trusted third party acting as a time stamping authority to prove existence of data without the possibility of backdating the timestamps

3. Auditing
   - An information system that logs all user activity by user identification can also defeat repudiation claims.

J. Use Cases

Representative use cases that deal with both research and clinical scenarios, within the medical center or in the cloud, are listed in Appendix A to use as guidance on when to use the tools listed in this section.
V. RESEARCH, EDUCATIONAL, AND MARKETING USES OF PATIENT DATA; INSTITUTIONAL REVIEW BOARD, AND PRIVACY REQUIREMENTS

Research and educational activities are not exempt from the privacy and security requirements for protected health information. Privacy and security policies protect the privacy of individually identifiable health information while allowing reasonable access to medical information by the researcher/educator.

Most human research operates under the common rule (45 CFR Part 46, Subpart A) and/or Food and Drug Administration (FDA) human subject protection regulations (21 CFR Parts 50 and 56). The HIPAA Privacy Rule provision for research (45 CFR 164.502(d) and 45 CFR 164.514) builds on existing federal protections and creates equal standards of privacy protection for research governed by federal regulations as well as research that is not.

The privacy rule under HIPAA regulations covers all human beings, living or dead. Researchers may use patient PHI under the following stipulations:

A. Research Authorization Form

The privacy rule allows a single authorization form for the use and disclosure of PHI by the researcher and may be combined with the research consent form. For specific criteria, see 45 CFR§164.508(b)(3)(i).

B. Waiver of Authorization

Research use and disclosure of PHI by the researcher without individual authorization can occur with an exemption (waiver) approved by the IRB/privacy board. Documentation must include identification of the IRB or privacy board, date of alteration/waiver documentation, and satisfaction of waiver criteria as provided in 45 CFR§164.512(i)(2).

C. Review Preparatory to Research

This review is a mechanism used when researchers need to assess the feasibility of conducting research prior to the beginning of a study. The review is initiated by submitting a request to the IRB or privacy board detailing the proposed study and recognizing the conditions set forth in 45 CFR§164.510(i)(ii).

D. Data Use Agreement

A covered entity for research and educational purposes may use or disclose health information that has been de-identified by eliminating the following unique identifying characteristics: name, postal address, all date elements (except year), telephone number, fax number, e-mail address, URL address, IP address, social security numbers, account numbers, license numbers, medical record number, health plan beneficiary number, device identifiers and their serial numbers, vehicle identifiers and serial number, biometric identifiers (finger and voice prints), full face photos and other comparable images, and any other unique identifying characteristics, numbers, or codes. Special situations in radiology might arise, for instance, in soft-tissue volume rendered magnetic resonance imaging (MRI) or computed tomography (CT) datasets that might lead to patient identification. The data use agreement must follow the specifications in 45 CFR§164.514(e)(1)-(4).

The standard for deidentification of DICOM objects is defined by the DICOM Standard PS 3.15-2011, Digital Imaging and Communications in Medicine (DICOM), Part 15: Security and System Management Profiles (http://dicom.nema.org/medical/dicom/current/output/html/part15.html). It is up to the user doing the deidentification to ensure that PHI is removed or cleaned according to the laws and practices in place at the time deidentification occurs. Further details on deidentification are explained at The Cancer Imaging Archive Public Access wiki, (https://wiki.cancerimagingarchive.net/display/Public/De-
Identification+Knowledge+Base). Volume rendering of high-resolution MR or CT head and neck images might produce recognizable visual features unless an effort is made to remove the facial features. Opinion varies about the likelihood of this risk for practical reidentification scenarios weighed against the utility of the data.

E. Research on PHI of Decedents Requires

1. A representation by the researcher that use/disclosure being sought is solely for research on PHI of decedents
2. PHI for which access is sought is necessary for the research purpose
3. Documentation of the death of individuals about whom information is being sought when requested by the covered entity

For more information, see 45 CFR§164.510(i)(iii).

F. Accounting for Research Disclosures

Under the Privacy Rule, individuals have the right to receive an accounting of disclosures of PHI during the 6 years prior to the individual’s request but no earlier than April 14, 2003, and must include specific information regarding each disclosure. For subsequent multiple disclosures to the same person a more general accounting is permitted.

The success of medical research and educational uses under HIPAA requires an understanding of rules and regulations, maintaining appropriate documentation (eg, patient authorization, IRB waiver), and working with the IRB/privacy board to ensure compliance.

VI. MEDICAL-LEGAL CONSIDERATIONS

Physicians and health care professionals should evaluate whether their use and disclosure of electronic medical information might implicate one or more of the following entities may have more restrictive laws and rules to consider. This is not an exhaustive list. Physicians and professionals should consult a qualified health care lawyer in their relevant jurisdiction to obtain counsel on specific medical-legal matters.

1. Joint Commission
2. HIPAA/HITECH
3. GDPR – General Data Protection Regulation
4. Local and state laws
5. Family Educational Rights and Privacy Act
6. Americans with Disabilities Act
8. Rehabilitation Act
9. Gramm-Leach-Bliley Act
10. Children’s Online Privacy Protection Act

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Collaborative Committee – members represent their societies in the initial and final revision of this technical standard

ACR
J. Anthony Seibert, PhD, FACR, Chair
Adam E. Flanders, MD

AAPM
Donald J. Peck, PhD, FACR

SIIM
Ross W. Filice, MD
Tom Kern, CIIP
James T. Whitfill, MD

Committee on Practice Parameters and Technical Standards – Medical Physics
(ACR Committee responsible for sponsoring the draft through the process)

Maxwell R. Amurao, PhD, MBA, Chair
Mary Ann Keenan, DMP, Vice Chair
Priscilla F. Butler, MS, FACR
Chee-Wai Cheng, PhD, FAAPM
William R. Geiser, MS
Per H. Halvorsen, MS, FACR
Loretta M. Johnson, PhD
Lijun Ma, PhD, FAAPM
Tariq A. Mian, PhD, FACR
Jonathon A. Nye, PhD
Matthew A. Pacella, MS, FACR
Anshuman Panda, PhD
Douglas E. Pfeiffer, MS, FACR
Premavathy Rassiah, PhD
Christopher J. Watchman, PhD

Mahadevappa Mahesh, MS, PhD, FACR, Chair, Commission on Medical Physics
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Eric B. Friedberg, MD, FACR, Chair
Sonia Gupta, MD, Co-Chair
Maxwell R. Amurao, PhD, MBA
Jacqueline A. Bello, MD, FACR
David A. Clunie, MB, BS
Bruce H. Curran, MS, ME, FACR
Richard Duszak, Jr., MD, FACR
Ross W. Filice, MD
Adam E. Flanders, MD
Martin W. Fraser, MS, FACR
Tobin C. Hyman, MS
Candice A. Johnstone, MD
Mary Ann Keenan, DMP
Tom Kern, CIIP
Paul A. Larson, MD, FACR
Mahadevappa Mahesh, MS, PhD, FACR
Mary S. Newell, MD, FACR
Donald J. Peck, PhD, FACR
Matthew S. Pollack, MD, FACR
J. Anthony Seibert, PhD, FACR
Timothy L. Swan, MD, FACR
James T. Whitfill, MD

REFERENCES


APPENDIX A

A. Research Inside Firewall of Institution

1. Data
   a. Loss
      i. Risk: moderate
      ii. Cost: low (assuming can be regenerated from PHI source)
   b. Unauthorized access
      i. Risk: moderate
      ii. Cost: low (if data anonymized)
   c. Tampering
      i. Risk: moderate
      ii. Cost: high (invalidate research)

2. Applications
   a. Downtime
      i. Risk: moderate
      ii. Cost: low
b. Unauthorized access
   i. Risk: moderate
   ii. Cost: low (if data anonymized) moderate

c. Tampering
   i. Risk: moderate
   ii. Cost: high (invalidate research)

3. Requirements
   Legal: 21CFR11 Safe Harbor anonymization, audit trails of who accessed and anonymized

4. Tools used
   a. Application and data hashes to detect tampering
   b. Anonymizer tools
   c. Auditing trails at the PHI source and at the anonymization tool

B. Research performed at multiple sites

1. Data
   a. Loss
      i. Risk: moderate
      ii. Cost: moderate (data has to be regenerated from PHI at all sites)
   b. Unauthorized access
      i. Risk: moderate
      ii. Cost: low (if data anonymized)
   c. Tampering
      i. Risk: moderate
      ii. Cost: high (invalidate research)

2. Applications
   a. Downtime
      i. Risk: moderate
      ii. Cost: low
   b. Unauthorized access
      i. Risk: moderate
      ii. Cost: low (if data anonymized) moderate
   c. Tampering
      i. Risk: moderate
      ii. Cost: high (invalidate research)

3. Legal Requirements
   21CFR 11 Safe Harbor anonymization, audit trails of who accessed and anonymized

4. Tools used
   a. Application and data hashes to detect tampering
   b. Anonymizer tools
   c. Auditing trails at the PHI source and at the anonymization tool
   d. Digital signing to verify identity of remote senders

C. PHI Care Inside Firewall

1. Data
   a. Loss
      i. Risk: variable (depends on data availability tools used)
      ii. Cost: high (patient care, medicolegal)
   b. Unauthorized access
      i. Risk: moderate (most FDA products have basic controls)
      ii. Cost: high (legal and confidentiality loss)
   c. Tampering
NOT FOR PUBLICATION, QUOTATION, OR CITATION

2. Applications
   a. Downtime
      i. Risk: moderate (most FDA products have basic controls)
      ii. Cost: high (patient care, medicolegal)
   b. Unauthorized access
      i. Risk: moderate (most FDA products have basic controls)
      ii. Cost: high (legal and confidentiality loss)
   c. Tampering
      i. Risk: moderate (most FDA products have basic controls)
      ii. Cost: high (patient care, medicolegal)

3. Requirements
   a. Legal: all PHI controls of 21CFR11 are required including report controls and digital signing
   b. Practice: high uptime, ease of use, responsive behavior, clinical imaging tools

4. Tools used
   a. Redundant storage and applications
   b. Authentication controls
   c. Access controls based on user role
   d. Auditing
   e. Digital signing

D. PHI Care in the Cloud (HIE or Cloud-Based Provider)

1. Data
   a. Loss
      i. Risk: moderate (most cloud providers have redundant storage)
      ii. Cost: high (patient care, medicolegal)
   b. Unauthorized access
      i. Risk: high (many more agents have potential access)
      ii. Cost: high (legal and confidentiality loss)
   c. Tampering
      i. Risk: high (many more agents have potential access)
      ii. Cost: high (patient care, medicolegal)

2. Applications
   a. Downtime
      i. Risk: moderate (most cloud services are redundant)
      ii. Cost: high (patient care, revenue loss)
   b. Unauthorized access
      i. Risk: high (many more agents have potential access)
      ii. Cost: high (legal and confidentiality loss)
   c. Tampering
      i. Risk: high (many more agents have potential access)
      ii. Cost: high (patient care, medicolegal)

3. Requirements
   a. Legal: all PHI controls of 21CFR11 are required including report controls and digital signing
   b. Practice: high uptime, ease of use, responsive behavior, clinical imaging tools

4. Tools used
   a. Redundant storage and applications
   b. Authentication controls
   c. Access controls based on user role
   d. Auditing
   e. Digital signing
APPENDIX B

Glossary

Anonymization – the process of removing of all identifiers or codes that directly or indirectly link a particular data point or sample to an identifiable person. These data/samples become irreversibly unlinked from any subject identifiers.

Biometrics – in this case, the user may pass a smartcard through the card reader and then have to provide a fingerprint or voice sample (which is compared to a stored record before the central computer admits the user).

De-identification – the process of modifying identifiers within data/samples so that the information does not involve Protected Health Information (PHI). There are 18 items to exclude for de-identification as listed in 45 CFR 64.514(b)(2).

Digital Certificate – accompanies an electronic message to verify the identity of a user sending the message and also enables a user to encrypt the message.

Domain Name System (DNS) – a distributed internet delivery service that is mainly used to translate between domain names and internet protocol (IP) addresses, and to control Internet e-mail delivery.

**EHR – Electronic health record – more encompassing version of EMR**

Electronic Media – refers to electronic storage media in PCs and removable/transportable digital memory medium such as magnetic tapes or disks, CDs, pen drives or flash drives, optical disks, or digital memory cards; or transmission media, such as the intranet, extranet, leased lines, dial-up lines, and/or private networks.

Electronic Medical Information – patient information including images stored on electronic media.

EMR – Electronic medical record.

Firewall – a program or hardware device that filters information coming through the Internet connection into a private network or computer system. If an incoming packet of information is flagged by the filters, it is not allowed through.

**GDPR - General Data Protection Regulation – the GDPR aims primarily to give control to citizens and residents over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the European Union.**


HIPAA Security Standards – the Federal Government’s requirements for the handling of electronic media and protected health information. The standards address the following:

1. Ensuring confidentiality, integrity, and availability of all electronic protected health information (ePHI) the covered entity creates, receives, maintains, or transmits.
2. Protecting against any reasonably anticipated threats or hazards to the security or integrity of ePHI.
3. Protecting against any reasonably anticipated uses or disclosures of ePHI that are not permitted or required.
4. Ensuring compliance by the workforce.

HIS – Hospital information system.
HITECH – Health Information Technology for Economic and Clinical Health Act of 2009; addresses the privacy and security concerns associated with the electronic transmission of health information through provisions that strengthen the civil and criminal enforcement of the HIPAA law and rules.

Information security – the measures taken to protect personal health information from unauthorized breaches of privacy.

IP – Internet Protocol – basic communication language of the Internet; can also be used in private networks (intranet or extranet) and is the lower layer of a 2-layer system that handles addresses and sees that the e-mail gets to the correct destination.

IRB – institutional review board – a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

LAN – local area network, a short-distance network used to link a group of computers together within a department.

Nonrepudiation – the concept of ensuring that a party cannot repudiate or refute the validity of a statement or contract. The most common application of electronic nonrepudiation is in the verification and trust of digital signatures.

PACS – picture archiving and communication system.

Patient Privacy – refers to the right of patients to determine when, how, and to what extent their health information is shared with others.

PHI – protected health information is any information relating to one’s physical or mental health, the provisions of one’s health care, or the payment for that health care. The US Department of Health and Human Services (DHHS or HHS) defines all of the following as individually identifiable health information:

1. Names and addresses (all geographic subdivisions smaller than a state)
2. Dates that identify – dates of birth, admission and/or discharge date(s), dates of death
3. Specific age if over 89
4. Telephone and/or fax numbers, Social Security numbers, medical record and/or account numbers, employee numbers, health plan numbers, email addresses, Web/URLs, IP address numbers, and vehicle identifiers such as license plate/serial numbers and/or certificate/license numbers.
5. Full face images and/or comparable images, biometric identifiers, such as finger prints and/or voice prints.
6. Any unique identification numbers, codes, and/or characteristics that may be traced back to an individual.

RIS – radiology information system.

Smartcards – devices in a credit card form factor that contain electronic information or tokens that identify and validate the user in conjunction with other biometric or password information.

SSL – Secure Sockets Layer – a cryptographic protocol (encode/decode) that provides secure communications on the Internet for data transfers.

TPO – treatment payment or administrative operation.

URL – Uniform Resource Locator – a reference (an address) to a resource that specifies its location on a computer network (eg, the Internet) and a mechanism for retrieving it.
Virtual Private Network (VPN) – a computer network in which links between nodes are carried by open connections or virtual circuits (e.g., the Internet) instead of by physical wires. Software uses encryption and other security mechanisms to ensure that only authorized users can access the network and that data cannot be intercepted.

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 the Practice Parameter

2004 (Resolution 12)
Revised 2009 (Resolution 3)
Revised 2014 (Resolution 37)
RESOLUTION NO. 23

Imaging Guided Procedures Core Privileges

WHEREAS, core privileging, being a well-recognized methodology that is currently widely used by other specialties and some radiology practices, will simplify both initial privileging and re-privileging for radiologists, their practices and their respective hospital medical staff offices; and

WHEREAS, ACR practice parameters include a number of imaging guided diagnostic radiology and interventional radiology procedures, and the qualification section of many of these documents specify criteria for providers who perform these procedures and these qualifications have been used by hospitals or other health care entities for privileging providers; and

WHEREAS, the imaging guided procedures addressed in the ACR Practice Parameters are amenable to being grouped into Core Privileges; and

WHEREAS, Interventional Radiologists (IRs) are recognized as specialists through the ABR and AOBR and have unique knowledge, training and experience applicable and translational across a broad spectrum of current and future minimally invasive imaging guided procedures; and

WHEREAS, many imaging guided procedures have also been and continue to be delivered by ABR and AOBR board certified Diagnostic Radiologists (DRs), as well as other DRs certified by Boards in Canada and Great Britain practicing in the United States, who have unique and in-depth knowledge of and experience with these imaging guided procedure, especially in smaller community, pediatric and rural hospitals; and

WHEREAS, a fundamental principle for core privileging and re-privileging is that it emphasizes the value of American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, the Royal College of Radiologists – Great Britain and the Collège des Médecins du Québec certification and a compilation of over-all training and experience; and

WHEREAS, it is recognized that a given radiologist may not have the skill set for all procedures in a set of core privileges, they may opt out of being privileged for a specific imaging guided procedure; and

WHEREAS, the ethics of each individual physician, mentoring, CME, and additional post-graduate training could address best practice staffing needs as determined locally, in the present and future; and
WHEREAS, it is recognized that other specialties also perform some of the imaging guided procedures that DRs and IRs perform; those specialties have their own responsibility to appropriately recommend qualifications for privileging; and

WHEREAS, hospitals and other healthcare organizations are the final local arbiter of physician privileging; therefore,

BE IT RESOLVED, that the ACR supports and encourages the use of core privileging methodology for physician privileging and re-privileging in the performance of imaging guided procedures by Diagnostic Radiologists and Interventional Radiologists; and

BE IT FURTHER RESOLVED, that should procedural experience numbers be used for privileging and re-privileging, the numbers should be inclusive of a global compilation of an individual radiologist’s imaging guided procedural experience, applicable to the spectrum of the core privileges; and

BE IT FURTHER RESOLVED, that a core privileging statement be included in present & future relevant ACR imaging guided procedural practice parameter qualification sections; and

BE IT FURTHER RESOLVED, that the ACR will prepare and regularly update a library of core privileging templates based on a compilation of institutional and national organizational core privileging documents provided as a resource for ACR members to use in their individual privileging and re-privileging environments.

Sponsored by: Board of Chancellors
Council Steering Committee
Society of Interventional Radiology
Society for Pediatric Radiology
California Radiological Society
Florida Radiological Society
Wisconsin Radiological Society
Virginia Chapter of the ACR
Fiscal Note

Imaging Guided Procedures Core Privileges

To support the resolution **Imaging Guided Procedures Core Privileges**, the ACR would incur the following estimated costs:

**Costs:**

- **De minimis (<$10,000)**
LATE RESOLUTION NO. 45

Proceedings from inaugural Medical Summit on Firearm Injury Prevention

Firearm Injury Prevention Consensus Statements

WHEREAS, The ACR was asked by the American College of Surgeons and participated in a Medical Summit on Firearm Injury Prevention. This was a multi-stakeholder effort including numerous medical organizations; and

WHEREAS, The ACR was requested to endorse the document resulting from that summit (including figures) entitled, “Proceedings from the Medical Summit on Firearm Injury Prevention: A Public Health approach to reduce death and disability in the United States, Chicago, IL, February 10-11, 2019” by no later than April 1, 2019; and

WHEREAS, The Consensus Statements from that document were determined by the ACR Executive Committee to reflect a more focused position than the proceedings; and

WHEREAS, The ACR Council adopted a resolution in 2015 that “The ACR recognizes that deaths and injuries related to firearms are a major public health concern (Res. 57); and

WHEREAS, The ACR Executive Committee, acting on behalf of the Board of Chancellors, determined that, given the policy nature of the consensus statements, the ACR Council is the appropriate body to consider endorsement of the consensus statements, even though endorsement would occur after the proposed deadline; therefore,

BE IT RESOLVED, That the ACR endorse the Consensus Statements included in “Proceedings from the Medical Summit on Firearm Injury Prevention: A Public Health Approach to Reduce Death and Disability in the United States”

Sponsored by: ACR Board of Chancellors
Consensus Statements on Firearm Injury Prevention: A Public Health Approach to Reduce Death and Disability in the United States

CONSENSUS STATEMENTS

The following represent a consensus-based approach to the issue of Firearm Injury prevention:

1. Firearm injury in the United States is a public health crisis.

2. A comprehensive public health and medical approach is required to reduce death and disability from firearm injury.

3. Research is needed to better understand the root causes of violence, identify people at risk, and determine the most effective strategies for firearm injury prevention.

4. Federal and philanthropic research funding must be provided to match the burden of disease.

5. Engaging firearm owners and populations at risk is critical in developing programs and policies for firearm injury prevention.

6. Healthcare providers should be encouraged to counsel patients and families regarding firearm safety and safe storage. Educational and research efforts are needed to support appropriate culturally competent messaging.

7. Screening for the risk of suicide, intimate partner violence, and interpersonal violence should be conducted across all healthcare settings and in certain high-risk populations (such as those with dementia). Comprehensive resources and interventions are needed to support patients and families identified as high risk for firearm injury, who have access to a firearm.

8. Hospitals and healthcare systems must genuinely engage the community in addressing the social determinants of disease, which contribute to structural violence in underserved communities.

9. Our professional organizations commit to working together and continuing to meet in order to ensure these statements lead to constructive actions which improve the health and well-being of our fellow Americans.
To support the resolution for **Firearm Injury Prevention Consensus Statements**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
### COMMISSIONS, COMMITTEES & TASK FORCES:

- **Commission on Publications and Lifelong Learning**
- **Commission on Membership & Communications**
- **Commission on Informatics**
- **Commission on Research**
- **Commission on Ultrasound**
- **Commission on Breast Imaging**

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34. **ACR Practice Parameter for the Performance of Whole-Breast NEW PP Ultrasound for Screening and Staging**

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<tr>
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<td>Theresa Branham</td>
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<tr>
<td>Moderator</td>
<td>Tracy Purdie</td>
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<tr>
<td>Recorder</td>
<td>Ryan Keefer</td>
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<td>Assistant</td>
<td>Hector Mendoza</td>
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<tr>
<td>Attorney</td>
<td>Tom Hoffman</td>
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<td>Observer</td>
<td>Jasmine Mirabile</td>
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RESOLUTION NO. 24

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

1. ACCREDITATION

a. ACR Accreditation Information

The American College of Radiology shall post on its website information related to practice parameters and technical standards and accreditation programs so that it is easily available in a user-friendly format at all times to all ACR members. This downloadable information would include practice parameters and technical standards, and accreditation information. This information would include overviews, flow charts, applications and related instructions, guidance documents in regard to new facilities/new equipment and answers to frequently asked questions; adopted 1999, 2009 (Res. 1-a).

(b) I. RADIOLOGICAL PRACTICE AND ETHICS

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

y. Standards: Implementation

The Commission on Quality and Safety (formerly the Commission on Standards and Accreditation) will submit Radiologic Practice Parameters and Technical Standards, as they are developed, to the Council Steering Committee for review and recommendation to the ACR Council; adopted 1989, amended 1999, 2009 (Res. 1-h).

(c) I. RADIOLOGICAL PRACTICE AND ETHICS

3. POSITION STATEMENTS

e. Endorsing AIUM’s Clinical Safety and Prudent Use in Obstetrics Statements

The American College of Radiology supports and endorses the following AIUM Clinical Safety Statement; adopted 1999, 2009 (Res. 12-a).

Prudent Use and Clinical Safety approved March 19, 2007
Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

No independently confirmed adverse effects caused by exposure from present diagnostic ultrasound instruments have been reported in human patients in the absence of contrast agents. Biological effects (such as localized pulmonary bleeding) have been reported in mammalian systems at diagnostically relevant exposures but the clinical significance of such effects is not yet known. Ultrasound should be used by qualified health professionals to provide medical benefit to the patient.

Prudent Use in Obstetrics approved March 19, 2007

The AIUM advocates the responsible use of diagnostic ultrasound and strongly discourages the non-medical use of ultrasound for entertainment purposes. The use of ultrasound without a medical indication to view the fetus, obtain a picture of the fetus or determine the fetal gender is inappropriate and contrary to responsible medical practice. Ultrasound should be used by qualified health professionals to provide medical benefit to the patient.

(d)  I. RADIOLICAL PRACTICE AND ETHICS
5. MISCELLANEOUS RADIOLOGIC PRACTICE AND ETHICS POLICIES
   e. Clinical Data

In order to afford optimal care to the patient, and to enhance the cost-effectiveness of each diagnostic examination, radiological consultations ought to be provided and radiographs interpreted within a known clinical setting. The ACR supports radiologists who insist on clinical data with each consultation request: In order to optimize value and guide the most appropriate medical imaging for the care of our patients, the ACR supports and encourages its members, requesting providers, and their institutions to ensure the availability of accurate, pertinent, and expedient clinical information at the time that imaging services are requested, performed, and interpreted. Clinical Decision Support and other systems that use Provider-led entity (PLE) developed Appropriate Use Criteria (AUC) can be particularly valuable tools in accomplishing this objective; adopted 1979, 1989, 1999, 2009 (Res. 30-d)

(e)  I. RADIOLICAL PRACTICE AND ETHICS
5. MISCELLANEOUS RADIOLOGIC PRACTICE AND ETHICS POLICIES
   q. Efficacy

1. Efficacy Studies
The ACR will continue to sponsor efficacy studies evaluating appropriateness, outcomes, and value; adopted 1979, 1989, 1999, 2009 (Res. 30-h).

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–AIUM–SRU Practice Parameter for the Performance of Contrast Enhanced Ultrasound

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–AIUM–SRU Practice Parameter for the Performance of Contrast Enhanced Ultrasound

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, ___ N.W.2d ___ (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

The clinical aspects contained in specific sections of this practice parameter (Introduction, 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, 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.

II. INDICATIONS

Indications for contrast-enhanced ultrasound (CEUS) are based on the current literature recommendations and clinical practice standards.

CEUS is safe for patients with contraindications for CT or MRI, such as pacemakers, allergies to gadolinium-based or iodinated contrast material, claustrophobia, immobility, or metal implants. Because of its lack of ionizing radiation and ease of performance without sedation, CEUS should be considered as a useful problem-solving tool and as an indicated first-line imaging modality in select settings as indicated below.

1. Liver
   a. Characterization of focal liver lesions in the noncirrhotic liver
      i. Further characterize incidentally found liver lesions on US
      ii. Evaluate incompletely characterized lesions on noncontrast or contrast-enhanced CT or MRI
   b. Characterization of focal liver lesions in the cirrhotic liver
      i. Assess nodules detected on surveillance US
      ii. Assess Li-RADS (LR); LR-2, LR-3, LR-4, or LR-M observation on prior contrast-enhanced CT or MRI
      iii. Detect arterial phase hyperenhancement (APHE) when mistiming is suspected as the reason for its absence on prior CT or MRI.
      iv. Assess biopsied lesions with inconclusive histology.
   c. Detection of metastases
   d. Vascular
      i. Determine hepatic artery, portal vein, and hepatic vein patency
      ii. Assess transjugular intrahepatic portosystemic shunt (TIPS) patency
      iii. Distinguish bland thrombus versus tumor in vein
   e. Response to therapy (ablation; transarterial chemoembolization (TACE) for hepatic malignancy) for assessment of residual viable disease [1-3]
   f. Help select appropriate sites for biopsy
   g. Assess for residual tumor postablation
2. Kidney and bladder
   a. Antegrade nephrostogram for evaluation of ureteral patency in the setting of indwelling nephrostomy tube [4]
   b. Assessment of native renal perfusion/cortical necrosis in the setting of acute renal failure
   c. Characterize indeterminate cystic renal lesions
   d. Differentiate between renal tumors and anatomical variants mimicking a renal tumor ("pseudotumors")
   e. Evaluate transplant perfusion: infarct or ischemia
   f. Identify renal abscesses in complicated acute pyelonephritis
   g. Follow-up of nonsurgical renal lesions
   h. Differentiate bladder cancer from hematoma in patients with hematuria
   i. Improve diagnosis of renal artery stenosis or resolve vascular patency questions
   h. Pediatric voiding cystourethrography (VCUG)
      i. Evaluation of prenatally detected hydroureronephrosis and urinary tract malformations
      ii. Diagnosis and follow-up vesicooureteral reflux
      iii. Characterization of urethral abnormalities

3. Endovascular aortic repair (EVAR) and cerebrovascular assessment
   a. Follow-up EVAR for the detection and classification of endoleaks
   b. Differentiate between total carotid and vertebral artery occlusion and residual flow through a tight stenosis

4. Pancreas
   a. Differentiate between cystic neoplasms and pseudocysts
   b. Differentiate vascular (solid) from avascular (eg, liquid or necrotic) components of a pancreatic lesion
   c. Follow-up of indeterminate cystic pancreatic lesions
   d. Improve the accuracy of percutaneous US-guided pancreatic procedures

5. Bowel
   a. Estimate disease activity in inflammatory bowel disease
   b. Monitor the effect of treatment in Crohn’s disease
   c. Distinguish abscesses from phlegmons and improve visualization of fistulous tracks

6. Spleen
   a. Diagnose splenic infarction
   b. Characterize indeterminate splenic lesions [5,6]

7. Scrotum
   a. Distinguish vascularized masses from nonvascularized, nontumorous focal testicular lesions
   b. Identify testicular infarction

8. Trauma
   a. In stable patients with blunt abdominal trauma, CEUS can be used as an alternative to CT to follow-up solid organ injury, particularly in children. It can assess for pseudoaneurysms and can be performed at the bedside.

9. Intracavitary injection
   a. Identify needle or confirm catheter position, delineate any cavity or duct, improved tracking of fistulae.
   b. Sonosalpingography [7]

10. Interventional guidance
    a. Avoid necrotic tissue to improve cytologic yield in the biopsy of tumors
    b. Assist in identifying biopsy targets inconspicuous on US or noncontrast CT
c. Assess for active bleeding after procedure

11. Other
   a. Assessment of vascularized versus nonvascularized lesions can be performed in any other part of the
   body in addition to the organs listed.
   b. Distinguishing necrotic from nonnecrotic lung in pediatric pneumonia [8]
   c. Distinguishing complex from simple ovarian cysts

III. QUALIFICATIONS OF PERSONNEL

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [9] and European Federation of Societies for Ultrasound in Medicine and Biology CEUS Minimum Training Requirements for the Practice of Medical Ultrasound in Europe [10,11].

Appropriate training and education are strongly advised for every investigator who performs CEUS examinations. Furthermore, investigators should ensure that their US scanning machine is optimized for CEUS acquisition and the postprocessing of data. The operator must gain sufficient knowledge of indications and contraindications of CEUS and training in US contrast agent administration and perform CEUS within the medicolegal framework.

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for an ultrasound examination 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). 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)

Depending on a state or institution's interpretation of the CMS rules of participation, a radiologist may add contrast to a "noncontrast" US order, depending on the indication for the study and/or findings identified during a routine US examination. Adding a same-day contrast study may decrease the time to final diagnosis and may decrease costs and harm by reducing unnecessary follow-up CT or MRI examinations [12].

V. SPECIFICATIONS OF THE EXAMINATION

Contrast Dose: In adults, the standard dose for most abdominal applications is 2.4 mL of sulfur hexafluoride lipid microspheres (SHLM) contrast (eg, Lumason®). In children, the dose is 0.03 mL/kg up to a maximum of 2.4 mL per injection. Intravascular administration of up to 5 mL of SHLM contrast (Lumason) in a single session is approved by the Food and Drug Administration (FDA).

The standard dose of perfluorin lipid microspheres (PLM) contrast (eg, Definity®) is 10 µL/kg. The standard dose of perfluorprotein microspheres (PPM) contrast (eg, Optison®) is 0.5 mL. Additional 0.5-mL doses may be given to improve characterization of a finding or overcome artifacts encountered during the initial injection.
Summary of scanning protocols:

1. Liver

   Hepatic imaging protocol is based on the ACR CEUS LI-RADS recommendations.
   a. CEUS of the liver is usually performed to assess targets clearly identified on precontrast B-mode imaging. CEUS may be limited in patients with high body mass index (BMI) and in patients with severe hepatic steatosis, mainly because of substantial US signal attenuation.
   b. Contrast Dose: Contrast dose specified by the manufacturer should be used for the majority of examinations. Imaging of very superficial liver lesions with higher-frequency probes will require contrast dose increase. In addition to patient factors, the contrast dose can be adjusted based on the sensitivity of the equipment used for CEUS examination [13, 14].
   c. Imaging should be performed continuously from contrast injection until peak arterial phase enhancement to characterize the presence, intensity and pattern of arterial phase enhancement. Alternatively, continuous imaging can be extended beyond peak arterial phase enhancement until 60 seconds after contrast injection to determine the presence of early washout. After 60 seconds, recording of static images should be performed intermittently (3-5 seconds every 30-60 seconds) to detect late washout and to assess its degree. Continuous insonation of large portions of the highly vascular liver may result in excessive destruction of microbubbles thereby limiting assessment for true washout.
   d. Imaging of multiple nodules often requires more than one contrast injection and careful planning of patient positioning to maximize the use of limited acoustic windows. In patients with multiple liver nodules, two or three nodules can usually be imaged at one session.

2. Other abdominal applications [15]

   Most abdominal organs enhance rapidly and intensely 10 to 15 seconds after US contrast administration. The arterial vessels enhance first, followed by diffuse parenchymal enhancement. Contrast enhancement usually persists for 4 to 6 minutes after injection. Unlike CT and MRI contrast agents, microbubbles are not excreted by the kidneys or biliary system. Therefore, no microbubbles are detected in the renal collecting or biliary systems.
   a. Because of the highly vascular nature of the kidney, CEUS can be performed with less than the standard dose.
   b. Imaging should be performed continuously from contrast injection until the imaging target is adequately characterized.

3. EVAR and vascular

   a. Contrast dose: CEUS examination of the aorta and great vessels is usually performed using a slightly decreased dose of US contrast (ie, 50%-75% of the standard dose [1.5-2.0 mL of SHLM contrast, 0.2 mL of PLM contrast, or 1.0 mL of PPM contrast]) [16].
   b. Imaging:
      i. Initial CEUS examination should focus on time of enhancement of the aneurysmal sac versus the endograft lumen.
      a) Contributing vessels can be identified.
      ii. The examination should continue for at least 10 minutes to ensure that delayed and low-flow endoleaks are identified.

4. Scrotum

   a. Contrast dose: CEUS examination of scrotum is performed with high-frequency transducers, requiring higher doses of contrast (4.8 mL of SHLM contrast, 0.4 mL of PLM contrast or 2 mL of PPM contrast).
   b. Imaging with linear high-frequency transducers should be performed. CEUS imaging should focus on the arterial phase as it is the most important aspect of the examination. Imaging should be performed continuously from contrast injection until the imaging target is adequately characterized. Presence and degree of arterial phase enhancement should be documented.
5. Pediatric voiding urosonography [17,18]
   a. Contrast dose: To date, published studies have used either SHLM contrast or PPM contrast. The FDA-recommended contrast dose and administration of SHLM contrast is a 1-mL injection into a bladder that is partially filled with normal saline. However, a suspension of US contrast agent and normal saline can also be infused into the bladder at a dose of approximately 0.2% of bladder filling volume. The optimal contrast dose may vary with the use of different US equipment and should be optimized for image quality.
   b. Imaging: Imaging of the bladder, retrovesical space to assess the distal ureters, and both kidneys is performed in the supine, lateral decubitus, and/or prone position during bladder filling. Multiple cycles of bladder filling and voiding are performed in neonates and infants to increase the rate of detection of reflux. The urethra is imaged from either a suprapubic or transperineal approach during voiding. Studies are documented with static images and cine clips.

6. Intracavitary injection
   No standard US contrast agent dose or imaging protocol has been established for intracavitary applications. The reported dose range is 0.1 to 1.0 mL SHLM contrast, 0.1 to 0.2 mL of PLM contrast, or 0.1 to 0.5 mL of PPM contrast diluted in ≥10 mL of 0.9 % normal saline. If scanning is performed using high-frequency US transducers, a higher concentration of contrast agent may be required for optimal visualization.

7. Interventional guidance
   a. Contrast Dose: Recommended dose of US contrast agents for interventional imaging is 2.4 mL of SHLM contrast, 0.2 mL of PLM contrast, or 1.0 mL of PPM contrast. Similar to other applications, dose of contrast material could be adjusted based on patient’s BMI, depth of the lesion, and transducer frequency.
      i. When performing interventional CEUS guidance, several injections of US contrast might be required.
      ii. The first bolus injection is used to identify the target lesion and plan the procedural approach.
      iii. The second bolus (or in some cases continuous contrast infusion) is used to guide biopsy needle placement.
      iv. When the target lesion begins to clearly appear following the second contrast agent injection (or infusion), the biopsy needle or ablation device is advanced into the target.
   b. Imaging
      i. In large/partially necrotic tumors, sampling should be performed based on arterial phase hyperenhancement of actively perfused viable tumor components.
      ii. In smaller lesions poorly seen on routine B-mode US, the biopsy is performed in the late phase of CEUS imaging, targeting areas of tumor washout surrounded by actively perfused normal liver parenchyma.

VI. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the US examination and its interpretation, including cine clips. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. 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 medical record. Retention of the US 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 [19].
Data storage and access

All relevant images should be properly labeled to include the target and plane of imaging. The report should include the type of contrast injected, number of injections, route and dose. The relevant images should be stored either digitally on a Picture Archiving and Communication System (PACS) or as hard copy images. Regardless of storage method, the images should be readily available for review by all physician teams caring for the patient and making medical decisions based upon the results. Image storage should meet all local, state, and federal requirements for medical record document retention. Current and prior studies must be accessible in a reasonable timeframe for the clinical needs of the medical staff and the medical facility. See the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging [20] for further details.

VII. EQUIPMENT SPECIFICATIONS

Depth of penetration and image clarity may be reduced by low mechanical index (MI) imaging. However, users should be aware that microbubble destruction can lead to artifactual or pseudo washout.

Image acquisition

All CEUS studies should be performed on a machine with contrast imaging capability and dual display mode. Each vendor has different proprietary methodology for optimal detection and display of CEUS. Regardless of the vendor, the modality and instrument settings that optimize visualization of contrast and opacification of vascular structures should be employed. Most of these techniques use a real-time low MI technique, usually <0.3 for continuous imaging. High MI mode may be chosen for rapid bubble destruction in the field of view to evaluate microbubble replenishment. The targeted lesion should be imaged with B-mode prior to the contrast study.

Contrast agent detection relies upon harmonic imaging, and fundamental (non-harmonic) imaging should be avoided. Suppression of background tissue signal by phase/amplitude modulation and harmonic techniques can increase the sensitivity of the machine to CEUS signal, but strongly reflective structures may still create artifact despite background suppression. Likewise, high doses of contrast may limit visualization of deeper structures; therefore, proper dosing of contrast is important.

Gain settings should be adjusted to reduce signal from background structures prior to CEUS injection. Scan plane should be selected to avoid overlying shadowing structures. The focal zone is typically placed at the deepest portions of the region of concern (organ or lesion). For deeper lesions, lower frequency is preferred for depth penetration and optimized microbubble signal. If higher frequency is selected, an increased volume of contrast may be necessary to achieve adequate contrast enhancement display since microbubble signal is higher at typical lower transducer frequencies, and higher frequency may also result in faster loss of microbubble volume because of bubble destruction.

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

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

Intravascular administration

Mild physiologic adverse reactions include nausea and vomiting, taste alteration, headache, vertigo, flushing, and rash. These have an incidence of about 5% [22] and resolve spontaneously without lasting effects.

US contrast agents (UCAs) are not contraindicated in patients with compromised renal function as they are not excreted by the kidneys. No blood tests are needed prior to administration.

1. Anaphylactoid (allergic-like) reactions
UCAs carry an FDA black box warning and are contraindicated in patients with a history of allergy to the agent or its constituent gas or shell.

Hypersensitivity events are due to anaphylactoid (allergic-like) reactions to the gas or shell. Anaphylactoid reactions include hypotension with tachycardia, bronchospasm, urticaria, and pruritus. The incidence of serious anaphylactoid reactions is 0.006% to 0.01% [23,24], which is comparable to gadolinium-based contrast agents and lower than that for iodinated contrast agents. A rate of 0.001% has been reported for life-threatening anaphylactoid reactions, less than the rate for CT or MR contrast agents [25].

In most cases, hypersensitivity events occur within a few minutes of injection. Resuscitation equipment and trained personnel should be available when UCAs are administered. Contrast reactions should be managed according to the ACR Manual on Contrast Media Version 10.3 [26] and the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [27].

UCAs have a similar safety profile in children [28-30].

2. Intravesical and intracavitary administration
Mild physiologic adverse events during intravesical administration of UCAs in children has been reported in 0.8% to 3.8% of cases and are thought to be primarily related to bladder catheterization and not the UCA [31,32].

Intracavitary administration of UCAs has not been associated with specific complications.

3. Pregnancy
There have been no studies of US contrast agents in pregnant patients for SHLM contrast or PLM contrast. Animal studies have shown no harm to the fetus at doses of SHLM contrast up to 8 to 17 times the human dose based on body surface area [33]. There are no studies on PPM contrast in pregnant humans, but teratogenic effects have been demonstrated in animal studies. The FDA recommends that PPM contrast be used in pregnancy only if the benefit outweighs the risk [34].

4. Breastfeeding
There are no data on the presence of UCAs in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s need for UCAs and any potential adverse effects on the breastfed infant from UCAs or from the underlying maternal condition. Milk can be pumped and discarded within 24 hours of contrast administration as a precautionary measure.
5. Bioeffects of bubble fragmentation

US pulses at moderate and high mechanical indices result in substantial microbubble oscillation and fragmentation, which are referred to as stable and inertial cavitation, respectively [35]. This microbubble oscillation can have a range of biological effects under certain conditions, ranging from short-term mild changes in cellular permeability at moderate mechanical indices [36-38] to hemolysis and capillary endothelial injury at higher mechanical indices [39-41]. The magnitude of cavitation is proportional to US amplitude [42] and inversely proportional to frequency.

There have been reports of ventricular arrhythmias in echocardiography following imaging protocols that result in microbubble fragmentation when a high mechanical index is applied [43]. However, no evidence of clinical bioeffects from cavitation during abdominal CEUS have been found in humans at clinically relevant doses of contrast, and no cellular injury has been seen with CEUS performed at the low power setting used in nondestructive imaging. However, given the evidence of bioeffects and that therapeutic applications of microbubbles are used with acoustic parameter ranges that have some overlap with diagnostic imaging parameters, microbubble insonation at moderate and high mechanical indices should be used cautiously. The AIUM recommends that practitioners be aware of the MI used for any study, with an MI of 0.4 as a threshold value for bioeffects [44]:

“Induction of premature ventricular contractions, microvascular leakage with petechiae, glomerular capillary hemorrhage, and local cell killing in mammalian tissue in vivo have been reported and independently confirmed for diagnostic ultrasound exposure with a mechanical index (MI) above about 0.4 and a gas body contrast agent present in the circulation.

“Although the medical significance of such microscale bioeffects is uncertain, minimizing the potential for such effects represents prudent use of diagnostic ultrasound. In general, for imaging with contrast agents at an MI above 0.4, practitioners should use the minimal agent dose, MI, and examination time consistent with efficacious acquisition of diagnostic information.”

Thus, MI above 0.4 for clearance pulses should be used sparingly and in accordance with the ALARA principle. Without a clearance pulse, contrast will usually be eliminated spontaneously from the circulation within 15 minutes.

Clinical CEUS should generally be performed with low mechanical index imaging of between 0.2 and 0.4.

PPM contrast contains human albumin, a derivative of human blood, and may confer a theoretical risk of viral or prion infection; additionally, it may not be used in patients with religious or ethical objections to the intravascular receipt of human blood products.

6. Quality control

All US devices, including those performing CEUS studies, require annual acceptance testing by a trained, qualified physicist and/or their designees. Routine annual quality control is also recommended. See the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [21] for additional details.

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 of the ACR Commissions on Ultrasound and Pediatric Radiology in collaboration with the ACOG, the AIUM, the SPR, and the SRU.
Collaborative Committee

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

ACR
Wui K. Chong, MD
Richard G. Barr, MD, PhD, FCR
Mark E. Lockhart, MD MPH

AIUM
Yuko Kono, MD, PhD, FAIUM, FAADLD

SRU
Andrei Lyshchik, MD, PhD
Harriet J. Paltiel, MD

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Beverly G. Coleman, MD, FACR, Chair
Jacqueline Anne Bello, MD, FACR, Chair
Matthew S. Pollack, MD, FACR, Chair
Mary S. Newell, MD, FACR, Vice Chair

Comments Reconciliation Committee
Sonia Gupta, MD – Chair
Elaine Lewis, MD, FACR – Co-Chair
Richard G. Barr, MD, PhD, FCR
Jacqueline A. Bello, MD, FACR
Wui K. Chong, MD
Beverly G. Coleman, MD, FACR
Richard Duszak, Jr., MD, FACR
Wui K. Chong, MD
David Fetzer, MD
Yuko Kono, MD, PhD, FAIUM, FAADLD
Stefanie Lee, MD

Mark E. Lockhart, MD MPH
Andrei Lyshchik, MD, PhD
Mary S. Newell, MD, FACR
Matthew S. Pollack, MD, FACR
Harriet J. Paltiel, MD
Michelle Robbin, MD
Shuchi K Rodgers, MD
Sheila Sheth, MD, FACR
Judy H. Squires, MD
Timothy L. Swan, MD, FACR

REFERENCES


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RESOLUTION NO. 26

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–SRU Practice Parameter for the Performance of Ultrasound Elastography

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–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND ELASTOGRAPHY

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, ___ N.W.2d ___ (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

Ultrasonic Elastography

2019 Resolution No. 26
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) and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among different organizations and are addressed by each separately.

Elastography measures the deformation of tissues after an external stress is applied. Softer tissues deform more than stiffer tissues. There are two major types of imaging-based elastography, strain elastography (SE), and shear wave elastography (SWE).

SE is a qualitative form of elastography that compares relative stiffness between tissues in a field of view (FOV). The stress can be by compression and subsequent release of the tissue by the transducer, breathing, or heartbeat of the patient, or an acoustic push using acoustic radiation force imaging (ARFI).

A second method of determining the stiffness of tissue is SWE. An ARFI pulse is used to generate shear waves, which propagate perpendicular to the ARFI pulse. The shear wave speed is estimated using B-mode imaging. SWE can be performed in a small region of interest (ROI), point shear wave imaging (pSWE), or over a larger FOV—2-D-SWE. Two-dimensional–SWE can be performed either as a single image or can be performed in real time. Some vendors provide a quality measure in 2-D–SWE. The quality measure assesses the raw data collected to estimate the shear wave speed and provides information on the accuracy of the measurement. The SWE technique is quantitative, providing a stiffness value either by the shear wave speed in meters per second (m/s) or converting to the Young’s modulus in kilopascals (kPa) [1,2].

Each elastography measure has advantages and disadvantages, and the appropriate technique should be used for the specific indication. The appropriate nomenclature should be used when describing the technique used, as recommended by the World Federation of Ultrasound in Medicine and Biology (WFUMB) [3].

II. INDICATIONS

There are two major indications for ultrasound elastography: (1) determination of the stiffness of an organ (eg, liver in chronic liver disease) and (2) determination of the stiffness of a lesion (eg, a breast mass).

1. Indications for assessment of stiffness of an organ include, but are not limited to:
   a. Liver stiffness, for example in cirrhosis
   b. Spleen stiffness, for example in assessment of portal hypertension
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2. Indications for assessment of stiffness of a lesion include, but are not limited to, lesions of the
   a. Breast
   b. Thyroid
   c. Prostate
   d. Tendons

III. QUALIFICATIONS OF PERSONNEL

To perform accurate elastography, the personnel should meet all requirements of the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [4]

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for an ultrasound elastography examination 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). 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

All forms of elastography must be performed with minimal initial pressure applied with the transducer as this can substantially affect the results. In general, optimal B-mode images are required to obtain accurate elastography results [5].

1. Stiffness of an organ

   a. SE should not be used as it is qualitative and does not give a quantitative stiffness value.
   b. Either pSWE or 2-D–SWE should be used.
   c. For liver stiffness, the recommendations of the SRU consensus or the WFUMB guidelines should be used for performing the examination [3,6].
      i. The patient should fast for at least 4 hours
      ii. The examination should be performed in the supine or the slight left lateral position with the arm raised above the head to increase the intercostal space
      iii. The measurements should be taken through an intercostal approach at the location of the best acoustical window
      iv. The measurements should be taken 1.5 to 2.0 cm below the liver capsule to avoid reverberation artifact. The optimal location for maximum shear wave generation is 4.0 to 4.5 cm from the transducer
      v. The transducer should be perpendicular to the liver capsule in both planes
      vi. Placement of the ROI should avoid large blood vessels, bile ducts, and masses
      vii. Ten measurements should be obtained from 10 independent images, in the same location, with the median value used for pSWE.
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viii. Three to five measurements may be appropriate for 2-D–SWE when a quality assessment parameter is used.
ix. The interquartile range of stiffness to the median (IQR/M) should be used as a measure of quality. The IQR/M should be <0.3 kPa and < 0.15 m/s for an accurate data set

2. Stiffness of a lesion

a. Either SE or 2-D–SWE can be used [7-10]. Because many masses are heterogeneous, the use of pSWE is discouraged as the area of maximum stiffness cannot be determined [11]
b. SE results can be interpreted either using the elastographic to B-mode ratio (E/B) (breast only), strain ratio (SR), or a five-point color scale [12]
c. When using the SR, the appropriate reference tissue should be used. When examining breast, fat is used as the reference tissue. When examining other organs, the normal tissue at a similar distance from the transducer is used as a reference
d. The number of measurements to be taken has not been well studied, but using three measurements is reasonable. General technique requirements for SE include:
   i. Scan with minimal initial compression on the tissue with the transducer
   ii. Use the optimal compression/release for the system (this can vary from patient breathing/heart beat while holding the transducer still to having to compress and release the tissues with the transducer by 1-2 mm)
   iii. Remain at the same plane through the lesion when acquiring data
   iv. Have a large FOV containing several different tissues
e. General technique requirements for SWE include
   i. Scan with minimal compression on the tissues with the transducer
   ii. Minimize movement
   iii. Position the patient so the lesion is at least 5 mm deep and less than 4 cm deep to the transducer, if possible
f. Lesion stiffness can contribute to morphologic feature analysis of a breast lesion and its BI-RADS® assessment. SE or SWE should not be used as the sole criterion of likelihood of breast malignancy. Practitioners should refer further to the ACR Practice Parameter for the Breast Ultrasound Examination [13].

VI. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Cine clips may be useful. 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 [14].

Because of differences between equipment and scanning techniques, when reporting elastography results, the ultrasound system, transducer used, and patient positioning should be documented. For SE, the ultrasound system and the display scale should be documented. For breast SE, the E/B distance ratio is recommended and should be reported. If the SR is used, then the tissue used for reference should be documented. For SE, if a color scale is used,
the scale should be documented (ie, four-point color scale, five-point color scale). For liver stiffness SWE, the number of measurements taken, the median value, and the IQR/M should be reported.

Examples of such documentation include:

1. Strain

   SE using manual compression, ARFI was performed on the lesion(s). The E/B distance ratio, SR [include reference tissue], color scale [state which one] was used to analyze the data.

   a. For breast: The E/B distance ratio was [#], this is suggestive of a [soft, stiff] lesion.

   b. For other organs: The strain imaging was interpreted using the SR [include reference tissue] or color scale [state which one]. The result is [give result], which is suggestive of a [soft, stiff] lesion.

2. SWE

   a. Liver

      Liver stiffness values were obtained using [pSWE, 2-D–SWE]. [#] of measurements were obtained with a median value of [# (state results in m/s and/or (kPa)]. The IQR/M was [#], suggestive of a [good, poor] data set. [The variance in the measurements is large (ie, IQR/M > 0.3) and, therefore, the accuracy of the measurement may be in question].

      i. This corresponds to [no to mild, moderate to severe, severe fibrosis, or cirrhosis].

      ii. If there is a complicating feature, the following should be added:

          In the setting of [markedly elevated liver function tests, nonfasting, congestive heart failure, etc], the degree of liver fibrosis may be overestimated.

   b. Breast

      Two dimensional–SWE was performed on the lesion(s). The highest stiffness value in the lesion or surrounding tissue was [# m/s and/or kPa]. This is suggestive of a [soft, indeterminate, stiff] lesion.

      If both SE and SWE are performed, a statement should be made if they are concordant or not.

   c. Other single organs

      Stiffness values were obtained using [pSWE, 2-D–SWE]. [#] measurements were made with a median value of [# m/s and/or kPa]. [Give conclusion – normal, indeterminate, or abnormal].

   d. Other lesions

      Two dimensional–SWE was performed on [specify lesion]. The stiffness value was [# m/s and/or kPa]. This is suggestive of a [soft, indeterminate, stiff] lesion.

VII. EQUIPMENT SPECIFICATIONS

The ultrasound equipment should have Food and Drug Administration (FDA)-approved elastography techniques. The power control on all systems should maintain the energy output within the recommended guidelines.

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education.

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [15].

Quality Control and Improvement

The Quantitative Imaging Biomarker Alliance (QIBA), a consortium of the Radiological Society of North America (RSNA), academia, industry, clinical practitioners, and government, has created a “profile” that describes a consensus standard approach for acquiring reliable shear wave elastographic measurements in chronic liver disease. It also contains requirements for equipment calibration and assessment of personnel performing the acquisitions. The profile makes claims for accuracy of the results (bias and variability) across different machines, operators, and sites that will be met if the profile is followed. The draft profile will be available after a limited public review is complete, but an easy to follow, step-by-step checklist based on the draft profile is available here [16]: https://qibawiki.rsna.org/images/1/15/SWS_BC_ProfileChecklist.pdf

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 SRU.

Collaborative Committee

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

ACR
Richard G. Barr, MD, PhD, FACR, Chair
Phoebe Freer, MD
Brian S. Garra, MD
Anna Holbrook, MD
Phan T. Huynh, MD, FACR
John M. Lewin, MD, FACR
Margaret Szabunio, MD, FACR

SRU
Deborah Levine, MD, FACR
Deborah J. Rubens, MD, FACR
Gary J. Whitman, MD, FACR

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahia, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards
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.
RESOLUTION NO. 27

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–ACOG–AIUM–SPR–SRU Practice Parameter for the Performance of Ultrasound of the Female 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 2014 (Resolution 23)*


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 reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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.
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 American College of Obstetricians and Gynecologists (ACOG), the Society for Pediatric Radiology (SPR), 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 four organizations and are addressed by each separately.

This practice parameter has been developed to assist physicians and other health care providers performing sonographic studies of the female pelvis. Ultrasound of the female pelvis should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information. In some cases, additional or specialized examinations may be necessary. Although it is not possible to detect every abnormality, adherence to the following practice parameter will maximize the probability of detecting most abnormalities. For ultrasound of the urinary bladder, see ACR–AIUM–SPR–SRU Practice Parameter for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum [1].

II. INDICATIONS

Indications for pelvic sonography include, but are not limited to, the following:

1. Evaluation of pelvic pain
2. Evaluation of pelvic masses
3. Evaluation of endocrine abnormalities, including polycystic ovaries
4. Evaluation of dysmenorrhea (painful menses)
5. Evaluation of amenorrhea
6. Evaluation of abnormal vaginal uterine bleeding (AUB)
7. Evaluation of postmenopausal bleeding (PMB)
8. Evaluation of delayed menses
9. Follow-up of a previously detected abnormality
10. Evaluation, monitoring, and/or treatment of infertility patients
11. Evaluation when there is limited clinical examination of the pelvis
12. Evaluation for signs or symptoms of pelvic infection
13. Further characterization of a pelvic abnormality noted on another imaging study
14. Evaluation of congenital uterine, gonadal, and lower genital tract anomalies
15. Evaluation of excessive bleeding, pain, or signs of infection after pelvic surgery, delivery, or abortion
16. Localization of an intrauterine contraceptive device (IUD)
17. Screening for malignancy in high-risk patients
18. Evaluation of incontinence or pelvic organ prolapse
19. Guidance for interventional or surgical procedures
20. Preoperative and postoperative evaluation of pelvic structures
III. QUALIFICATIONS 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 [2].

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 a pelvic ultrasound examination 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). 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 section details the examination to be performed for each organ and anatomic region in the female pelvis. All relevant structures should be identified by the transabdominal and/or transvaginal approach. A transrectal or transperineal approach may be useful in patients who are not candidates for introduction of a vaginal probe transducer and in assessing the patient with pelvic organ prolapse. More than one approach may be necessary [3,4].

A. General Pelvic Preparation

For a complete transabdominal pelvic sonogram, the patient’s bladder can be distended if necessary to displace the small bowel from the field of view and to provide an optimal acoustic window to better visualize the pelvic structures, particularly if a transvaginal examination cannot be performed. Occasionally, overdistention of the bladder may compromise the evaluation. When this occurs, imaging may be repeated after partial bladder emptying. If an abnormality of the urinary bladder is detected, it should be documented and reported.

For a transvaginal sonogram, the urinary bladder is preferably empty. The patient, the sonographer, or the physician may introduce the vaginal transducer, preferably under real-time monitoring. Consideration of having a chaperone present should be in accordance with local policy [5,6].

B. Uterus

The vagina and uterus provide anatomic landmarks that can be used as reference points for the other pelvic structures, whether normal or abnormal. In examining the uterus, the following should be evaluated: (a) the uterine size, shape, and orientation; (b) the endometrium; (c) the myometrium; and (d) the cervix. The vagina may be imaged while introducing the transducer and can be as a landmark for the cervix [7,8]. If evaluation of the vaginal mucosa and rectovaginal septum are desired, instillation of 20 mL of sterile gel into the vagina with distention of the vaginal fornices may be helpful [9].
Overall uterine length is evaluated in sagittal view from the fundus to the cervix (to the external os, if it can be identified). **The length can be measured as a straight line from the fundus to the external os using outer-to-outter technique or by measuring from the fundal region along the endometrial lining and endocervical canal using outer-to-outter technique** [10]. The depth of the uterus (anteroposterior dimension) is measured in the same sagittal view from its anterior to posterior walls, perpendicular to the length. The maximum width is measured in the transverse or coronal view. If volume measurements of the uterine corpus are performed, the cervical component should be excluded from the uterine length measurement.

Abnormalities of the uterus should be documented [11-13]. The myometrium and cervix should be evaluated for contour changes, echogenicity, masses, and cysts as well as symmetry between anterior and posterior myometrium. Fixed retroflexion of the uterus, particularly in the presence of posterior adenomyosis, should be recognized as a possible indicator of deeply infiltrating endometriosis (DIE) in the posterior cul-de-sac [14]. **Size and location of clinically relevant lesions should be documented.** Masses that may require follow-up or intervention should be measured in at least two dimensions, acknowledging that it is not usually necessary to measure all uterine fibroids. **Size and location of clinically relevant fibroids should be documented.**

The endometrium should be analyzed for thickness, focal abnormality, echogenicity, and the presence and characteristics of fluid or masses in the cavity. The thickest part of the endometrium should be measured perpendicular to its longitudinal plane in the anteroposterior diameter from echogenic to echogenic border, using outer-to-outter technique [10] (see Figure 1). The adjacent hypoechoic myometrium and fluid in the cavity should be excluded (see Figure 2). **In reproductive-aged postmenarchal patients, assessment of the endometrium should allow for variations expected with phases of the menstrual cycle and with hormonal supplementation** [13,15,16]. It should be reported if the endometrium is not adequately seen in its entirety or is ill-defined; **in this circumstance, measurement should not be included in the report.** Sonohysterography may be a useful adjunct to evaluate the patient with AUB or to further clarify an abnormally thickened endometrium **and to further evaluate an incompletely visualized endometrium.** (See the ACR–ACOG–AIUM–SRU Practice Parameter for the Performance of Sonohysterography [17]). If the patient has an intrauterine contraceptive device IUD, its location should be documented.
Figure 1. Measurement of endometrial thickness.

The endometrial thickness measured in its thickest portion from echogenic to echogenic border (calipers) perpendicular to the midline longitudinal plane of the uterus.

Figure 2. Measurement of endometrium with fluid in cavity.
In the presence of endometrial fluid, the measurement of the two separate layers of the endometrium (calipers), excluding the fluid, are added to determine the endometrial thickness.

The addition of 3-D to 2-D ultrasound (transabdominal, transvaginal, transperineal, and/or transrectal) can be helpful in many circumstances, including, but not limited to, evaluating the relationship of masses to the endometrial cavity, identifying uterine congenital anomalies and thickened and/or heterogenous endometrium, and evaluating the location and orientation of an IUD and the integrity of the pelvic floor [14,18-25].

C. Adnexa Including Ovaries and Fallopian Tubes

When evaluating the adnexa, an attempt should be made to identify the ovaries first because they can serve as a major point of reference for assessing the presence of adnexal pathology. Ovarian size may be determined by measuring the ovary in three dimensions (width, length, and depth longitudinal, transverse, and anteroposterior diameters) on views obtained in two orthogonal planes [26,27] with calculation of ovarian volume as necessary. Any ovarian abnormalities should be documented [28-33].

The ovaries may not be identifiable in some females. This occurs most frequently prior to puberty and after menopause when the ovaries are smaller and/or follicles are not consistently present to serve as a landmark [34], or in the presence of a large leiomyomatous uterus. The adnexal region should be surveyed for abnormalities, particularly masses and dilated tubular structures.

If an adnexal abnormality is noted, its relationship to the ovaries and uterus should be assessed. The size and sonographic characteristics of adnexal masses should be documented. The addition of 3-D to 2-D ultrasound can be helpful to differentiate ovarian multiseptated cysts from hydosalpinges. Additionally, the use of the "slide-by" technique can demonstrate the presence of absence of mobility of the adnexal structures [35]. Abnormal ovarian location, such as in the posterior cul-de-sac with adhesion, particularly to the uterus, pelvic side wall, or contralateral ovary, should be documented as this may indicate endometriosis, or other sources of adhesions, or displacement of the ovary in the setting of ovarian torsion. Documentation should include whether the mass is cystic or solid, and, if cystic, simple or complex. A detailed description of complex cysts should be provided, including presence or absence of septations (thick or thin), solid components, mural nodules, excrescences or papillations, and vascular characteristics if appropriate. If sonographic characteristics are suggestive of a specific diagnosis, such as hemorrhagic cyst, endometrioma, mature teratoma, hydrosalpinx, or pedunculated fibroid, this information should also be provided.

Spectral, color, and/or power Doppler ultrasound may be useful to evaluate the vascular characteristics of pelvic lesions [36-39].

D. Cul-de-Sac

The cul-de-sac and bowel posterior to the uterus may not be clearly defined. This area should be evaluated for the presence of free fluid, loculated fluid, or mass. If a mass is detected, its size, position, shape, sonographic characteristics, and relationship to the ovaries and uterus should be documented. Differentiation of normal loops of bowel from a mass may be difficult if only a transabdominal examination is performed. A transvaginal examination may be helpful to distinguish a suspected mass from fluid and feces within the normal rectosigmoid colon. The rectosigmoid colon wall may be imaged from the posterior vaginal fornix [40]. Special attention to the posterior cul-de-sac should be made in women with pelvic pain, fixed retroflexion of the uterus, sonographic evidence of posterior adenomyosis and in those with known or clinically suspected endometriosis [14,40]. Hypoechoic masses with tapering ends in the rectosigmoid wall may be seen in DIE [40,41]. The presence of adhesions in the cul-de-sac may be inferred in the absence of a normal uterine sliding sign [40,42] during dynamic imaging.
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. Cine clips may be useful. 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, anatomic landmark, 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 [43].

VII. EQUIPMENT SPECIFICATIONS

The sonographic examination of the female pelvis should be conducted with a real-time scanner, preferably using sector, curved linear, and/or endovaginal endocavitary transducers. The transducer or scanner should be adjusted to operate at the highest clinically frequency appropriate for the clinical circumstance, realizing that there is a trade-off between resolution and beam penetration [5].

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:

All probes transducers should be cleaned after use. Vaginal Any transducer probes in contact with mucosa should be covered by a protective sheath prior to use insertion. Following the examination, the sheath should be disposed of and the probe transducer cleaned with high-level disinfectant in an antimicrobial solution. The type of solution and amount of time method of high-level disinfection for cleaning may depend on manufacturer’s specifications and infectious disease 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [44].

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Guidelines 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 the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the ACOG, the AIUM, the SPR, and the SRU.
Collaborative Committee
Members represent their societies in the initial and final revision of this practice parameter.

ACR
Marcela Bohm-Velez, MD, FACR, Chair
Safwan Safar Halabi, MD
Jamie Hui MD
Pallavi Sagar, MD
Scott Young, MD

ACOG
Wendy R. Brewster, MD, PhD
Bethany Skinner, MD

AIUM
Reem Abu-Rustum, MD
Beryl Benacerraf, MD
Bryann Bromley, MD
Steven Goldstein, MD

SPR
Harris L. Cohen, MD
Cicero T. Silva, MD

SRU
Kirsteen Burton, MD, PhD
Lori Mankowski Gettle, MD, MBA

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)
Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)
Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACR

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Amy Kotsenas, MD, FACR, Chair
Aradhana Venkatesan, MD, Co-Chair
Richard A. Barth, MD, FACR
Jacqueline A. Bello, MD, FACR
Beryl Benacerraf, MD
Genevieve Bennett, MD

Lori Mankowski Gettle, MD, MBA
Steven Goldstein, MD
Safwan Safar Halabi, MD
Jamie Hui, MD
Mary S. Newell, MD, FACR
Beverley Newman, MB, BCh, BSc, FACR

PRACTICE PARAMETER
Pelvic Ultrasound
2019 Resolution No. 27
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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.

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Revised 2014 (Resolution 23)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 28

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of Neurosonography in Neonates and Infants

Sponsored By: ACR Council Steering Committee

PRACTICE PARAMETER

ACR–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF NEUROSONOGRAPHY IN NEONATES AND INFANTS

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, ___ N.W.2d ___ (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

Neurosonography

2019 Resolution No. 28
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, 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 for Pediatric Radiology (SPR), 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 four organizations and are addressed by each separately.

This practice parameter has been developed to assist physicians and sonographers performing sonographic studies of the brain in neonates and infants. For the purpose of this practice parameter, infants are defined primarily as those in whom the anterior fontanelle remains open. Neurosonography should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information. In some cases, additional or specialized examinations may be necessary. Although it is not possible to detect every abnormality, adherence to the following practice parameter will maximize the detection of most abnormalities of the brain in neonates and infants that can be imaged with ultrasound.

II. INDICATIONS/CONTRAINDICATIONS

Indications for neurosonography in preterm or term neonates and infants include, but are not limited to, evaluation for the following entities:

- Abnormal increase in head circumference
- Evaluation for Hemorrhage or parenchymal abnormalities in preterm and term infants [1-7]
- Evaluation for Ventriculomegaly (hydrocephalus) [1-5]
- Evaluation for the presence of Vascular abnormalities [2-5,8-10]
- Evaluation for possible or Suspected hypoxic ischemic injury (hypoxic ischemic encephalopathy) [2-5,11-15]
- Evaluation and follow-up of Patients on hypothermia, extracorporeal membrane oxygenation (ECMO), and other support machines [16]
- Evaluation for the presence of Congenital malformations [2-5]
- Evaluation of Signs or symptoms of central nervous system disorder (eg, seizures, facial malformations, macrocephaly, microcephaly, intrauterine growth restriction (IUGR)) [2-5,17]
- Evaluation of Congenital or acquired brain infection [2-5]
- Evaluation of Suspected or known head trauma, eg, complications of fall, cephalohematoma, or subgaleal hematoma including fracture, subdural hematoma, and/or subarachnoid hemorrhage [2-5,18,19]
- Craniostenosis [20,21]
- Follow-up or surveillance of previously documented abnormalities, including prenatal abnormalities [2-5]
- Screening prior to surgery. Surgical procedures

There are no contraindications to neurosonography.
III. QUALIFICATIONS 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 [22].

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 neurosonography 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). 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

(See also section VII, Equipment Specifications)

Standard Imaging Examination of the Neonate and Infant [2-5,23]

Any prior imaging should be reviewed prior to sonographic evaluation if available.

The coronal view, by convention, should have the patient’s right side on the left side of the image. Representative coronal views should be obtained by sweeping through the entire brain, from anterior to posterior, using the anterior fontanelle as a sonic window. Coronal views should include the following, sequentially:

- Frontal lobes anterior to the frontal horns of the lateral ventricles with orbits visualized deep to the skull base.
- Frontal horns or bodies of lateral ventricles and interhemispheric fissure.
- Lateral ventricles at level of lateral and third ventricles
  - Include lateral ventricles at the level of the foramina of Monro (outlining the course of the choroid plexus from the lateral into the third ventricle), interhemispheric fissure, cingulate sulcus (if developed), corpus callosum, septum pellucidum or cavum septi pellucidi, caudate nuclei, putamina, globi pallidi, and Sylvian fissures. The foramina of Monro should also be depicted, outlining the course of the choroid plexus from the lateral into the third ventricle
- Lateral ventricles slightly posterior to the foramina of Monro, the point at which the lateral and third ventricles communicate. Include pons and medulla, thalami, and choroid plexus in the roof of the third ventricle and in the caudothalamic grooves.
- Level of quadrigeminal plate cistern and cerebellum. Include cerebellar vermis and cisterna magna posteriorly and inferiorly, bodies of lateral ventricles bordered by caudate nuclei and thalami, and temporal horns.
• Echogenic glomi of choroid plexuses at posterior aspect of the lateral ventricles at level of trigones. Include splenium of corpus callosum at divergence of lateral ventricle and periventricular white matter lateral to posterior horns of lateral ventricles.
• Posterior to occipital horns. Include parietal and occipital lobes and posterior interhemispheric fissure.
• Extra-axial fluid spaces as needed: use high-frequency linear (≥9 mHz) transducers to obtain coronal magnification view of extra-axial fluid space, including only peripheral brain structures (superior sagittal sinus at level of frontal horns; measure sinocortical distance, craniocortical distance, and width of interhemispheric fissure) [24]. Color Doppler evaluation of the bridging veins may be performed on this view to help differentiate between subarachnoid hemorrhage and subdural hemorrhage.

The transducer may be tilted from side to side to image as much of the superficial peripheral surfaces of the cerebral hemispheres as possible. The appropriate frequency of the transducer should be selected to ensure that the superficial and deep structures are well depicted. In some larger term or older infants, more than one transducer frequency may be needed for optimal evaluation of the supra- and infratentorial structures. High-frequency linear transducers may be utilized for additional detail of abnormalities as needed.

The sagittal view, by convention, should place the anterior aspect of the brain on the left side of the image. The right side, or left side, and midline should be clearly annotated. Sequential representative sagittal views are obtained with appropriate degrees of left and right transducer angulation because the frontal horns are somewhat more medial than are the bodies of the lateral ventricles. For the midline view, the transducer should be held in a straight sagittal plane parallel to the midline of the brain. These views should include the following:

• Right and left parasagittal to demonstrate the insula
• Right and left parasagittal to demonstrate the Sylvian fissure
• Right parasagittal to image the deep white matter (periventricular regions)
• Right and left parasagittal views of lateral ventricles including caudothalamic groove
• Right and left parasagittal views of lateral ventricles, showing choroid plexus
• Additional parasagittal views to include all parts of lateral ventricles
• Midline sagittal views to include the corpus callosum, cavum septi pellucidi, and cavum vergae, if present; third and fourth ventricles; aqueduct of Sylvius; brainstem; cerebellar vermis; cisterna magna; and sulci, if present. The branches of the anterior cerebral artery (pericallosal artery and callosomarginal artery) may be visualized as needed.
• Midline anterior cerebral artery pulsed Doppler assessment of resistive index, as needed [25], especially for infants with suspected hypoxic ischemic encephalopathy.
• Superior sagittal sinus with color Doppler, as needed

The mastoid view is primarily used to visualize the cerebellum and may be obtained from both the right and left mastoid fontanels as needed. On an anterior axial image at the level of the brainstem, the third ventricle, cerebral peduncles, thalamus, and basilar cisterns can also be demonstrated. A more posterior axial image shows the fourth ventricle, posterior vermis and folia of the cerebellar hemispheres, tentorium, and cisterna magna [18-19]. Additional views, if necessary, may be taken through the posterior fontanelle, or mastoid fontanelle, the foramen magnum any open suture, burr hole, craniotomy defect, or thin areas of the temporal and parietal bones [26]. The trans temporal approach may also be used to visualize the circle of Willis and its major branches. The foramen magnum approach may be used to evaluate the brain stem and upper cervical spine, particularly in infants with known or suspected Chiari 1 or 2 malformations.

Posterior fontanelle, axial, and sagittal views may be used, as necessary, to clarify abnormalities suspected in the occipital areas, posterior horns of the lateral ventricles, and cerebellum [26]. For patients with ventricular shunt tubes, additional oblique views via the anterior fontanelle and/or axial views may should be obtained when a shunt tube and its tip are not visualized on routine scans.
When clinically indicated, spectral, color, and/or power Doppler may be useful to evaluate vascular structures through a fontanelle or a transcranial approach. Color or power Doppler may be useful in cases of suspected sinus venous thrombosis [27,28]. Spectral Doppler may be useful in patients with hydrocephalus and hypoxic ischemic brain injury [28].

When there is concern for craniosynostosis, additional imaging may be performed with a high-resolution linear transducer held perpendicular to the expected course of the coronal, sagittal, lambdoid, and metopic sutures [21].

Video clips may be obtained for better demonstration of questionable abnormalities, as needed [29].

VI. DOCUMENTATION

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 should 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 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.

VII. EQUIPMENT SPECIFICATIONS

Neurosonographic examinations should be conducted with sector or curved and/or linear transducers that can fit within and image through the anterior fontanelle with the appropriate settings determined by the depth of penetrability [2-5]. Linear transducers are useful in evaluating superficial structures, such as the skull or scalp, such as the superior sagittal sinus. If the anterior fontanelle is not available, imaging may be performed through available sutural openings or by using a transcranial approach via the thinner squamosal portion of the temporal bone. This approach may require a lower frequency transducer in order to penetrate through the bone. The transducer should be adjusted to operate at the highest clinically appropriate frequency, realizing that there is a trade-off between resolution and beam penetration. Higher frequencies are used in premature babies, neonates, and young infants, and lower frequencies are used in older infants and babies.

Doppler power output should be as low as reasonably achievable (ALARA) to answer the diagnostic question.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).
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 Guidelines 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 the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the AIUM, the SPR, and the SRU.

Collaborative Committee

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

ACR
Henrietta Kotlus Rosenberg, MD, FACR, Chair
Carol Barnewolt, MD
Richard Bellah, MD
Tara M. Catanzano, MD, BCh
Brian Coley, MD, FACR
Safwan Halabi, MD
Terry Levin, MD, FACR

AIUM
Lynn Fordham, MD
Rob Goodman, MD
Usha Nagaraj, MD

SPR
Judy Ann Estroff, MD
Tara L. Holm, MD
Brooke S. Lampl, DO

SRU
Sherwin S. Chan, MD, PhD
Judy H. Squires, MD

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Committee on Practice Parameters – Pediatric Radiology
Safwan S. Halabi, MD  Richard B. Towbin, MD, FACR

Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Amy Kotsenas, MD, FACR, Chair  Rob Goodman, MD
Greg Nicola, MD, FACR, Co-Chair  Safwan Safar Halabi, MD
Carol Barnewolt, MD  Tara L. Holm, MD
Richard A. Barth, MD, FACR  Brooke S Lampl, DO
Richard Bellah, MD  Paul A Larson, MD, FACR
Jacqueline A. Bello, MD, FACR  Terry Levin, MD, FACR
Bryann Bromley, MD  Usha Nagaraj, MD
Tara M. Catanzano, MD, BCh  Mary S. Newell, MD, FACR
Sherwin S. Chan, MD  Beverley Newman, MB, BCh, BSc, FACR
Beverly G. Coleman, MD, FACR  Ms. Marsha Neumyer
Brian Coley, MD, FACR  Matthew S. Pollack, MD, FACR
Dr. Asim Choudri  Henrietta K. Rosenberg, MD, FACR
Sammy Chu, MD  Dr. Erin Rowe
Dr. Harris Cohen  Sheila Sheth, MD, FACR
Dr. Jorge Lee Diaz  Dr. Cicero Silva
Richard Duszak, Jr., MD, FACR  Judy Hereford Squires, MD
Judy Ann Estroff, MD  Timothy L. Swan, MD, FACR
Lynn Fordham, MD

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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RESOLUTION NO. 29

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of Peripheral Venous Ultrasound Examination

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 33)*

ACR–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF PERIPHERAL VENOUS ULTRASOUND EXAMINATION

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, ___ N.W.2d ___, (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

Peripheral Venous Ultrasound

2019 Resolution No. 29
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 for Pediatric Radiology (SPR), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, physician qualifications Written Request for the Examination, procedure Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education quality control vary among the organizations and are addressed by each separately.

This document is intended to assist practitioners performing noninvasive ultrasound evaluation of peripheral veins venous structures. The pediatric population may require targeted evaluations depending on the clinical situation. Occasionally, an additional and/or specialized examination may be necessary. For the pediatric patient, the examination may be tailored according to the size of the patient and the specific clinical question asked. Although it is not possible to detect every abnormality, adherence to the following practice parameter will maximize the probability of detecting most of the abnormalities that occur in the veins of the extremities.

II. INDICATIONS FOR PERIPHERAL VENOUS EXAMINATIONS

The indications for peripheral venous ultrasound examinations include, but are not limited to, the following [1-4]:

1. Evaluation of possible venous thromboembolic disease or venous obstruction in symptomatic or high-risk asymptomatic individuals. Evaluation for suspected deep venous thrombosis (DVT) or venous obstruction based on clinical assessment, a risk score based on the clinical prediction rules, (eg, the Wells score), and/or D-dimer levels. This includes patients with intermediate or high risk (likelihood) based on pretest probability, low-risk (likelihood) patients with a positive D-dimer test, patients with positive D-dimer tests, and patients whose pretest probability for DVT has not been evaluated.

2. Serial evaluation for DVT may be necessary in some high-risk individuals (eg, based on history, pretest probability, and/or D-dimer test or persistent or worsening symptoms) whose initial examination is negative for DVT [5].

3. Evaluation of patients with iliofemoral thrombus or occlusion, or with asymmetric iliofemoral Doppler waveforms [6].

4. Assessment of venous insufficiency, reflux, or varicosities

5. Postprocedural assessment of venous ablation or other interventions.

6. Assessment of dialysis access

7. Venous mapping prior to surgical procedures (see also the ACR–AIUM–SRU Practice Parameter for the Performance of Ultrasound Vascular Mapping for Preoperative Planning of Dialysis Access [7])

8. Evaluation of veins prior to venous access

9. Evaluation of suspected or known vascular anomaly

10. Follow-up for patients with known venous thrombosis at or near the anticipated end of anticoagulation to determine if residual venous thrombosis is present. Repeat ultrasound at or near the end of
anticoagulation is recommended to establish a new baseline and to determine if scarring is present [1,8].

10. Follow-up of patients with known calf (distal) DVT who are not being treated but are being monitored for progression [5]. If calf DVT is being followed and not treated, the first follow-up examination is usually at 5 to 7 days [9].

11. Follow-up of patients with limited lower-extremity evaluations when either the calf veins or portions of the thigh veins could not be imaged. In general, follow-up should be done within 5 to 7 days [10,11].

12. Follow-up of patients with suspected recurrent DVT and with equivocal findings. In general, follow-up should be done within 3 days and if still equivocal repeated at 7 to 10 days [12].

13. Follow-up of patients with known venous thrombosis on therapy and who undergo a clinical change and where a change in thrombus burden in the response will alter treatment [13].

14. To help determine the source of a known pulmonary embolism

15. High-risk asymptomatic patients may undergo screening if the benefit of screening is warranted.

A limited study to assess the patency of the upper-extremity veins to be used for catheter placement may be performed, especially in the setting of a documented upper-extremity DVT. If thrombus is discovered, then a full examination should be performed unless otherwise requested by the clinician.

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 a peripheral venous ultrasound examination 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

V. SPECIFICATIONS OF THE EXAMINATION

The requesting health care provider should be encouraged to provide the pretest probability of acute DVT and/or the results of D-dimer assay, if known [3,15,16].

Note: The words proximal and distal refer to the relative distance from the attached end of the limb per Gray’s Anatomy. For example, the proximal femoral vein is closer to the hip, and the distal femoral vein is closer to the
knee. The longitudinal or long axis is parallel to or along the length of the vein. Transverse or short axis is perpendicular to the long axis of the vein. Compression can be documented using cine clips or without and with compression images. “It is the consensus of the ACR’s Economics Committee on Coding and Nomenclature and the ACR’s Economics Committee of the Commission on Ultrasound that duplex codes should only be used when grayscale and both spectral and color Doppler are performed” [17].

A. Venous Thromboembolic Disease: Lower Extremity

1. Technique:

   a. The evaluation is from the inguinal ligament to the ankle.
      This represents a change from prior guidelines [1]. The major reasons for the change are: (1) a single, comprehensive protocol avoids errors identifying those who need scanning to the ankle and those who do not, (2) a single ultrasound to the ankle excludes DVT safely without the need for a serial examination in most patients, (3) the examination to the calf may explain symptoms in patients where cases of calf DVT or other abnormalities are detected. The study to the ankle will detect more calf DVT recognizing that treatment for calf DVT is not entirely established. There are benefits to detecting DVT regardless of whether calf DVT is followed with serial ultrasound or treated [18-22].

   b. Compression ultrasound: Venous compression is applied every 2 cm or less in the transverse (short axis) plane with adequate pressure on the skin to completely obliterate the normal vein lumen. The fullest visualized visible extent of the common femoral, femoral (formerly known as the superficial femoral [23]), and popliteal, and posterior tibial and peroneal veins must be imaged scanned using optimal grayscale compression technique. The popliteal vein is examined distally to the tibioperoneal trunk. The proximal deep femoral and proximal great saphenous vein should also be examined at the confluence with the femoral vein. The great saphenous vein is examined at the sapheno-femoral junction. Venous compression is applied every 2 cm or less in the transverse (short axis) plane with adequate pressure on the skin to completely obliterate the normal vein lumen.

   c. Focal symptoms will generally require evaluation of those areas, such as, for example, gastrocnemius or soleal veins. Focal symptom evaluation is especially important if the standard sonographic examination did not confirm the presence of DVT. Patients with calf vein DVT, with DVT involving one of duplicated veins, or with superficial thrombophlebitis may present with tenderness or pain rather than swelling, and such cases of venous thrombus may be detected by these scans.

   d. All studies, unilateral or bilateral, should include At a minimum (even if the examination is otherwise unilateral), right and left common femoral or right and left external iliac venous spectral Doppler waveforms. should be recorded to Recordings should evaluate for asymmetry and/or loss of respiratory phasicity [24]. Both sides should be assessed with similar patient posture and similar respiration so symmetry can be assessed. A Popliteal venous spectral Doppler waveforms of the symptomatic leg should also be obtained. All spectral Doppler should be obtained from the long axis. Routine spectral Doppler distal augmentation is not necessary to diagnose DVT [25].

   e. Color or spectral Doppler evaluation can be used to support the presence or absence of an abnormality [26]. Color Doppler using distal augmentation can be helpful to identify vessels and to distinguish complete versus incomplete occlusion.
2. Recordings

a. For normal examinations, images or cine loops are recorded at selected sites to represent a subset of the images seen during the more comprehensive scanning at a minimum:

i. Grayscale images (or cine loops) should be recorded without and with compression at each of the following levels, at a minimum:
   a. Common femoral vein
   b. Junction Confluence of the common femoral vein with the great saphenous vein
   c. Proximal Deep femoral vein at the confluence with the femoral vein separately or along with the proximal femoral vein
   d. Proximal Femoral vein at the upper thigh.
   e. Distal Femoral vein at the midthigh
   f. Popliteal Femoral vein at the distal thigh
   g. Popliteal vein
   h. Representative without and with compression images (or cine loops) of posterior tibial and peroneal veins with both veins on the images or as separate images for each vein

ii. Color and spectral Doppler waveforms from the long axis should be recorded at each of the following levels, at a minimum:
   a. Right common femoral or external iliac vein
   b. Left common femoral or external iliac vein
   c. Popliteal vein on the symptomatic side, or on both sides if the examination is bilateral

b. Abnormal symptoms or findings generally require additional images to document the complete extent of the abnormalities.
   i. Symptomatic areas such as the calf generally require additional evaluation and additional images if the cause of the symptoms is not readily elucidated by the standard examination.
   ii. The extent and location of sites where the veins fail to compress completely should be clearly recorded and generally require additional images. Long-axis views without compression and color/power Doppler may be helpful to characterize the abnormal findings vein.
   iii. Symptomatic areas such as in the calf and thigh generally require additional evaluation and additional images if the cause of the symptoms is not readily clarified elucidated by the standard examination.

iii. The patient presentation, clinical indication, or clinical management pathways may require protocol adjustments (eg, such as more detailed evaluation of the superficial venous system), evaluation of the deep calf veins, or a bilateral study [27-29].

d. Other vascular and nonvascular abnormalities, if found, should be recorded but may require additional imaging for diagnosis or further characterization. Anatomical variations, such as duplications, should be noted.

B. Venous Insufficiency: Lower Extremity

1. Technique

a. When evaluating for venous insufficiency, the location and duration of reversed blood flow should be determined during the performance of—Reflux is evaluated as documented by spectral Doppler waveforms showing baseline and response to accepted provocative maneuvers [30,31]. Abnormal reflux time should be reported [32]. Measurement units must be consistent and can be expressed
in units of either milliseconds or seconds. For competent veins, the report can state: “There is no abnormal reflux” without or with reporting the actual normal reflux time.

b. Duplex interrogation should be performed at as many levels as necessary to ensure a complete examination based on the clinical indications and a standard protocol \[31,33-35\]. Veins in the superficial and deep system should be evaluated for reflux.

c. Augmentation with squeezing of the calf musculature should generally be used. Valsalva may be used at the groin; however, augmentation of flow with calf compression should generally be used. A rapid cuff inflator inflation system may also be used.

d. The patient should be standing positioned in the erect position for the detection or exclusion of reflux. A minimum of 45° reverse Trendelenburg position can be used if erect scanning the standing examination is not feasible possible. The examined leg should be in a non-weight-bearing position. A sitting position can be used for evaluating the superficial and perforating veins of the calf. The patient should not be studied for reflux in the less than 45° supine position.

e. All spectral Doppler waveforms and measurements should be obtained from the long axis.

2. Recording

a. Recordings should document the presence, absence, and location of reflux. Varicosities and abnormal perforating veins should generally also be documented. At a minimum, abnormal reflux times should be measured and reported.

b. Recording of the transverse diameter of the vein size of vessels must be performed. may be helpful for clinical management

c. Visible varicosities should be documented, and their connection to larger veins should be reported.

d. Anatomical variations, such as hypoplastic or aplastic segments, significant accessory veins, or duplications should be noted.

e. The patient presentation, clinical indication, or clinical management pathways may require protocol adjustments, such as more detailed evaluation of perforating veins, the deep venous system, or a bilateral study.

f. Other vascular and nonvascular abnormalities, for example chronic postthrombotic changes or obstruction of the deep veins, should be commented upon if found and should be recorded but may require additional imaging for diagnosis or further characterization.

3. Interpretation

a. A single negative ultrasound from the thigh to the ankle generally excludes acute DVT. A more limited study generally requires follow-up in one week or further evaluation \[1\].

b. Abnormal findings include acute DVT, chronic postthrombotic change, and indeterminate (equivocal) results. Indeterminate studies generally need other confirmatory tests or follow-up. Follow-up may be as short as 1 to 3 days and up to a week based on findings, symptoms, or risk factors.
c. A negative study is usually accurate to exclude femoropopliteal DVT but less accurate to exclude calf DVT. The report may state this: "No DVT in the femoropopliteal veins. No DVT in visible portions of the calf veins."

d. Technically compromised studies do occur, most commonly at the calf veins and femoral vein in Hunter's canal [26,36,37]. Difficult body habitus is a major cause of technically compromised studies. In such circumstances, the study can at times be improved by positioning the patient in a reversed Trendelenburg (improving venous distention), using a lower-frequency transducer, and by use of color Doppler, possibly with augmentation, to evaluate for filling defects. Minor issues, such as inability to visualize a less than 3-cm segment in an otherwise normal study is unlikely to be significant. In such circumstances, normal color flow and normal spectral waveform can help exclude DVT, whereas abnormal Doppler should raise clinical suspicion. More compromised studies may require additional evaluation such as D-dimer or follow-up imaging.

e. Follow-up after an initially negative study may be warranted (1). Persistent or worsening symptoms, high-risk groups, and those with concern for iliocaval DVT may require further evaluation.

f. Follow-up after a positive study may be warranted. Calf vein DVT that is not treated may be followed weekly, generally up to two weeks, to exclude extension. Acute DVT on treatment does not need short-term follow-up unless change will affect management.

g. Abnormalities in superficial veins and the findings of nonvascular abnormalities should be mentioned in the report. If a specific diagnosis cannot be made, additional evaluation/imaging may be recommended.

C. Venous Thromboembolic Disease: Upper Extremity [38-40]

1. Technique

Upper-extremity duplex evaluation consists of grayscale, and color, and spectral Doppler assessment of all the accessible portions of the internal jugular, subclavian, axillary, and brachiocephalic (innominate) veins as well as compression grayscale ultrasound of the brachial, basilic, cephalic, internal jugular, and axillary veins in the upper arm to the elbow. All accessible veins should be scanned using optimal grayscale and Doppler techniques as well as appropriate positioning. Venous compression is applied to accessible veins in the transverse plane with adequate pressure on the skin to completely obliterate the normal vein lumen. Supine position, if possible, is preferred. Symmetrical posture to prevent false asymmetry, if possible, is preferred.

Symptomatic areas, such as the forearm, may require additional evaluation if the cause of the symptoms is not already clarified elucidated by the standard examination.

2. Recording

a. For each normal examination, at a minimum:
i. Grayscale images or cine loops should be recorded without and with compression at each of the following levels:
   a. Internal jugular vein
   b. Peripheral subclavian vein
   c. Brachial vein in the upper arm
   d. Cephalic vein in the upper arm
   e. Basilic vein in the upper arm
   f. Focal symptomatic areas, if present

ii. Color and spectral Doppler images should be recorded at each of the following levels using appropriate color technique to demonstrate filling of the normal venous lumen:
   a. Internal jugular vein
   b. Subclavian vein
   c. Axillary vein
   d. If seen, the innominate brachiocephalic vein, brachial vein, cephalic vein, and basilic vein should be recorded with color Doppler.

iii. All studies, unilateral or bilateral, should include At a minimum (even if the examination is otherwise unilateral), the right and left subclavian venous spectral Doppler waveforms should be recorded to evaluate for asymmetry or loss of cardiovascular pulsatility and respiratory phasicity.

iv. All spectral Doppler should be obtained from the long axis.
   a. Right subclavian vein
   b. Left subclavian vein (from same location in the vein and in same patient position as the right one)

b. Abnormal examinations generally require additional images. The extent and location of sites where the veins fail to compress or fill with color completely should be clearly recorded and generally require additional images. Long-axis views without compression may be helpful to characterize the abnormal vein.

c. The patient presentation, clinical indication, or clinical management pathways may require protocol adjustments, such as imaging the forearm veins or performing a bilateral study [27-29].

d. Other vascular and nonvascular abnormalities, if found, should be recorded, but may require additional imaging for diagnosis or further characterization.

D. Vein Mapping

Mapping of superficial leg or arm veins is performed to determine the patency, size, condition (such as calcification or thickening), and course of superficial veins to be used for vein grafts. If found, duplications and anatomic anomalies should be noted. The location of the vein may be marked on the skin overlying the veins. Tourniquets or other methods to accentuate the veins may be used based on the clinical indication (eg, mapping prior to hemodialysis grafts or fistulas).

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 [41].

VII. EQUIPMENT SPECIFICATIONS

Equipment must be capable of duplex imaging: both real-time imaging with compression of the veins and Doppler evaluation of the blood flow signals originating from within the lumen of the veins. Imaging should be conducted at the highest clinically appropriate frequency, realizing that there is a trade-off between resolution and beam penetration. This should usually be at a frequency of 5 MHz or greater, with the occasional need for a lower frequency transducer. In most cases, a linear or curved linear transducer is preferable, but sector scanners can be helpful for difficult patients or for the medial subclavian or innominate brachiocephalic veins. Evaluation of the blood flow signals originating from within the lumen of the vein should be conducted with a carrier frequency of 2.5 MHz or above. A display of the relative amplitude and direction of moving blood should be available.

Imaging and blood flow analysis are currently performed with duplex sonography using range gating. Color Doppler can be used to facilitate the examination.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [42].

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

Collaborative Committee

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

ACR
Laurence Needleman, MD, FACR, Chair

AIUM
Joseph F. Polak, MD
NOT FOR PUBLICATION, QUOTATION, OR CITATION

Gail N. Morgan, MD, FACP
Sheila Sheth, MD, FACP

Margarita V. Revzin, MD

SPR
Rachelle Goldfisher, MD
Cicero T. Silva, MD

John S. Pellerito, MD
Michelle L. Robbin, MD

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACP, Chair
Marcela Böhm-Velez, MD, FACP
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD
Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACP
Jason M. Wagner, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACP, Chair
Timothy J. Carmody, MD, FACP
Tara M. Catanzano, MD, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD
Terri L. Levin, MD, FACP
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACP

Beverly G. Coleman, MD, FACP, Chair, Commission on Ultrasound
Richard A. Barth, MD, FACP, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACP, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACP, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACP, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Johnson Lightfoote, MD, FACP – Chair
Aradhana Venkatesan, MD – Co-Chair
Richard A. Barth, MD, FACP
Jacqueline A. Bello, MD, FACP
George Berdejo, MD
Beverly G. Coleman, MD, FACP
M. Robert DeJong, RDMS, RVT
Richard Duszak, Jr., MD, FACP
Rachelle Goldfisher, MD
Gail N. Morgan, MD
Laurence Needleman, MD, FACP
Marsha Neumyer, BS, RVT, FSVU, FSDMS, FAIUM
Mary S. Newell, MD, FACP
Beverley Newman, MB, BCh, BSc, FACP
John S. Pellerito, MD
Joseph F. Polak, MD
Matthew S. Pollack, MD, FACP
Margarita V. Revzin, MD
Michelle Robbin, MD
Sheila Sheth, MD, FACP
Cicero T. Silva, MD
Timothy L. Swan, MD, FACP

PRACTICE PARAMETER
Peripheral Venous Ultrasound
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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.

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RESOLUTION NO. 30

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SRU Practice Parameter for the Performance of Peripheral Arterial Ultrasound using Color and Spectral Doppler

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–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF PERIPHERAL ARTERIAL ULTRASOUND USING COLOR AND SPECTRAL DOPPLER

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, ___ N.W.2d ___ (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.
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 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 noninvasive evaluation of the peripheral arteries using color and spectral Doppler waveform analysis ultrasound. The sonographic examination of patients with peripheral vascular disease will, in general, complement the use of other physiologic tests, such as pressure measurements, pulse volume plethysmographic recordings, and continuous wave Doppler. In selected cases a tailored examination is used to answer a specific diagnostic question. 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 extremity arteries.

II. INDICATIONS FOR PERIPHERAL ARTERIAL EXAMINATIONS

The indications for peripheral arterial ultrasound examination include, but are not limited to, the following:

1. The detection of stenoses or occlusions in segment(s) of the peripheral arteries in symptomatic patients with suspected arterial occlusive disease. These patients could present with recognized clinical indicators, such as claudication, rest pain, ischemic tissue loss, aneurysm, or arterial embolization [1-18].

2. The monitoring of sites of previous surgical interventions, including sites of previous bypass surgery with either synthetic or autologous vein grafts [19-25]

3. The monitoring of sites of various percutaneous interventions, including angioplasty, thrombolysis/thrombectomy, atherectomy, or stent placement [22,26-30]

4. Follow-up for progression of previously identified disease, such as documented stenosis in an artery that has not undergone intervention, aneurysms, atherosclerosis, or other occlusive diseases

5. The evaluation of suspected vascular and perivascular abnormalities, including such entities as arteritis, fibromuscular dysplasia, masses, aneurysms, pseudoaneurysms, arterial dissections, vascular injuries, arteriovenous fistulae, thromboses, emboli, or vascular malformations [31-36]

6. Mapping of arteries prior to surgical interventions [37-41]
7. Clarifying or confirming the presence of significant arterial abnormalities identified by other imaging modalities

8. Evaluation of arterial integrity in the setting of trauma

9. Evaluation of patients suspected of thoracic outlet syndrome, such as those with positional numbness, pain, tingling, or a cold hand

10. Allen’s test to establish patency of palmar arch [42,43]

11. Temporal artery evaluation for to rule out temporal arteritis and/or to localize temporal arterial biopsy for suspected diagnosis of temporal arteritis [32,33]

Additional uses of Doppler ultrasound can include preoperative mapping for dialysis access and postoperative follow-up (see the ACR–AIUM–SRU Practice Parameter for the Performance of Ultrasound Vascular Mapping for Preoperative Planning of Dialysis Access [44] and the ACR–AIUM Practice Parameter for the Performance of Vascular Ultrasound for Postoperative Assessment of Dialysis Access) [45].

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 [46].

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 a peripheral arterial ultrasound examination 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). 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 sonographic examination consists of grayscale/color Doppler imaging and spectral Doppler waveforms in the appropriate arterial segments. Color Doppler should be used to improve detection of arterial lesions by identifying visual narrowing and changes in color seen in stenoses and to guide placement of the sample volume for spectral Doppler assessment [10].
A. Appropriate Techniques and Diagnostic Criteria

Specific sonographic techniques must be tailored to the clinical indication, the different arterial segments studied, and the specific pathology being evaluated. Diagnostic criteria for stenosis differ between native and postoperative and postprocedural arteries.

Velocity measurements are obtained from angle-corrected longitudinal spectral Doppler waveforms obtained from longitudinal images. Every attempt should be made to acquire images where the angle created by the direction of blood flow and the direction of the ultrasound beam is kept at \( \leq 60 \) degrees. Velocity estimates made from images using larger angles are less reliable.

For spectral Doppler, velocity ratio, absolute velocity, pulsatility indices and acceleration time have published criteria. One or more criteria may be used. The criteria may be validated for some but not all arterial segments (eg, acceleration time has been studied in the iliac and common femoral arteries). Waveform shape, presence or absence of turbulence and direction of flow may be used for appropriate indications.

For arterial stenoses, color Doppler should be optimized to detect narrowing of the lumen and high velocity (typically seen as aliasing) in the stenotic region.

B. Arterial Occlusive Disease (Peripheral Arterial Disease)

Physiologic tests of the arterial system such as ankle brachial index (ABI), segmental pressure, continuous wave Doppler and plethysmographic waveform analysis are frequently the initial examinations performed to determine the presence of arterial disease and to identify patients appropriate for imaging [1,36,47]. These studies are complementary and not equivalent to the sonographic examination.

The ABI may help evaluate the hemodynamic consequences of lower extremity arterial disease. A contemporaneous ABI, along with imaging, is complementary and supports the imaging findings or may suggest non visualized disease, or if discrepant, helps avoid pitfalls.

Representative longitudinal color Doppler and/or gray scale images along with angle-corrected spectral Doppler waveforms with velocity measurements should be documented for each normal arterial segment(s).

Suspected abnormalities should be documented with longitudinal gray scale and color Doppler images. Transverse images may be helpful. Documentation of flow abnormality can be performed by obtaining cine clips.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images proximal to, at, and distal to sites of suspected stenosis. The sonographer/technologist should evaluate the vessel thoroughly throughout the stenosis to determine the highest peak systolic velocity (PSV). The highest PSV within the abnormal segment should be compared to the normal segments.

The highest angle-corrected peak systolic velocity in a stenosis should be recorded from a longitudinal image. A spectral Doppler waveform with velocity measurements should be recorded in the normal arterial segment 1 to 4 cm proximal (upstream) to a suspected stenosis. A waveform distal to a stenosis should be recorded since it is helpful to document a drop in velocity beyond the stenosis and poststenotic disturbed flow/turbulence. Distal abnormalities, as well as a poststenotic tardus parvus waveform, are signs of hemodynamic significance. If present, collateral branches should be recorded and documented including direction of flow within the reconstituted artery.
The location of any diseased or occluded segment(s) should also be documented. Estimated lengths of diseased or occluded segments may be helpful.

Gray scale, color and spectral Doppler An evaluation of the following arterial segments should generally be performed as indicated below. The accessible portion of the entire vessel or the arterial segment(s) of interest should be evaluated.

1. Lower extremity
   a. Common femoral artery
   b. Proximal deep femoral artery
   c. Proximal superficial femoral artery
   d. Mid superficial femoral artery
   e. Distal superficial femoral artery/popliteal artery above the knee
   f. Popliteal artery PSVs above and below the knee

If clinically appropriate, gray scale, color and spectral Doppler imaging of the common and external iliac, deep femoral tibioperoneal trunk, anterior tibial, posterior tibial, peroneal, and dorsalis pedis arteries should be performed.

Evaluating multiple sites in an artery may be needed to adequately evaluate the vessel.

However, a focused or limited examination may be appropriate in certain clinical situations.

2. Upper extremity
   a. Subclavian artery
   b. Axillary artery
   c. Brachial artery

If clinically appropriate, gray scale, color and spectral Doppler imaging of the innominate, radial, and ulnar arteries and the palmar arch should be performed.

However a focused or limited examination may be appropriate in certain clinical situations.

Representative longitudinal color Doppler and/or grayscale images along with angle-corrected spectral Doppler waveforms with velocity measurements should be documented for each normal arterial segment(s). Suspected abnormalities should be documented with longitudinal grayscale and color Doppler images. Transverse images may be helpful.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images proximal to, at, and distal to sites of suspected stenosis. The sonographer/technologist should evaluate the vessel thoroughly throughout the stenosis to determine the highest peak systolic velocity. The highest peak systolic velocity in a stenosis should be recorded from an angle corrected longitudinal spectral Doppler image. A spectral Doppler waveform with velocity measurements should be recorded in the normal arterial segment 1 to 4 cm proximal (upstream) to a suspected stenosis. A waveform distal to a stenosis should be recorded since it is helpful to document a drop in velocity beyond the stenosis and poststenotic disturbed flow/turbulence. Distal abnormalities, as well as a poststenotic tardus parvus waveform, are signs of hemodynamic significance.

The location of any diseased or occluded segment(s) should also be documented. Estimated lengths of diseased or occluded segments may be helpful.
C. Evaluation of Surgical and Percutaneous Interventions

1. Bypass grafts

An attempt should be made to scan the full length of any arterial bypass graft using gray scale and color Doppler whenever possible with color Doppler.

Representative longitudinal color Doppler and/or gray scale images should be documented for normal segments.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images.

Angle-corrected spectral Doppler waveforms and peak systolic velocity measurements should be documented in the native artery proximal to the graft anastomosis, at the proximal anastomosis, at representative sites along the graft, at the distal anastomosis, and in the native artery distal to the anastomosis.

Suspected abnormalities should also be imaged with longitudinal gray scale ultrasound. Representative longitudinal color and/or gray scale images of stenoses should be documented. Transverse images may be helpful.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images proximal to, at, and distal to sites of suspected stenosis. The sonographer/technologist should evaluate the graft conduit and the contiguous segments of the native arteries thoroughly throughout the stenosis to determine the highest peak systolic velocity.

The highest angle-corrected peak systolic velocity in a stenosis should be recorded from an angle-corrected longitudinal spectral Doppler image. A spectral Doppler waveform with velocity measurements should be recorded in the normal arterial segment 1 to 4 cm proximal (upstream) to a suspected stenosis. A waveform distal to a stenosis should be recorded since it is helpful to document a drop in velocity beyond the stenosis and poststenotic disturbed flow/turbulence and/or tardus parvus waveform. Distal abnormalities, as well as a poststenotic tardus parvus waveform, are signs of hemodynamic significance. The presence of low PSVs and low-resistance waveforms within an otherwise normal graft should be noted as this can imply an increased risk of graft occlusion.

2. Endovascular interventions

An attempt should be made to sample the site of arterial interventions as well as the segment immediately proximal (upstream) and distal (downstream) to the site of intervention. Stents should generally be scanned longitudinally along their entire length by gray scale and color Doppler, and representative images within the stent should be obtained. Transverse images may be helpful to document stent distortion or luminal narrowing by the outside plaque.

Representative longitudinal color Doppler and/or gray scale images should be documented.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images. All velocity measurements must be obtained from a longitudinal image.

Angle-corrected spectral Doppler waveforms obtained from a longitudinal image and peak systolic velocity measurements should be documented in the native artery proximal to the intervention, at representative sites within an area of intervention (eg. proximal stent, mid stent, distal stent) interventional site, and in the native artery distal to the intervention.
Suspected abnormalities should also be scanned imaged with longitudinal gray scale ultrasound. Representative longitudinal color and/or gray scale images of stenoses should be documented. Transverse images may be helpful.

Angle-corrected spectral Doppler waveforms should be obtained from longitudinal images proximal to, at, and distal to sites of suspected stenosis. The sonographer/technologist should evaluate the vessel thoroughly throughout the stenosis to determine the highest peak systolic velocity.

The highest angle-corrected peak systolic velocity in a stenosis should be recorded from an angle-corrected longitudinal spectral Doppler image. A spectral Doppler waveform with peak systolic velocity measurements should be recorded in the normal arterial segment 1 to 4 cm proximal (upstream) to a suspected stenosis. A waveform distal to a stenosis should be recorded since it is helpful to document a drop in velocity beyond the stenosis and poststenotic disturbed flow/turbulence and/or tardus-parvus waveform. Distal abnormalities, as well as a poststenotic tardus parvus waveform, are signs of hemodynamic significance.

D. Other

1. Suspected soft-tissue abnormalities in proximity to arteries
   The entire area of a suspected soft-tissue abnormality should be imaged. If appropriate Spectral and color Doppler should may be performed to document determine the presence and nature of presence or absence of blood flow in the region of the suspected abnormality.

2. Pseudoaneurysms
   In evaluating patients with suspected pseudoaneurysms, the sonographer/technologist should evaluate vasculature and adjacent soft tissues in transverse and longitudinal planes, using color Doppler, at, above, and below the arterial puncture site since the vessel may have been punctured at or several centimeters away from the skin wound. For example, for evaluation of the groin area, Doppler interrogation should be performed from the distal external iliac artery to the proximal superficial femoral artery. Generally, scan at and on either side of the site of trauma/puncture since the vessel may have been punctured at or several centimeters from the skin wound. Imaging in the longitudinal plane must also be obtained with representative color and spectral Doppler.

   Hematomas should be differentiated from pseudoaneurysms with appropriate technique to detect flow, thereby avoiding false positive results. Hematomas, if present, should be documented.

   When a pseudoaneurysm is identified, the overall size of the pseudoaneurysm sac, the size of the residual lumen (in cases of partially thrombosed PSA), and the length and width of the communicating channel (neck) should be documented with appropriate gray scale and color Doppler techniques. Spectral Doppler waveforms should be obtained in the communicating channel to demonstrate “to-and-fro” flow.

   In case of therapeutic intervention, color and/or spectral Doppler may be used as a guide to therapy and as a means of documenting therapeutic success [36,48-52].

   When present, the size and location of hematomas should be documented.

   The presence of hematomas should be documented and differentiated from pseudoaneurysms with appropriate technique and Doppler image optimization to demonstrate absence of flow to detect thereby avoiding false positive results. Hematomas, if present, hematomas should be documented.
3. Abnormal communication between artery and vein (arterio-venous fistula (AVF))

Color and spectral Doppler may be used to document the location of abnormal vascular communications. Spectral Doppler waveforms should be documented from the artery proximal to, in the area of, and distal to abnormal communications. Flow within the fistula should be recorded, if found. A spectral Doppler waveform from the draining vein should be documented above and below the fistula.

Color Doppler is particularly useful for identifying the level of such communications because the flow disturbances in a fistula often create color Doppler signals in the adjacent soft tissue from transmitted vibrations and pressure changes (color bruit).

4. Peripheral aneurysms

The location of aneurysms should be documented. The widest diameter of the artery or aneurysm should be measured (outer wall to outer wall) on gray scale images in short a plane perpendicular to the long-axis of the lumen. If present, patency of the vessel and the presence of intraluminal thrombus should be documented with gray scale and color and spectral Doppler images.

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 [53].

VII. EQUIPMENT SPECIFICATIONS

Peripheral arterial sonography should be performed with a real-time scanner with a linear array or curved array transducer equipped with pulsed Doppler and color Doppler capability. (Power or energy Doppler may be used if needed.) A linear array transducer helps visualize vessels with better resolution than most curved array transducers is preferred if it allows for adequate penetration. The transducer should operate at the highest clinically appropriate frequency, recognizing that there is a trade-off between resolution and penetration. This should usually be at a frequency of 3.5 MHz or greater, with the occasional need for a lower frequency transducer. Evaluation of the flow signals originating from within the lumen of the vessel should be conducted with a carrier frequency of 2.5 MHz or greater.

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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [54].

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Collaborative Committee

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

ACR
Laurence Needleman, MD, FACR
John S. Pellerito, MD
Jason M. Wagner, MD

AIUM
John Blebea, MD
M. Robert DeJong, RDCS, RDMS, RVT
Gowthaman Gunabushanam, MD

SRU
Jill A. Jones, MD

Committee on Practice Parameters – Ultrasound

(ACR Committee responsible for sponsoring the draft through the process)
Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Daihya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters & Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Madeleine Lewis, MD, Chair
Mark Alson, MD, FACR, Co-Chair
John Blebea, MD
Jacqueline A. Bello, MD, FACR
George Berdejo, MD
Harris L. Cohen, MD
M. Robert DeJong, RDCS, RDMS, RVT
Beverly G. Coleman, MD, FACR
Richard Duszak, Jr., MD, FACR

Laurence Needleman, MD, FACR
Mary S. Newell, MD, FACR
Marsha Neumyer, RDMS
Harriet Paltiel, MD
John S. Pellerito, MD
Joseph Polak, MD, MPH
Matthew S. Pollack, MD, FACR
Margarita Revzin, MD, MS, FSRU
Sheila Sheth, MD, FACR

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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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NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 31

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–AIUM–SRU Practice Parameter for the Performance of Vascular Ultrasound for Postoperative Assessment of Hemodialysis Access

Sponsored By: ACR Council Steering Committee

he 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 24)*

ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF VASCULAR ULTRASOUND FOR POSTOPERATIVE ASSESSMENT OF HEMODIALYSIS ACCESS

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, ___ N.W.2d ___ (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

Postoperative Dialysis Access

2019 Resolution No. 31
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 3 organizations and are addressed by each separately.

As the number of patients with kidney failure requiring hemodialysis each year exceeds 660,000 patients, initial creation and maintenance of a functional hemodialysis access is an important increasingly critical health care concern [1]. To improve the care of hemodialysis patients, the National Kidney Foundation established the Kidney Disease Outcomes Quality Initiative (KDOQI) in 2000 and updated it in 2006 [2-4]. The project set recommendations for placement and monitoring of hemodialysis accesses. Although there have been no hemodialysis access monitoring updates from KDOQI since 2006, additional information on the subject has been published, indicating that there has been a movement toward earlier and more frequent hemodialysis in patients with chronic kidney disease (CKD), which in turn has resulted in more complications requiring an estimated 68% increase in interventions to repair accesses [5].

The failure rate of hemodialysis access in the first year is high [6]. In 5.1% of patients, early thrombosis occurs within 18 days of arteriovenous fistula (AVF) creation and is associated with small arterial diameter, forearm location, small draining vein diameter, protamine use, female gender, surgeon frustration/concern during access creation procedure, and reduced or absent thrill at surgery [7]. After fistula maturation and use, subsequent failure is frequently associated with thrombosis secondary to underlying focal stenosis, most commonly at the anastomosis. Clinical monitoring of AVF access function is recommended to detect deterioration in function of the access before thrombosis occurs [8-10]. However, in arteriovenous grafts (AVGs), an occult stenosis may be present in a significant number of patients with normal findings on clinical evaluation [11,12]. In one study the reported sensitivity of clinical examination for venous anastomotic stenosis in AVGs was only 36% to 57% [13,14]. In patients who have abnormal flow volumes, salvage procedures or surgical revision may lengthen the life of the access, but there is conflicting data in the literature [15-18]. In a data analysis of 40,132 CMS beneficiaries, the benefits of percutaneous intervention were greatest in patients with new-access or low-access flow rates [6]. Differences in flow parameters within an arteriovenous fistula AVF versus an graft AVG must be considered, as there are different diagnostic Doppler criteria for stenosis diagnostic criteria are associated with these two access types. This practice parameter is intended to help physicians in the performance of hemodialysis access monitoring evaluation by ultrasound, to ensure a high-quality diagnostic examination and to promote further understanding of potential salvage options.

These practice parameters will address primarily upper-extremity hemodialysis access. Although lower extremity hemodialysis grafts have a significant role in patients without usable upper extremity access, the diagnostic Doppler diagnostic criteria for lower-extremity hemodialysis graft evaluation are less well-defined.
II. INDICATIONS/CONTRAINDICATIONS

A. Indications for hemodialysis access ultrasound include, but are not limited to, the following:

1. Patients whose vascular access is unable to deliver Hemodialysis access blood flow inadequate for dialysis, defined as flow volume 500 to 600 ml/min or patients who have interval 25% decrease in blood flow rate greater than 400 ml/min.

2. Patients who develop persistent ipsilateral upper-extremity edema or pain after access placement or during a hemodialysis session.

3. Patients with delayed maturity, prolonged immaturity (>6 weeks) of a surgically created AVF.

4. Patients suspected of having a pseudoaneurysm (PSA), AVF, or graft stenosis, perigraft soft-tissue infection, or adjacent fluid collection.

5. Patients with decreased or absent thrill or abnormal bruit over fistula hemodialysis access.

6. Follow-up after intervention revision of an immature fistula.

7. Patients with clinical signs or symptoms of vascular steal (cold fingers or hand, or other signs of distal limb hand/digit ischemia) typically during or immediately following hemodialysis but that may occur at other times.

8. Access collapse during hemodialysis.

9. Prolonged bleeding (>20 min) from access needle sites after dialysis despite local pressure.

10. Unexplained decrease in delivered dose of hemodialysis (Kt/V). Kt/V is the product of dialyzer clearance and time divided by volume of water in the patient.

11. Repeated difficult cannulation.

12. Thrombus aspiration during hemodialysis.

13. Elevated venous pressure greater than 200 mmHg on a 300 ml cc/min pump.

14. Elevated recirculation time of >15% or greater.

There are no absolute contraindications to performance of this examination, but there may be physical limitations that prevent a complete duplex Doppler examination, such as the presence of indwelling catheters, open wounds, recent surgery, pain, scar tissue or calcification especially in the regions of multiple puncture sites, severe edema, contractures, or other reasons for immobility.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [19].

IV. WRITTEN REQUEST FOR THE EXAMINATION

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

The written or electronic request for postoperative hemodialysis access ultrasound 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). 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)

V. SPECIFICATIONS OF THE EXAMINATION

The ultrasound examination for evaluating postoperative hemodialysis access is designed to detect abnormalities that may cause the access to thrombosis, poor function poorly, not be accessible for dialysis, or produce undesired undesirable upper-extremity symptoms symptomatology in the arm and to assess for causes of AVF nonmaturation.

It is important to understand the anatomic configuration of the hemodialysis access to enable accurate and complete evaluation characterization of the usability of the access. Review of clinical records can be useful if there is history of documented variant anatomy or surgery, such as failed fistulas or jump grafts.

AVFs are most commonly placed in the upper extremity, either in the forearm or upper arm. A forearm AVF directly connects an artery (usually radial) to a vein (usually cephalic) at the wrist or distal forearm to increase flow in the draining vein (forearm cephalic vein AVF). This allows This results in dilatation and wall thickening of the vein, allowing for to allow for frequent cannulation for hemodialysis. An An upper arm AVF can is typically created at the antecubital fossa and connects the brachial artery to the cephalic vein or at transposes the deeper basilic vein, which is usually transposed more anterolaterally in the upper arm for easier access and is called a basilic vein transposition fistula.

If AVF creation is not possible or not preferred, a prosthetic graft may be placed to create an AVG. A graft is a tube connecting an artery and vein that is used to provide a conduit for needle access during hemodialysis. Graft configurations may include a forearm loop graft anastomosed between the brachial artery and an antecubital vein at the antecubital fossa, an upper arm straight graft from the brachial artery at the antecubital fossa to the axillary or proximal basilic vein, or an upper arm loop graft anastomosed to the axillary artery and axillary vein.

 Regardless of Whether an examination is requested for failure to mature or dysfunction, in a previously usable hemodialysis access, the components of the sonographic study of both AVFs and grafts are similar [20,21]. Copious amounts of ultrasound gel and careful attention to apply only limited pressure from applied by the transducer will minimize deformity of the vein, which may affect measurements of the vein diameter. Evaluation of arterial inflow, venous outflow, turbulent or stenotic flow, anterior AVF vein wall depth from skin outpouching, and identification of PSAs or large accessory veins competing vein branches, and depth from the skin surface or an area of significant diameter narrowing are basic components of the of a hemodialysis access examination. Characterization of any collection/mass near the access should be performed.

Note: For anatomic localization of an abnormality in the upper-extremity venous structures, the words “cranial” and “caudal” are preferred because there is some uncertainty in the use of the terms “proximal” and “distal” with regards to the veins. Alternatively, the location of a draining vein stenosis may be described by its distance from the anastomosis. The longitudinal, or long, axis is parallel to or along the length of the vessel vein. Transverse, or short, axis is perpendicular to the long axis of the vessel vein. For When measuring the velocity describing the location in the feeding artery or draining vein to be selected to measuring the velocity that is used as the denominator in the peak velocity ratio of a stenosis, the location may be described as term “2 cm upstream” indicating the distance from the anastomosis may be used. The artery supplying the anastomosis is commonly described as the “feeding artery” or “arterial inflow.”
A. Upper-Extremity AVF Examination for Fistula Dysfunction

**Decreased blood flow in a hemodialysis fistula is a hallmark of access dysfunction.** Sonographic evaluation of an AVF seeks to detect stenosis, which may limit flow within the AVF and progress to thrombosis. The most common site of stenosis is the arteriovenous anastomosis [15,22]. The draining vein is another focus of the postoperative AVF ultrasound since it is the region that is accessed for hemodialysis, sometimes resulting in stenosis [23].

Initial evaluation to measure fistula diameter and to detect stenosis is performed with grayscale imaging. **Significant stenosis is usually defined as luminal narrowing equal to or exceeding 50% compared with the normal vascular segment (artery or vein) located upstream to the stenosis [15,24,25].** Using color and spectral Doppler in a long axis plane, the peak systolic velocity (PSV) at the anastomosis is compared with the PSV in the feeding artery 2 cm upstream from the anastomosis. A PSV ratio (anastomosis/artery 2 cm upstream) greater than 3:1 has been suggested to represent a stenosis with diameter reduction greater than 50% [26-28]. A **small study using PSV >375 cm/s for detection of AVF anastomotic stenosis >50% demonstrated sensitivity and specificity of 96% (26/27) and 76% (13/17), respectively [29].** However, the **any anastomotic stenosis may should be correlated confirmed** with grayscale imaging because there is often sharp angulation of the venous origin at the anastomosis, which may **elevate PSV, simulating a Doppler findings of stenosis [30].** It is important to note that although a stenosis is present, AVF vein blood flow may be adequate and the AVF useable for hemodialysis [31].

**Incorrect Inaccurate** Doppler angle correction and incorrect Doppler settings can also contribute to velocity measurement error [32]. The Doppler angle of insonation should be maintained at ≤60°, and the angle correction cursor should be parallel to the vessel wall. In the setting of stenosis, the resistive index (RI) measured within the inflow artery is greater than 0.5 in 84% (99/118) of patients, compared with an RI < 0.5 in 71% (10/14) of those without dysfunction [33].

In addition to the area of the anastomosis, any visible narrowing of the draining vein on grayscale imaging or area of color aliasing of flow within the vein should be further assessed with velocity measurements by spectral Doppler. The PSV at the narrowing is compared with the PSV of the vein 2 cm upstream (caudal). A draining vein PSV ratio (narrowed draining vein/vein 2 cm upstream) greater than 2:1 suggests stenosis of ≥50%, whether present in a patient with either AVF or AVG graft [21]. Alternatively, a large retrospective study of stenoses (excluding the anastomotic region) showed poor accuracy of the PSV ratio and better sensitivity (89%) for 50% stenosis using PSV < 500 cm/s. However, the location of stenosis was not described, and volume flows were not reported [34]. Doelman et al using PSV > 375 cm/s detected draining vein stenoses, including those in the cephalic vein with 91% sensitivity (31/34) and 95% specificity (71/75), respectively [29]. If there is poor draining vein flow in the absence of anastomotic stenosis, the downstream (cranial) venous system may be stenotic or thrombosed. Assessment of spectral Doppler waveforms in the ipsilateral internal jugular vein and subclavian vein can **suggest detect signs of** central stenosis, which may be further assessed with other imaging modalities. Central stenoses can be present even with high flow in an access, causing arm swelling. Note that multiple abnormalities may be present in a single dysfunctional access [35].

An AVF must have adequate arterial inflow in order to mature and function [36]. The **rate prevalence of an inflow arterial stenosis may be is much higher in dysfunctional AVFs (40%) or grafts (29%) than in functional accesses,** and more than half of all patients with inflow arterial stenosis have associated venous abnormalities [24]. Poststenotic arterial waveforms with parus and tardus characteristics should be considered abnormal in the inflow vessel (feeding artery). The failure to document velocity elevation in the presence of lumen diameter reduction **luminal narrowing on grayscale** B-mode may indicate inflow disease/stenosis or low systemic pressure. Fortunately, inflow stenosis is uncommon (5% of patients) in a newly created AVF [28,37,38].

The direction of arterial flow in the artery distal (caudal) to from the anastomosis of an AVF may be evaluated to determine if flow in the artery hand is reversed or bidirectional. **Reversal of Distal arterial flow steal is common in AVFs,** although it is usually asymptomatic and does not require intervention [39]. Symptoms of hand ischemia after AVF creation are more common in diabetics with arterial disease in the setting of previous failed AVFs [40].
Arterial steal symptoms are more common in upper arm accesses with a brachial artery anastomosis. In a large prospective series of AVF-related hand ischemia, 7% of patients with hemodialysis access AVFs had symptoms and 4% required intervention. Intervention is associated with female gender, diabetes, capacious outflow veins, and coronary artery disease [41]. Hand ischemia may occur for several reasons: inflow artery stenosis or occlusion, either in the feeding or a more proximal artery (such as the subclavian artery), outflow artery stenosis or occlusion, poor arterial collaterals, or excessive fistula flow volume. Doppler ultrasound evaluation may assist in the diagnosis of each of these etiologies [42]. Alternatively, in addition, pulse-volume recordings (PVRs) of the upper extremities with and without access compression will provide an indication of adequacy of flow and impact of the access on digital perfusion as some patients may have fixed arterial disease as a cause for their digital ischemia. Alternatively, the fistula can be manually compressed just beyond the arterial anastomosis to see if this maneuver redirects flow toward the hand and alleviates symptoms.

Other nonstenotic abnormalities, such as PSA, hematoma, and abscess, can be diagnosed by a combination of grayscale and duplex Doppler ultrasound. Color Doppler should be used to evaluate any collection adjacent to the fistula. Grayscale and color Doppler imaging can diagnose aneurysmal dilatation, which may not be detected angiographically if mural thrombus fills at least 50% of the lumen [33]. A small aneurysm in a draining vein may not require treatment if the overlying skin remains intact. However, a PSA secondary to repeated needle sticks in a graft or rarely AVF may worsen and lead to hemorrhage; it can require surgical management if >1-cm diameter, especially if it contains mural thrombus [43].

B. Evaluation of AVF for Failure to Mature

A normal AVF may take up to 3 months to fully mature and be usable for dialysis. Additionally, a large proportion (28%-60% 53%) of surgically created AVFs are do not initially adequately mature such that they become usable for hemodialysis within a typical maturation period of 6 weeks to 6 months [44-47]. The mature AVF must be easily palpable and support allow cannulation by ≥ two 17-gauge needles. Clinical determination of fistula maturity by skilled nursing was reportedly 80% accurate [48] in one study; however, palpation had 96% sensitivity in another study if a thrill was present [49]. If an adequate AVF is not clinically identified in the first 4 to 8 weeks after surgical access creation, ultrasound can be performed to assess for detect a potentially correctable anatomic problem. In a series of 153 patients with surveillance Doppler evaluation 4 to 8 weeks after access creation (but before attempted hemodialysis), ultrasound detected nine occluded fistulas. An additional 40% had significant lesions even though only 17% had an abnormal clinical examination. In this series, 70% of the AVFs that underwent secondary intervention matured, compared with 25% without intervention [50]. If the fistula is still not usable after 3 months despite interventions, it is considered as failure to mature [51]. A prospective study of 602 fistulas suggested that low blood flow and small venous diameter at 2 weeks after intervention secondary to repeated needle sticks in a graft or rarely AVF may not develop optimally at 6 weeks [48]. Follow-up evaluation of the 602 AVFs showed that measurement of AVF blood flow rate, AVF diameter, and distance of the anterior AVF vein wall from the skin was moderately predictive of AVF maturation [52]. A separate study showed increased risk of failure to mature if blood flow was <413 ml/min at 2 weeks after fistula creation [53].

The anastomosis is evaluated for stenosis using the same diagnostic criteria defined in the section above on upper-extremity AVF examination for fistula dysfunction. Again, a greater than 3:1 PSV ratio of anastomosis compared with the feeding artery 2 cm upstream should suggest anastomotic stenosis. Special attention is given to detect stenosis of the draining vein, using a 2:1 threshold ratio for stenosis at the point of narrowing relative to 2 cm upstream.

Volumetric Blood flow is measured in the midportion of the AVF draining vein where in a region of the vein that is straight and non-tapering, without turbulent flow typically around 10 cm cranial to the anastomosis [35]. The Doppler gate is adjusted to encompass the lumen of the vein with alignment of the sample volume markers perpendicular to the venous walls. The angle of Doppler insonation for blood flow calculation is standardized at 60° or less to minimize the degree of measurement error. A sequence of three to five cardiac cycles is obtained to
allow calculation of time-averaged velocities, and the average of three separate measurements is reported [17]. On follow-up examinations, blood flow should be measured in the same location.

If no stenosis is identified, thresholds for AVF vein venous diameter and blood flow and AVF depth from the skin may suggest whether the AVF is adequately mature for hemodialysis [52]. An AVF with venous diameter of at least 0.4 to 0.6 cm and blood flow of at least 500 to 600 ml/min predicts that an AVF has a high likelihood of supporting successful hemodialysis [20,35]. The lower range of values may be chosen to reduce abandonment of a fistula that may subsequently mature and recognizes the measurement error in determining measuring flow volumes. In one study, fistulas measuring >0.4 cm in diameter and with volume flow > 500 ml/min were usable for hemodialysis in 95% of patients, whereas, those measuring < 0.4 cm in diameter and with volume flow < 500 ml/min matured in only 33% of patients [20]. Another study of 125 hemodialysis fistulas and bridge grafts found that a volume flow threshold of 800 ml/min had improved accuracy for detection of access dysfunction relative to a 500 ml/min threshold [54]. Yet another study found a 0.5-cm diameter to be a better diameter threshold than 0.4 cm [49]. A draining vein that is greater than 0.5 to 0.6 cm deep to the skin surface may mature but be too deep for consistent cannulation, and the draining vein in these situations may require superficialization. Lastly, there should be at least 5 to 6 cm of straight vein to allow placement of the dialysis needles.

Venous branches are noted and documented based on size and distance from the anastomosis. In these patients, large draining venous branches (competing accessory veins) may be surgically ligated to increase flow through the main draining vein to allow AVF maturation [55]. The venous drainage to the level of the medial subclavian vein may be evaluated if not done previously on a preoperative study because downstream central venous stenosis or thrombosis may inhibit AVF maturation.

Therapy for AVF dysfunction depends upon the underlying abnormality and its location. Treatment of stenosis in the anastomotic/juxta-anastomotic region relies primarily on balloon angioplasty. Persistent dysfunction after 2 to 3 weeks following angioplasty should encourage repeat ultrasound to evaluate for a second abnormality or insufficient dilatation. If there are accessory veins associated with stenosis, they are addressed by treating the underlying stenosis first. If no stenosis is present, the accessory veins can be treated with surgical ligation, coiled during angiography, or percutaneously occluded with minimally invasive image-guided ligation. For treatment of a deep draining vein, an incision can be made to allow the vein to rise closer to the surface, or superficial lipectomy can be performed. Successful superficialization may allow hemodialysis access maturation in 3 to 6 weeks [56].

C. Upper-Extremity Examination for Graft Dysfunction

As part of a complete study, the graft should be evaluated with grayscale, color, and spectral Doppler. Graft failure that is due to thrombosis is easily diagnosed by physical examination, but ultrasound can be used. Differentiation of occlusive versus nonocclusive thrombosis can be made by color or power Doppler. In a graft, the venous anastomosis is the most common site location of stenosis. A PSV ratio (anastomosis/graft 2 cm upstream) greater than 2:1 is used as a threshold to diagnose a 50% stenosis at the venous anastomosis, and a 3:1 ratio suggests a 75% stenosis [11,21]. If there is a borderline PSV ratio suggesting stenosis, PSV > 400 cm/s or visible narrowing greater than 50% can help make the diagnosis [27]. In another study, Doelman et al used PSV > 310 cm/s to detect stenosis with a sensitivity and specificity of 95% (20/21) and 100% (10/10), respectively, at the venous anastomosis. PSV measurement at the mid graft should be obtained. Likewise, the draining vein in the limb cranial to the graft should be evaluated with color Doppler for signs of narrowing or aliasing. In regions of suspected narrowing in the draining vein of a graft, a PSV ratio (stenosis versus inflow venous segment 2 cm) should be calculated with a 2:1 threshold ratio applied for diagnosis of stenosis in a manner similar to the draining vein of an AVF. The sites of any stenoses are documented, and the length of stenosis is noted. A normal color Doppler examination is useful because it precludes the need for further imaging [57].
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The arterial anastomosis of a hemodialysis grafts has more variability in flow velocity relative to the upstream feeding artery than in a fistulas. A PSV ratio greater than 3:1 should raise concern for stenosis at the arterial anastomosis of a graft, but there is lower specificity than at other locations [21]. Using a threshold PSV > 310 cm/sec for detection of stenosis, the sensitivity and specificity has been reported to be ≤60, respectively, at the arterial anastomosis [29]. As part of a complete study, the graft should be inspected with grayscale, color, and spectral-Doppler. PSV measurement at the mid-graft should be obtained. Likewise, the draining vein in the limb cranial to the graft should be evaluated with color Doppler for signs of narrowing and/or aliasing. In regions of suspected narrowing in the draining vein of a graft, a PSV ratio should be calculated with a 2:1 threshold ratio applied for diagnosis of stenosis in a manner similar to the draining vein of an AVF. The sites of any stenoses are documented, and the length of stenosis is noted. A normal color Doppler examination is useful since it precludes the need for further imaging.

Normal blood flow volumes within grafts are commonly higher than in AVFs, but even flow rates of 500 to 1,300 ml/min have been reported with graft stenosis. Blood flow volume less than 500 ml/min should lead to a fistulogram even if no anatomic etiology for the low blood flow volume is found.

The venous outflow should be followed into the subclavian vein to assess for stenosis. The central veins of the chest can also be examined. In the absence of any other etiology for access dysfunction, the central veins of the chest should be evaluated even if they were normal at evaluation prior to graft placement, especially if there is reason to suspect central venous stenosis, such as arm swelling, shoulder collaterals, or history of prolonged or multiple subclavian or internal jugular vein catheterizations. In some patients, multiple stenoses may be present; persistent slow flow after treatment of an inflow stenosis may unmask a central abnormality. Close attention to detail is required because some central stenoses may be missed by sonographic evaluation [57].

Evaluation of the feeding artery should be performed in the same manner as done for AVF evaluation described above. Reversal of flow in the distal artery may occur and is often asymptomatic, similar to patients with AVFs.

Grafts may have disruption/degeneration of the polytetrafluoroethylene (PTFE) material, and this may be directly visible on grayscale. There may be associated hematoma adjacent to the area of disruption. If disruption of the graft material is suspected, the finding can be further evaluated by Doppler to detect PSA or graft degeneration. A patent PSA will appear anechoic with or without associated mural thrombus with swirling of flow on color Doppler and a yin-yang appearance within the sac similar to the appearance of PSAs in other parts of the body.

D. Routine Sonographic Monitoring of Functional Access

There is uncertainty, and even doubt Controversy remains in the literature as to whether or not aggressive routine monitoring and angioplasty of a hemodialysis access, especially in a graft, can prevent predict or affect subsequent thrombosis and significantly extend patency and longevity or cumulative patency [6,58-67]. A recent Cochrane analysis suggests that correction of surveillance-detected stenosis in absence of access dysfunction does not extend access longevity but may have promise in fistulas by reducing hospitalizations and catheter use [68]. Accordingly, recent “ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological testing Part II: Testing for Venous Disease and Evaluation of Hemodialysis Access: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force” guidelines suggest that routine surveillance is rarely appropriate for the asymptomatic functioning of hemodialysis AVF or AVG [69].

VI. DOCUMENTATION

Each organization addresses this requirement individually. 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 [70].

VII. EQUIPMENT SPECIFICATIONS

The sonographic evaluation of the peripheral veins and arteries should include both real-time imaging of the vessels and their contents and evaluation of the flow signals originating from within the lumen using grayscale as well as color and spectral Doppler with careful attention to the anastomoses and any area of perceived narrowing/stenosis or intraluminal echoes/thrombus of the veins. Grayscale imaging of the anastomosis is critical as color Doppler may obscure thrombus synchiae or overwrite focal narrowing, resulting in either overestimation or underestimation of stenosis. Real-time imaging should be conducted at the highest clinically appropriate frequency, realizing that there is a trade-off between resolution and beam penetration. This should usually be at a frequency of 7 MHz or greater, with the occasional need for a lower frequency transducer, such as during insonation of the central veins. To determine flow rates, higher resolution transducers are needed, preferably 9 to 15 MHz. In most cases, a linear or curved linear transducer is preferable to obtain optimal adequate images.

The flow signals originating from within the lumen of the vessels should be evaluated with a Doppler frequency of 2.5 MHz or above. A display of the relative amplitude and direction of moving blood should be available.

Imaging and flow analysis are currently performed with duplex sonography using range gating in the center of the vessel and angle correction with a Doppler angle < 60°. Color Doppler is used to detect aliasing that is indicative of stenosis and to facilitate the examination. Color and spectral Doppler are also useful for evaluation of PSA or nonocclusive thrombus. Appropriate gain and scale settings should be used. The wall filter should be chosen as appropriate for the vessel interrogated.

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

Each organization addresses this requirement individually. 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [71].

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.
Collaborative Subcommittee

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

ACR
Mark E. Lockhart, MD, MPH, Chair
Nirvikar Dahiya, MD, MBBS, FAIUM
Michelle L. Robbin, MD

AIUM
Laurence Needleman, MD, FACR
Marsha Neumyer, BS, RVT, FSVU, FSDMS, FAIUM
Victoria Teodoresca, MD, MBA

SRU
Lauren Alexander, MD
Leslie M. Scoutt, MD, FACR

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Marcela Böhmer-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACR
Jason M. Wagner, MD

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Timothy Crummy, MD, FACR – Chair
Elaine Lewis, MD, FACR – Co-Chair
Lauren Alexander, MD
Carol Barnewolt, MD
Jacqueline A. Bello, MD, FACR
George Berdejo, RVT, BA
Bryann Bromley, MD
Beverly G. Coleman, MD, FACR
Nirvikar Dahiya, MBBS
Richard Duszak, Jr., MD, FACR
Mark E. Lockhart, MD MPH
Laurence Needleman, MD, FACR

Marsha Neumyer, BS, RVT, FSVU, FSDMS, FAIUM
Mary S. Newell, MD, FACR
Beverley Newman, MB, BCh, BSc, FACR
Matthew S. Pollack, MD, FACR
Margarita Revzin, MD
Michelle L. Robbin, MD
Sheila Sheth, MD, FACR
Leslie M. Scoutt, MD, FACR
Timothy L. Swan, MD, FACR
Victoria Teodoresca, MD, MBA
Jade J Wong-You-Cheong, MD

REFERENCES


PRACTICE PARAMETER

Postoperative Dialysis Access

2019 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.

PRACTICE PARAMETER Postoperative Dialysis Access 2019 Resolution No. 31
Development Chronology for this Practice Parameter

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Revised 2014 (Resolution 24)
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RESOLUTION NO. 32

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of Duplex Sonography of Native Renal Vessels

Sponsored By: ACR Council Steering Committee

PRACTICE PARAMETER
Renal Sonography Ultrasound
2019 Resolution No. 32

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 2013 (Resolution 14)*

ACR–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF DOPPLER SONOGRAPHY OF NATIVE RENAL VESSELS NATIVE RENAL ARTERY DOPPLER SONOGRAPHY

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 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. For 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

References:
1. Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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.
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

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

Ultrasound using grayscale imaging, color Doppler imaging, and spectral Doppler analysis and color Doppler imaging (CDI) is a proven and useful procedure for evaluating the renovascular system. Occasionally, an additional and/or specialized examination 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 renovascular abnormalities.

II. INDICATIONS/CONTRAINDICATIONS

Indications for renal artery duplex sonography include, but are not limited to:

1. Evaluation of patients with hypertension particularly when there is a moderate to high strong suspicion of renovascular hypertension (for example, uncontrolled hypertension despite optimal medical therapy, hypertension with progressive decline in renal function, progressive decline in renal function associated with angiotensin-converting enzyme (ACE) inhibition therapy, abrupt onset of hypertension) [1,2]
2. Follow-up of patients with known renovascular disease who have undergone renal artery stent placement, angioplasty or surgical bypass, other renal artery intervention or who have a known unilateral stenosis with concern for a stenosis in the contralateral kidney
3. Evaluation of an abdominal or flank bruit
4. Evaluation of a suspected vascular abnormality, such as an aneurysm, pseudoaneurysm, arteriovenous malformation, or arteriovenous fistula, or following treatment of any of the above
5. Evaluation of vascular causes of renal insufficiency in a patient at risk for renovascular disease
6. Evaluation of renal perfusion artery blood flow in patients with known aortic dissection, trauma, or other abnormalities or conditions that may compromise renal blood flow to the kidneys
7. Evaluation of discrepant renal size
8. Concern for aortic or renal artery orifice thrombus thrombosis in infants who have or have had an aortic catheter, such as an umbilical artery arterioal catheter
9. Evaluation for congenital or syndromic causes of renovascular hypertension
10. Evaluation for renal vein thrombosis
11. Evaluation of the renal vein for renal tumor extension and differentiation of renal vein tumor thrombus from bland thrombus
12. Evaluation of the renal vein in patients suspected of Nutcracker syndrome
There are no absolute contraindications to performing this examination.

### III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [3].

### IV. WRITTEN REQUEST FOR THE EXAMINATION

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

The written or electronic request for renal duplex sonography 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)

### V. SPECIFICATIONS OF THE EXAMINATION

The study is generally performed for both kidneys. If not, the report should state the reason for a unilateral study (eg, evaluation of renal stent, known solitary kidney).

**Obtaining the following grayscale images and Doppler evaluation is recommended when possible:**

#### A. Renal Arteries

The study consists of grayscale imaging of the kidneys and **limited grayscale views of the aorta** with color and spectral and color Doppler of the **intrarenal and extrarenal and intrarenal vessels and suprarenal aorta**.

1. **Grayscale Imaging**

   The longest renal length should be measured and reported. In patients who have not had recent cross-sectional imaging of the kidneys, a complete renal ultrasound examination may be considered. See the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum [4]. Longitudinal and transverse views of the aorta should be obtained at the level of the kidneys and above.

2. **Color and Spectral and Color Doppler Evaluation**

   Analysis of main renal artery and intrarenal arterial waveforms should be used performed to evaluate for renal artery stenosis.
Careful attention to technique is important to ensure accurate examination results, including selecting a transducer that is appropriate for the patient’s body habitus, optimizing color Doppler parameters, using an appropriate spectral Doppler sample volume, optimizing the velocity scale for the size of the waveform to avoid aliasing (this may require adjusting the scale (pulse repetition frequency), baseline, or frequency); or selecting a lower frequency transducer; and using the lowest feasible angle of insonation. Angle correction is essential for determining blood flow velocity. The angle between the direction of flowing blood and the applied Doppler ultrasound beam signal should not exceed 60°.

a. Main renal artery and aorta evaluation

The entire main renal artery should be scanned along its long axis using optimized color Doppler parameters. Occasionally, power Doppler or grayscale imaging may be necessary to localize a portion of the artery. Inability to visualize a specific part the entire or part (especially eg, the origin) of the entire main renal artery should be reported.

Spectral Doppler should be performed along the length from the origin to the hilum at the lowest feasible angle of insonation.

Spectral Doppler waveforms should be obtained along the length of the main renal artery from the origin to the hilum at the lowest feasible angle of insonation.

The greatest At a minimum, the highest peak systolic velocities should be recorded at the origin/proximal, portion, at mid aspect, and hilar segments of the main renal artery near the hilum [5-22]. Peak systolic velocity should also be recorded at any site of color aliasing, narrowing, or suspected stenosis. If there is a significant stenosis, additional Doppler waveforms should be recorded within the stenosis and distal to the stenosis. In small children/infants, one measurement of peak systolic velocity in the main renal artery is acceptable [21].

An effort should also be made to search for accessory/duplicated renal arteries [21,23,24]. When visualized, peak systolic velocities should be recorded as described above.

An appropriate angle-corrected spectral Doppler waveform from the abdominal aorta at or slightly cephalic to the level of the origins of the renal arteries should be recorded. Aortic peak systolic velocity is used to calculate the ratio of the peak systolic velocity in the renal artery to the aorta (RAR).

Renal artery stent evaluation should include recording of peak systolic velocities in the proximal renal artery (if possible), within the stent, and distal to the stent (if possible) [25].

In infants who have developed aortic thrombus after catheterization, the relationship of the clot to the renal arterial orifices and the flow around the thrombus should be documented. If the thrombus is located near a renal artery orifice, renal arterial and intraparenchymal waveforms should be obtained waveforms should be obtained in the main and intraparenchymal renal arteries to assess renal perfusion.

b. Intrarenal evaluation

Spectral Doppler waveforms should be recorded from segmental or interlobar arteries in the upper and lower poles and in the interpolar region (mid-portion) of each kidney. It is important to use a fast sweep speed and optimize the velocity scale to ensure accurate and reproducible measurements results. If acceleration index measurements are used in assessment, angle correction is needed; the angle of insonation should be as low as possible, usually 20-30° or less.
Intrarenal analysis consists of quantitative and/or qualitative evaluation of the Doppler waveforms. Quantitative evaluation may include acceleration times, acceleration indices [26,27], or resistive indices [28-30]. For qualitative analysis, the morphology of the waveform should be assessed for a normal \textit{sharp} systolic upstroke or \textit{abnormal} tardus parvus changes [22,24,26,27]. Particularly, in children, because of motion, it may be important to document more than one spectral Doppler interrogation of a region to ensure optimal interpretation.

3. Contrast-enhanced ultrasound (CEUS)

The use of microbubble ultrasound contrast agents may be helpful in identification of the main renal artery(ies) and branches and in detection of duplicated or accessory renal arteries. Note: This would be an off-label use of CEUS based upon current FDA approval status.

B. Renal Veins

1. For routine evaluation of the renal veins (ie, in an examination not performed specifically for evaluation of suspected renal vein pathology), grayscale and color Doppler longitudinal view of the main renal vein with accompanying spectral Doppler waveform should be obtained.

2. If there is specific concern for renal vein stenosis or thrombosis, or if abnormal findings are made on routine views, then a more detailed protocol may be performed and may include the following:
   a. Grayscale Imaging: Evaluation of the main renal vein should be performed in longitudinal and transverse views. Notes should be made of any area of stenosis and/or intraluminal thrombus.
   b. Color and Spectral Doppler Evaluation: Analysis of main renal vein and intraparenchymal renal vein waveforms should be performed to evaluate for renal vein stenosis. Peak velocity should be recorded proximal to, within, and distal to the stenosis. In the presence of thrombus, color and spectral Doppler may be used to evaluate for vascularity of the thrombus and presence or absence of extension of thrombus into the inferior vena cava (IVC) should be documented.
   c. CEUS: The use of microbubble ultrasound contrast agents may be helpful in identification of main renal vein stenosis or thrombosis as well as tumor neovascularity within thrombus. Note: This would be an off-label use of CEUS based upon current FDA approval status.

VI. DOCUMENTATION

Each organization addresses this requirement individually. 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 include 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 and communication efforts should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [31].

VII. EQUIPMENT SPECIFICATIONS

Duplex and color Doppler ultrasound of the renal arteries should be performed in real time using a scanner with color and spectral Doppler capabilities. Transducer selection should be based on body habitus. For adults, mean...
frequencies between 2 and 5 MHz are most commonly used. In adults, typically used transducer frequencies range from 2 to 9 MHz. In neonates, transducer frequencies of 7 to 15 MHz are typically used.

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

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ACKNOWLEDGEMENTS

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

ACR
Nirvikar Dahiya, MBBS, Chair
Lorna P. Browne, MB, BCh
Harriet J. Paltiel, MD
Maryellen R.M. Sun, MD
Sharlene A. Teefey, MD, FACP

AIUM
Edward I. Bluth, MD, FACP
Laurence Needleman, MD, FACP
John S. Pellerito, MD, FACP

SPR
Monica Epelman, MD
Erica Riedesel, MD
Judy H. Squires, MD

SRU
Shweta Bhatt, MB, BS
Leslie M. Scoutt, MD

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACP, Chair
Marcela Böhme-Velez, MD, FACP
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Jamie Hui, MD
Stephen I. Johnson, MD
David U. Kim, MD
Harriet J. Paltiel, MD
Henrietta K. Rosenberg, MD, FACP
Jason M. Wagner, MD

PRACTICE PARAMETER

Renal Sonography Ultrasound
2019 Resolution No. 32
Committee on Practice Parameters – Pediatric Radiology  
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair  
Timothy J. Carmody, MD, FACR  
Tara M. Catanzano, MB, BCh  
Lee K. Collins, MD  
Kassa Darge, MD, PhD  
Monica S. Epelman, MD  
Dorothy L. Gilbertson-Dahdal, MD  
Safwan S. Halabi, MD  

Kerri A. Highmore, MD  
Sue C. Kaste, DO  
Terry L. Levin, MD, FACR  
Matthew P. Lungren, MD, MPH  
Helen R. Nadel, MD  
Sumit Pruthi, MBBS  
Pallavi Sagar, MD  
Richard B. Towbin, MD, FACR

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound  
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology  
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety  
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards  
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Eric Friedberg, MD, FACR, Chair  
Madeleine Lewis, MD, Co-Chair  
Richard A. Barth, MD, FACR  
Jacqueline A. Bello, MD, FACR  
Shweta Bhatt, MB, BS  
Edward J. Bluth, MD, FACR  
Lorna P. Browne, MB, BCh  
Beverly G. Coleman, MD, FACR  
Nirvikar Dahiyar, MBBS  
Kassa Darge, MD, PhD  
Richard Duszak, Jr., MD, FACR  
Monica Epelman, MD  
Laurence Needleman, MD, FACR

Ms. Marsha Neumyer  
Mary S. Newell, MD, FACR  
Beverley Newman, MB, BCh, BSc, FACR  
Harriet J. Paltiel, MD  
John S. Pellerito, MD, FACR  
Matthew S. Pollack, MD, FACR  
Erica Riedesel, MD  
Leslie M. Scrott, MD  
Sheila Sheth, MD, FACR  
Judy H. Squires, MD  
Maryellen R.M. Sun, MD  
Timothy L. Swan, MD, FACR  
Sharlene A. Tefey, MD, FACR

REFERENCES


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Development Chronology for this Practice Parameter
2008 (Resolution 9)
Revised 2013 (Resolution 14)
Amended 2014 (Resolution 39)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AIUM–SPR–SRU Practice Parameter for the Performance of an Ultrasound Examination of Solid Organ Transplants

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–AIUM–SPR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF AN ULTRASOUND EXAMINATION OF SOLID ORGAN TRANSPLANTS

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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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 for Pediatric Radiology (SPR), 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 organizations and are addressed by each separately.

This practice parameter has been developed to assist practitioners performing ultrasound studies of solid organ transplants (liver, kidney, or pancreas). Sonography is a proven and useful procedure for the evaluation of transplanted solid organs. Although it is not possible to detect every abnormality of a transplanted organ using ultrasound examination, adherence to the following practice parameter will maximize the probability of detecting abnormalities. Because of the differences in anatomic and imaging considerations for each type of transplanted organ (liver, kidney, or pancreas), the ultrasound examination of each organ type will be approached in separate sections in the current document.

Throughout this practice parameter, references to Doppler evaluation may include spectral, color, or power Doppler individually or in any combination. Whenever a long axis view is indicated, it could be either a in the sagittal or coronal plane. Both long axis and transverse views may be obtained with oblique transducer orientation to obtain long-axis and short-axis views of the relative to the organ being evaluated being insonated. The performance of any ultrasound examination is subject to limitations of acoustic window and/or penetration, and therefore it is understood that it may not be feasible or possible to obtain specific images or measurements suggested throughout this practice parameter.

II. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

Each organization will address this section in its document.

See the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [1].

III. INDICATIONS/CONTRAINDICATIONS

Indications for an ultrasound examination of the solid organ transplant include, but are not limited to, the following:

A. Liver transplant
   1. Performance of a screening ultrasound to establish a baseline following transplantation as per hospital surveillance protocol [2,3]
   2. Evaluation for vascular patency and for suspected thrombosis or stenosis [4]
   3. Evaluation for possible fluid collection or assessment of drainage catheter output
4. Assessment of the biliary tree for dilation, stricture, biloma, or abscess
5. Assessment of the transplant in the setting of abnormal liver function tests [4-5]
6. Evaluation for pain, fever, sepsis, or other clinical issues
7. Follow-up of abnormal findings on prior transplant ultrasound
8. Evaluation for recurrent malignancy or posttransplant lymphoproliferative disorder [5-9]
9. Evaluation for cirrhosis or recurrent underlying liver disease
10. Re-evaluation of the liver transplant and vasculature after final abdominal wall closure
11. Evaluation for iatrogenic injury or complications following biopsy of the transplanted liver

B. Renal Transplant
1. Performance of a screening ultrasound to establish a baseline following transplantation as per hospital surveillance protocol
2. Evaluation for vascular patency and for suspected thrombosis or stenosis [10]
3. Evaluation for possible fluid collection or assessment of drainage catheter output [10]
4. Evaluation for suspected hydronephrosis, hydroureter, or bladder abnormality
5. Assessment of the transplant in the setting of abnormal laboratory or clinical values (eg, elevated creatinine, low or decreased urine output).
6. Evaluation for pain, fever, sepsis, hematuria, or other clinical issues
7. Evaluation of the transplant in the setting of hypertension or bruit
8. Follow-up of abnormal findings on prior transplant ultrasound
9. Evaluation for iatrogenic injury or complications following biopsy of the transplanted kidney
10. Evaluation for recurrent malignancy or posttransplant lymphoproliferative disorder
11. Follow-up of abnormal findings on prior transplant ultrasound
3. Evaluation for pain, fever, sepsis, or abnormal laboratory or clinical values (eg, elevated creatinine, low or decreased urine output)
4. Evaluation for vascular patency
5. Assessment of hematuria or known or suspected hydronephrosis, hydroureter, or bladder abnormality
6. Evaluation for possible fluid collection or assessment of drainage catheter output
7. Evaluation of the transplant in the setting of hypertension or bruit
8. Evaluation for iatrogenic injury or complications following biopsy of a transplanted kidney
9. Evaluation for malignancy, either recurrent or post-transplant lymphoproliferative disorder

C. Pancreas Transplant
1. Performance of a screening ultrasound to establish a baseline following transplantation as per hospital surveillance protocol
2. Evaluation for vascular patency and for suspected thrombosis or stenosis
3. Evaluation for possible fluid collection or assessment of drainage catheter output
4. Assessment of the transplant in the setting of abnormal laboratory values or clinical parameters (eg, elevated blood glucose, lipase levels)
5. Assessment of the transplant in the setting of infection, pancreatitis, or other clinical issues
6. Follow-up of abnormal findings on prior transplant ultrasound
7. Evaluation for iatrogenic injury or complications following biopsy of the transplanted pancreas
8. Evaluation of response to treatment (eg, immunosuppressive therapy in the setting of rejection)
9. Assessment of graft dysfunction in patients with abnormal laboratory values or clinical parameters (eg, elevated blood glucose)
10. Evaluation for suspected stenosis or thrombosis of the vasculature.
11. Evaluation of pain at or near the surgical site
12. Evaluation of response to treatment (eg, immunosuppressive therapy in the setting of rejection)
13. Evaluation for iatrogenic injury or complications following biopsy of a transplanted pancreas
14. Assessment of the transplant in the setting of infection or pancreatitis

Ultrasound of the transplanted liver, kidney(s), or pancreas should be performed when there is a valid medical reason. There are no absolute contraindications.

IV. WRITTEN REQUEST FOR THE EXAMINATION

Each organization will address this section in its document.

The written or electronic request for an examination of the sold organ transplant 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). 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

In addition to grayscale imaging, spectral, color, and/or power Doppler are used in the evaluation of transplanted organs. Careful attention to technique is necessary to optimize the color and spectral Doppler examination. This includes using an appropriate sample volume and optimizing the spectral Doppler waveforms, which may require adjusting the settings (eg, scale, baseline, pulse repetition frequency [PRF]). When obtaining spectral Doppler measurements, the sample gate should be placed in the center of the arterial lumen, and its size should be optimized for the size of the vessel being insonated. Angle correction is needed for all velocity measurements and should be obtained using an angle of insonation of <60°. For any vessel, if no flow is identified, an attempt should be made to ensure that Doppler parameters have been optimized (eg, decrease PRF, reduce wall filter); the use of power Doppler and microvascular settings may be helpful. Spectral analysis may include measurements such as velocity, resistive index, and acceleration time. If there is difficulty identifying the transplant vasculature or perfusion, a contrast ultrasound examination may be helpful.

A. Liver

Grayscale, color Doppler, and spectral Doppler examinations of the liver transplant vasculature should be performed. Prior to the ultrasound examination, the surgical anatomy and reconstructive techniques for that particular patient should be confirmed when this information is available. Comparison with prior examinations should be made when possible.

1. Grayscale evaluation of the transplanted liver: A complete grayscale examination of the liver should be performed, including long-axis and transverse views. The liver parenchyma should be assessed for focal and/or diffuse abnormalities, and the echogenicity and echotexture of the liver should be noted. The liver
surface can be evaluated for nodularity using a high-frequency transducer. The biliary tree should be
evaluated and the caliber of the common bile duct measured when possible. The subphrenic and subhepatic
spaces should be investigated for possible fluid collections, as can the abdominal wall near the surgical
incision in patients with recent transplantation. Grayscale images of the hepatic vessels, including the
portal vein, hepatic veins, and inferior vena cava (IVC), should be obtained. In patients in whom recurrent
fibrosis is suspected, elastography may be a helpful noninvasive means of detecting and quantifying
the degree of fibrosis [11-13].

2. Doppler evaluation of the transplanted liver: The vessels that should be examined include the main hepatic
artery and right and left intrahepatic arteries, hepatic veins, IVC, main portal vein, and intrahepatic portal
veins in whole-liver transplants. The extrahepatic main hepatic artery, solitary hepatic artery,
hepatic vein, and portal vein should be evaluated in segmental or partial liver transplants. The
vascular anastomoses (hepatic arterial, portal venous, hepatic venous, and IVC) should be interrogated.

a. Hepatic arteries: The hepatic arteries should be interrogated to confirm normal flow and exclude
complications such as hepatic artery thrombosis, stenosis, pseudoaneurysm, or arteriovenous fistula.

i. Main hepatic artery: The main hepatic artery should be imaged along its length when possible. An
attempt should be made to interrogate the native artery, region of the anastomosis, and the donor
artery. Doppler evaluation should be obtained to demonstrate the presence of flow, configuration
of the vessel evaluating for redundancy, and any possible areas of color Doppler aliasing, which
may suggest turbulent or high-velocity flow. Spectral Doppler waveform morphology should be
assessed. Velocity measurements may be obtained at the anastomosis and within the native and
donor portions of the hepatic artery and at any areas of color-flow aliasing. Doppler indices
calculated from spectral Doppler waveforms obtained at these locations may include the peak
systolic velocity (PSV), the resistive index (RI = systolic velocity-diastolic velocity/systolic
velocity), and acceleration time (AT = time between end diastole and the first systolic peak) [3].

ii. Intrahepatic arteries: The presence of flow should be confirmed in the intrahepatic (right and left
hepatic) arteries. RI should be calculated from spectral Doppler waveforms obtained at these
locations. Spectral Doppler waveform morphology should be assessed visually. ATs can also be
measured if the waveform appears abnormal, as in a tardus parvus waveform [14,15].

Comparison should be made with prior examinations when possible. Although the hepatic arterial
waveform may normally change normally with time, some changes in waveform configuration,
RI, or PSV may require further evaluation [4,16-18].

If there is difficulty in confirming hepatic arterial flow on routine grayscale and Doppler
examinations, ultrasound contrast examination may be helpful in evaluating hepatic artery
thrombosis, stenosis, or hepatic artery hypoperfusion syndrome/splenic arterial steal [19-25].
Ultrasound contrast in this setting can improve flow detection in the hepatic artery and may
be helpful in other vessels as well.

b. Portal vein: The main portal vein and its right and left branches should be scanned in their entirety
including the portal vein anastomosis. Images should document the presence of flow, and direction of
flow, and any areas of possible color Doppler aliasing. Spectral Doppler evaluation should include an
assessment of the waveform as well as angle-corrected peak velocity measurements proximal, at, and
distal to the main portal vein anastomosis. If there appears to be a significant change discrepancy in
velocities within the portal vein, an anastomotic to preanastomotic velocity ratio can be performed
[26,27].

c. Hepatic veins and IVC: The type of surgical anastomosis (piggyback or side-to-side technique with
or without cavotomy versus interposition) and any preoperative anatomic variants should be
determined before scanning when possible. Color and spectral Doppler tracings should be obtained
from the right, middle, and left hepatic veins; from the IVC in whole-liver transplants; and from the
existing hepatic veins and IVC in partial-liver transplants. In the case of a piggyback or side-to-side hepatic venous anastomosis, both the recipient IVC and the piggybacked hepatic vein confluence/donor IVC segment should be interrogated. Flow should be verified and the waveform assessed for the degree of phasicity [27,28].

Comparison with any prior examinations should be made when possible. Follow-up examinations may be helpful if the initial ultrasound examination shows an abnormal waveform.

B. Renal Transplant

Grayscale, color Doppler, power Doppler, and spectral Doppler examinations of the renal transplant(s) should be performed. Prior to the ultrasound examination, the surgical anatomy should be confirmed when this information is available. Comparison with prior examinations should be made when possible.

1. Grayscale evaluation of the transplant kidney [29]. Longitudinal and transverse views should be obtained of the transplant kidney and bladder, and the longest renal length should be measured. Renal cortical echogenicity should be noted, and evaluation for focal lesions should be performed. The renal collecting system should be assessed for evidence of hydronephrosis and, if present, the level of obstruction determined. The perinephric space should be assessed for evidence of fluid collections. Transverse and longitudinal images of the urinary bladder should be obtained included. If a ureteral stent is in place, an attempt should be made to determine the proximal and distal extent of the stent [30,31]. **Visualization of a ureteral jet should be reported if it is seen** [4,16,18,32].

For patients in whom more than one transplant kidney is present and evaluation of more than one transplant is required, each component of the examination should be performed for each renal transplant. Images for each graft should be clearly labeled in such situations as appropriate (eg, “medial kidney,” “lateral kidney”).

2. Doppler evaluation of the transplant kidney [14,33-36]. Doppler evaluation of the transplanted kidney or kidneys should be performed for assessment of transplant vascularity. The vessels that should be examined include the main renal artery and vein, including anastomoses whenever possible, the adjacent external iliac artery and vein, and the intrarenal arteries of the transplanted kidney. **If the main renal transplant artery and vein are anastomosed to vessels other than the external iliac vessels, ie, the common iliac artery/vein or aorta/ IVC, these anastomoses should be specifically interrogated.**

   a. Main renal artery or arteries: The number of main renal arteries should be recorded. If more than one artery is present with separate anastomoses, each anastomosis should be similarly evaluated. Color Doppler images of the main renal artery or arteries from the transplant kidney to the anastomosis should be obtained wherever possible. Velocity measurements should be obtained at the anastomosis as well as in the proximal, mid, and distal aspects of the renal artery, and distal to the anastomosis whenever possible. At any areas of color-flow aliasing suggestive of high-velocity flow should be interrogated with spectral Doppler and velocity measurements obtained. Doppler indices should include PSV and may include AT, RI, and/or pulsatility index (PI), and/or renal artery to external or common iliac artery PSV ratio [37,38]. Occasionally the renal artery may be anastomosed to the common iliac artery or the aorta. Dual-screen or split-screen images using grayscale and color Doppler are useful to record any vessel caliber discrepancies or stenoses.

   b. Main renal vein: Color Doppler images should be obtained from the transplant renal vein throughout its course from the kidney renal hilum to the anastomosis. Spectral Doppler images should be obtained from the transplant renal vein at the anastomosis and distal to the anastomosis [27,28,32].

   c. External iliac artery and vein: Color and spectral Doppler images of the external iliac artery and vein should be obtained cephalad proximal, at, and distal to the main renal artery and main renal vein anastomoses. **If the anastomoses are to vessels other than the external iliacs, these anastomotic regions should be interrogated in a similar fashion.** Calculation of renal artery to iliac artery PSV ratio may be helpful in evaluating for renal artery stenosis [31,39].
NOT FOR PUBLICATION, QUOTATION, OR CITATION

C. Pancreas Transplant

Grayscale, color Doppler, and spectral Doppler examinations of the pancreas transplant should be performed. Prior to the ultrasound examination, the surgical anatomy should be confirmed when this information is available. Comparison with prior examinations should be made when possible. The sonographic evaluation of the transplanted pancreas may be limited by reduced acoustic windows, thereby limiting the ability to obtain which may impact the feasibility of obtaining the suggested images.

1. Grayscale evaluation of the transplanted pancreas [44-48]. Imaging of the entire pancreas transplant should be performed in transverse and longitudinal planes. The echogenicity and echotexture of the pancreatic parenchyma should be assessed. The orientation of the graft should be ascertained, and grayscale images of the arterial y-graft, arterial vasculature, and donor portal vein should be obtained to assess for evidence of intraluminal abnormalities. The pancreatic duct should be imaged assessed. The peritransplant space should be assessed for fluid collections. For patients with enteric drainage of the transplanted pancreas, evaluation of the adjacent bowel may be helpful to depict assess for areas of dilatation that such as may suggest obstruction. For patients with urinary bladder drainage of the transplanted pancreas, images of the urinary bladder should be obtained in transverse and longitudinal planes. If a pancreatic stent is in place, attempts should be made to determine the location of the proximal and distal portions of the stent.

2. Doppler evaluation of the transplanted pancreas. The structures that should be examined include the transplant arterial Y-graft, the transplant superior mesenteric artery (SMA) and splenic artery, the recipient artery (typically the common or external iliac artery), the transplant superior mesenteric vein, splenic vein, and portal vein, and the recipient vein (typically an iliac vein or superior mesenteric vein) [46].
   a. Transplant arteries: Color Doppler images should be obtained of the Y-graft from the recipient arterial anastomosis, across both limbs of the Y-graft to both the SMA and splenic arterial anastomoses. Images should be assessed for any areas of color-flow aliasing. Spectral Doppler images should be obtained within the recipient artery proximal to the Y-graft anastomosis and within the Y-graft itself, and the with assessment of waveform assessed for morphology [46,48].

Spectral Doppler images with angle correction should be obtained within the splenic artery and SMA of the transplanted pancreas and at any areas of color-flow aliasing. Doppler indices obtained at these locations should include PSV and may include RI resistive indices [46,49,50].

Color or power Doppler images of the entire pancreas transplant should be obtained to assess global vascularity of the graft. Spectral Doppler evaluation of intrarenal pancreatic arteries should be performed in the pancreatic head, body, and tail, and RI resistive indices may be calculated [39].

b. Transplant veins: Color and spectral Doppler images should be obtained of the graft splenic vein, superior mesenteric vein, and portal vein to the recipient venous anastomosis. Spectral Doppler assessment with angle correction and measurement of peak velocity may be performed within the graft portal vein, at the graft portal vein-venous anastomosis and distal to the anastomosis, and within the recipient vein [51]. Additional measurements at areas sites of color-flow aliasing may be helpful. Intraparenchymal venous flow should also be documented in the head and tail of the transplant pancreas.
VI. DOCUMENTATION

Each organization will address this section in its document.

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. The initials of the operator should be accessible on the images or electronically on PACS. 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 [52].

VII. EQUIPMENT SPECIFICATIONS

Grayscale and Doppler evaluation of the transplant parenchymal organs should be performed in real-time using a scanner with color and spectral Doppler and spectral capabilities. Transducer selection should be based on body habitus and the location of the transplant. Curvilinear and sector transducers may be used; in adults, mean frequencies between 2 and 6.9 MHz are most commonly used, whereas in children, higher frequencies may be employed. Higher frequencies may also be employed with more superficially placed renal and pancreas transplants. Linear-array transducers may be used for further anatomic detail in superficially located kidney or pancreas transplants as well as in pediatric patients.

When Doppler studies are performed, the Doppler frequency may differ from the imaging frequency. The equipment should be adjusted to operate at the highest clinically appropriate frequency, realizing that there is a trade-off between resolution and beam penetration. Image quality 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.

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

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [53].

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).

PRACTICE PARAMETER

Solid Organ Transplants
2019 Resolution No. 33
Collaborative Committee
Members represent their societies in the initial and final revision of this practice parameter.

ACR
Helena Gabriel, MD, Chair
Nirvikar Dahiya, MBBS
Stephen I. Johnson, MD
Pallavi Sagar, MD
Maryellen R.M. Sun, MD

AIUM
Sara M. O’Hara, MD
Harriet J. Paltiel, MD
Radha Persaud, RDMS, RDCS, RT

SPR
Rachelle Goldfischer, MD
Judy H. Squires, MD

SRU
Anil Chauhan, MD
Refky Nicola, MS, DO

ACR Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Marcela Böhm-Velez, MD, FACR
Kaleigh Burke, MD
Nirvikar Dahiya, MD, MBBS, FAIUM
Christopher Fung, MD
Helena Gabriel, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley G. Coleman, MD, FACR, Chair, Commission on Ultrasound
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards
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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

2014 (Resolution 25)
BE IT RESOLVED, that the American College of Radiology adopt the ACR Practice Parameter for the Performance of Whole-Breast Ultrasound for Screening and Staging

Sponsored By: ACR Council Steering Committee

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ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF WHOLE-BREAST ULTRASOUND FOR SCREENING AND STAGING

PREAMBLE

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NEW

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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 has been developed to assist practitioners performing ultrasound examination of an entire breast. When ultrasound is used in a focused manner to evaluate specific areas of clinical or imaging concern, or as guidance for interventional procedures or biopsy, relevant American College of Radiology (ACR) practice parameters (see the ACR Practice Parameter for the Performance of a Breast Ultrasound Examination and the ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures [1,2]) should be consulted.

II. INDICATIONS

Although x-ray mammography is the only imaging modality proven through randomized controlled trials to reduce breast cancer–related mortality, mammography has limitations in depicting cancers in dense fibroglandular tissue. Many states have passed legislation mandating direct notification to women regarding breast density. In addition to the masking phenomenon of dense breast tissue on mammograms, concern for dense fibroglandular tissue as an independent risk factor for breast cancer has led many practices to offer supplemental screening for dense-breasted women, often with ultrasound (US). The potential additive benefit of supplemental screening ultrasound is supported by ACRIN 6666, an American College of Radiology Imaging Network multicenter screening trial of physician-performed handheld whole-breast ultrasound combined with mammography compared with mammography alone in women with elevated risk and dense breasts. First-year results of that study were 4.2 cancers per 1,000 women screened in addition to those detected with mammography [3] but with less than 10% positive predictive value for biopsies (PPV3). Additional screening studies, both multiple and single site, initially had similar results. A report of combined results for years 2 and 3 of ACRIN 6666 showed doubling of PPV3, with an increase also of PPV3 for mammography [4]. Thus, high false-positive rates were expected to diminish after continuing experience with adjunctive screening using US and did so in one 4-year follow-up report of several Connecticut practices, where the aggregate PPVs for biopsy nearly tripled [5].

Indications for whole-breast US may include, but are not limited to:

1. Screening, as an optional adjunct to screening mammography, for:
   a. Women with a high lifetime breast cancer risk (20% or greater) who are not candidates for breast MRI or cannot easily access breast MRI;
   b. Women with heterogeneously or extremely dense breasts for whom supplemental screening options have been suggested [6,7].

2. Cancer staging, in patients newly diagnosed with breast cancer who are not candidates for breast MRI or who cannot easily access breast MRI [8,9].

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PERSONNEL

A. Physician

Physicians who supervise, perform, and/or interpret breast US examinations should be licensed medical practitioners with training and experience in breast US. These physicians should understand the appropriate indications for and the benefits and limitations of breast ultrasound as well as ultrasound technology and
instrumentation, equipment operation and calibration, and ultrasound safety. They should be knowledgeable in the anatomy, physiology, and pathology of the breast and axilla. They should be familiar with mammography and other complementary imaging modalities and capable of correlating the results of these studies with breast ultrasound findings.

Maintenance of Competence

Physicians should perform and interpret 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 of this practice parameter.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) and should include CME in ultrasonography as is appropriate to his or her practice [10].

B. Sonographer or Technologist

The sonographer or technologist performing the examination should be certified or eligible for breast ultrasound certification by a nationally recognized certifying body.

IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for a whole-breast ultrasound examination 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

A. Examinations should include permanent identification containing:

1. Facility name and location
2. Examination date
3. Patient’s first and last name
4. Identifying number and/or date of birth
5. Designation of right and/or left breast
6. Sonographer’s and/or physician’s identification number, initials, or other identifier

B. Methods and Technical Factors [7]

1. Whole-breast ultrasound can be performed with a general-purpose ultrasound machine or any of several systems designed specifically for whole-breast ultrasound. If a general-purpose machine is employed, a
linear high-frequency transducer with a center frequency of at least 12 MHz if possible should be used for breast scanning. Handheld whole-breast screening ultrasound relies on the operator to identify and capture images of any findings. Because lesion characterization by ultrasonography is highly dependent on technical factors, operators should optimize gain settings, focal zone selections, and fields-of-view when capturing images of specific findings. Please see the ACR Practice Parameter for the Performance of a Breast Ultrasound Examination [1].

2. Semiautomated whole-breast ultrasound involves adding to a general-purpose ultrasound machine of a robotic arm on which the high-frequency linear transducer is mounted. The arm guides the transducer over the breast, producing uniplanar images in sequential scan rows that are stitched together into a single continuous video for each breast. As a trained operator is needed to position the transducer for each scan and maintain appropriate pressure throughout the examination, this technique is considered semiautomated. Proprietary viewing software enables the localization of findings by using the nipple, scan row, and frame number as reference points.

3. Several manufacturers have developed or are developing dedicated automated breast ultrasound systems with special transducers and proprietary viewing applications. These scanners vary in patient positioning (supine or prone), transducer configuration, and multiplanar image reconstruction algorithms, but all have methods for imaging the entire breast and depicting it in the coronal plane. Supine automated systems cover the whole breast by obtaining at least three acquisitions in the transverse plane using wide linear or reverse curvilinear high-resolution transducers. Prone automated systems ordinarily obtain a single acquisition for each breast in the coronal plane using helical or torus-type transducers, some with the breast suspended in a water bath. Examinations are interpreted on workstations using proprietary software tools that localize and correlate findings on each of the views. A detailed description of the unique features and operational parameters of each of these devices is beyond the scope of this document.

4. Prior to beginning a whole-breast ultrasound screening examination, careful note should be taken of any clinical signs, symptoms, or previously identified abnormalities for which further imaging evaluation has been recommended. The interpreting physician should be advised of any such circumstances. If any of these exists, diagnostic examination is appropriate and should be recommended.

C. Practice Considerations

1. Except when whole-breast ultrasound is performed by the interpreting physician using a handheld high-resolution transducer, image acquisition is uncoupled from interpretation. For this reason, whole-breast ultrasound primarily is a screening examination; as outlined in section II, the exception is cancer staging for patients who cannot undergo breast MRI. If a patient who needs diagnostic breast imaging undergoes screening whole-breast ultrasound, the report should note this and include recommendation for appropriate diagnostic imaging.

2. Whole-breast ultrasound should be interpreted in the context of mammography if performed. Contemporaneous mammograms are not necessary for all patients, but recent mammographic images if any should be available to the physician interpreting whole-breast ultrasound. Older mammograms also may prove useful by confirming stability of mammographic correlates for benign-appearing sonographic findings. If whole-breast ultrasound has been performed previously, the current examination should be compared with prior studies, if available.

3. Interpretation of whole-breast ultrasound performed as a screening examination should focus on identifying any findings meriting diagnostic evaluation. Such findings may or may not be sufficiently characterized by semiautomated, automated whole-breast ultrasound, or technologist-performed handheld whole-breast ultrasound. Patients with indeterminate findings should receive an ACR Breast Imaging Reporting and Data

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4. Handheld whole-breast ultrasound negative—those not showing a lesion—should be annotated with breast side (right or left) and quadrant. Images of specific findings captured during handheld whole-breast ultrasound should be labeled with laterality, clock-face location, distance from the nipple, and transducer orientation (radial or antiradial, transverse or longitudinal, or oblique). It is preferable to use clock-face rather than quadrant notation for specific findings. Distance from the nipple should be measured from the nipple itself rather than the edge of the areola, as areolar width varies.

5. Assigning BI-RADS® assessments of Category 0 (Incomplete), Category 1 (Negative), or Category 2 (Benign) to whole-breast ultrasound screening will facilitate outcomes tracking and auditing, as these functions should be performed separately for screening and diagnostic examinations [7].

6. Patients may undergo screening whole-breast ultrasound and subsequent diagnostic breast imaging on the same date. Each examination should receive its own assessment, although a single report may be generated with an overall assessment and management recommendations for the combined examinations. Therefore, physicians performing handheld whole-breast ultrasound screening may wish to consider ending the screening examination before performing diagnostic (ie, focused) evaluation of any findings.

7. For the minority of whole-breast ultrasound studies performed in the diagnostic setting, the practice parameters for focused breast ultrasound apply. Lesions should be characterized by feature categories and descriptors as listed and exemplified in BI-RADS®. The BI-RADS® sonographic feature categories for interpreting masses include shape, orientation, margin, echo pattern, posterior acoustic features, and associated features, and special cases, such as cysts and lymph nodes [7].

8. In accordance with BI-RADS® [7,8], at least three measurements should be given for each lesion when possible. To facilitate reproducibility, lesions should be evaluated and measured in two orthogonal planes: either radial versus antiradial or transverse versus longitudinal. The longest dimension in each plane should be given, as well as a third measurement perpendicular to either of the first two. If the maximum dimension is on a plane oblique to the standard orientation used, it also should be recorded.

9. As for all radiographic imaging, interpreting physicians are responsible for assessing image quality. Facilities should have policies and protocols for remediating technically inadequate studies.

VI. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Images should be recorded in a retrievable and reviewable image storage format. Retention of the ultrasound examination images should be based on clinical need and in accordance with relevant legal and local health care facility requirements.

A whole-breast handheld ultrasound screening examination should document at minimum each of the four quadrants and the subareolar region [11]. The axilla may be included per facility practice.

An official interpretation (final report) of the ultrasound examination should be included in the patient’s medical record. It is recommended that the report include: the indication, specifically whether the examination was performed for screening or diagnostic purposes, and the areas scanned. Any findings should be described by location, applicable descriptors, and measurements, if appropriate. The use of an accepted reporting system such as BI-RADS® US is recommended.

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Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [12].

VII. EQUIPMENT SPECIFICATIONS

Breast ultrasound should be performed with a high-resolution, real-time, linear-array, broad-bandwidth transducer operating at a center frequency of at least 12 MHz, if possible, and preferably higher. Automated whole-breast ultrasound may be performed with a dedicated system that has been cleared by the food and drug administration (FDA). Focal zones should be electronically adjustable. In general, the highest frequency capable of adequate penetration to the depth of interest should be used.

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

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

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [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 Practice Parameters – Breast Imaging of the ACR Commission on Breast Imaging and the Committee on Practice Parameters – Ultrasound of the ACR Commission on Ultrasound.

Drafting Committee
Lillian K. Ivansco, MD, MPH, Chair
Catherine S. Giess, MD
Carolyn A. Haerr, MD
Beverly E. Hashimoto, MD, FACR

Ellen B. Mendelson, MD, FACP, FSBI, FSRU
Linda Moy, MD
Mary S. Newell, MD, FACP
Karla A. Sepulveda, MD

Committee on Practice Parameters – Breast Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Linda Moy, MD, Chair
Catherine S. Giess, MD, Vice-Chair
Phoebe Freer, MD
Sarah M. Friedewald, MD
Carolyn A. Haerr, MD
Lillian K. Ivansco, MD, MPH

Cindy Lee, MD
John M. Lewin, MD, FACP
Mary S. Newell, MD, FACP
Haydee Ojeda-Fournier, MD
Karla A. Sepulveda, MD
Karen S. Zheng, MD
NOT FOR PUBLICATION, QUOTATION, OR CITATION

Committee on Practice Parameters – Ultrasound
(ACR Committee responsible for sponsoring the draft through the process)

Sheila Sheth, MD, FACR, Chair
Jamie Hui, MD
Marcela Böh m-Velez, MD, FACR
Stephen I. Johnson, MD
Kaleigh Burke, MD
David U. Kim, MD
Maria A. Calvo-Garcia, MD
Harriet J. Paltiel, MD
Nirvikar Dahiy a, MD, MBBS, FAIUM
Henrietta K. Rosenberg, MD, FACR
Christopher Fung, MD
Sharlene A. Teefey, MD, FACR
Helena Gabriel, MD
Jason M. Wagner, MD
Beverly E. Hashimoto, MD, FACR

Comments Reconciliation Committee
Samir B. Patel, MD, FACR, Chair
Paul A. Larson, MD, FACR
Mark D. Alson, MD, FACR, Co-Chair
John M. Lewin, MD, FACR
Jacqueline A. Bello, MD, FACR
Ellen B. Mendelson, MD, FACR, FSBI, FSRU
Beverly G. Coleman, MD, FACR
Linda Moy, MD
Richard Duszak, Jr., MD, FACR
Mary S. Newell, MD, FACR
Kimberly N. Feigin, MD, FACR
Matthew S. Pollack, MD, FACR
Phoebe Freer, MD
Karla A. Sepulveda, MD
Catherine S. Giess, MD
Sheila Sheth, MD, FACR
Carolyn A. Haerr, MD
Dana H. Smetherman, MD, FACR
Beverly E. Hashimoto, MD, FACR
Timothy L. Swan, MD, FACR
Lillian K. Ivansco, MD, MPH
Michael J. Ulissey, MD, FACR

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
COMMISSIONS, COMMITTEES & TASK FORCES:

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

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ACR STAFF:

Director       Brian Monzon
Moderator    Helen Abernathy
Recorder     Shannon Rexrode
Assistant    Vanessa DeShane
Observer     Gloria Romanelli
RESOLUTION NO. 35

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) F. RADIATION ONCOLOGY

4. INTEGRATED MULTIDISCIPLINARY CARE OF CANCER PATIENTS


(b) L. THIRD PARTY CARRIERS AND COMPENSATION

7. COMPENSATION

The ACR strongly advises that radiology and the public are in most circumstances best served by independent practice and separate billing by radiologists in most hospitals and that radiology services should not be billed by others at rates higher than those paid to the radiologist; 1979, 1989, amended 1999, 2009 (Res. 30-f).

(c) L. THIRD PARTY CARRIERS AND COMPENSATION

10. CPT CODING IN HOSPITAL AND NON-HOSPITAL SETTINGS

The American College of Radiology will use its best efforts to promote coding systems that ensure appropriate reporting of services provided both in hospital and non-hospital settings; 1989, amended 1999, 2009 (Res. 30-g).

(d) L. THIRD PARTY CARRIERS AND COMPENSATION

17. MEDICARE FUNDING FOR RADIOLOGY PROCEDURES

The ACR will encourage Congress and the Centers for Medicare and Medicaid Services to take into account training, experience, certification, and quality assurance when funding radiology procedures performed by untrained, noncertified practitioners to ensure that Medicare patients receive the best quality radiology available for the taxpayers’ dollars.
Payment should be rendered only for those studies for which a separate official interpretation is rendered; 1989, amended 1999, 2009 (Res. 30-j)).

(e) L. THIRD PARTY CARRIERS AND COMPENSATION

23. PHYSICIAN PAYMENT

The American College of Radiology opposes the implementation of any program that may result in the rationing of the delivery of medical care.


Sponsored by: ACR Council Steering Committee
Ten Year Extension of Policy

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

Costs:

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

RESOLUTION NO. 36

BE IT RESOLVED,

that the American College of Radiology adopt the ACR–NASCI–SNMMI–SPR–STR Practice Parameter for the Performance of Cardiac Scintigraphy

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 44)*

ACR–NASCI–SNMMI–SPR–STR PRACTICE PARAMETER FOR THE PERFORMANCE OF CARDIAC 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 care1. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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

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1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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 North American Society for Cardiovascular Imaging (NASCII), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the Society for Pediatric Radiology (SPR), and the Society of Thoracic Radiology (STR).

It is intended to guide physicians performing and interpreting cardiac scintigraphy in adults and children [1,2]. Properly performed imaging with radiopharmaceuticals that localize in either the myocardium or the blood pool is a sensitive means of detecting and quantitatively assessing various conditions involving the heart. As with all other scintigraphic techniques, maximum diagnostic accuracy is achieved by correlation with clinical findings, imaging with other radiopharmaceuticals not discussed in this practice parameter, and other diagnostic tests.

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3], with particular attention paid to the prescribing and handling of radiopharmaceuticals.

The first part of this practice parameter addresses myocardial perfusion imaging, and the second part covers gated cardiac blood-pool imaging and first-pass cardiac imaging, including left-to-right shunt evaluation.

The primary goals of cardiac scintigraphy are to evaluate myocardial perfusion and/or ventricular function, to detect physiologic and anatomic abnormalities of the heart, and to stratify cardiac risk.

In addition to the performance parameters that follow, as a general rule, significant incidental findings should be identified and reported for both imaging with radiopharmaceuticals and on the CT used for attenuation correction. Because sestamibi localizes in proportion to blood flow and mitochondrial content, angiogenesis/neovascularization seen in neoplasms may result in abnormal uptake and should be reported if seen (ie, breast cancer can be incidentally detected during stress testing). Attenuation correction CT should be reviewed for incidental findings (eg, lung nodules/masses, bulky lymphadenopathy).

PART I

MYOCARDIAL PERFUSION IMAGING

II. INDICATIONS AND CONTRAINDICATIONS

Myocardial perfusion imaging encompasses single-photon emission computed tomography (SPECT) or planar techniques, stress and/or rest, gated or ungated. Indications for these examinations include, but are not limited to, the following [4]:

1. Detecting the presence, location, and extent of ischemic coronary artery disease in conjunction with stress testing
2. Evaluating the physiologic significance or sequelae of coronary artery stenosis
3. Monitoring the effects of treatment of coronary artery disease, including revascularization and medical therapy
4. Detecting myocardial infarction
5. Evaluating the viability of dysfunctional myocardium (hibernating myocardium)
6. Stratifying the risk assessment of acute coronary syndromes, including preoperative risk [5]
7. Stratifying the risk after myocardial infarction
8. Evaluating ventricular function and measuring ventricular volumes using gated images

The ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [6].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for cardiac scintigraphy 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

1. Radiopharmaceutical
   a. Technetium-99m sestamibi and Technetium-99m tetrofosmin

   Sestamibi and tetrofosmin are taken up by the myocardium proportional to the regional myocardial perfusion. Unlike thallium, very little redistribution occurs. Measurement of regional myocardial perfusion during stress and rest requires two separate intravenous injections. Imaging is usually begun starts 15 to 120 minutes after administration of the radiopharmaceutical. Numerous imaging protocols have been described (eg, 1-day rest/stress, 1-day stress first or stress only, 2-day stress/rest, and rest thallium-stress sestamibi or other dual-radiopharmaceutical techniques). The protocol chosen selection should reflect the needs of the patient and the logistics of the institution. One-day total administered activity of up to 44 mCi (1,630 MBq) of sestamibi or tetrofosmin may be used in most patients. One-day rest/stress protocols typically use a 1:3 ratio for the rest-and-stress injected activities. The stress injection should be given 1 to 2 minutes prior to cessation of exercise. Patients may require larger total administered activity based upon body habitus to obtain diagnostic image quality. In stress/rest protocols, if the stress examination is normal, the rest examination does not need to be performed [7,8]. Routine use of thallium and dual-isotope protocols, such as rest thallium-stress sestamibi, is discouraged because of the higher patient radiation exposure without significant clinical benefits.
b. Thallium-201 (thallous chloride)

Thallium-201 has significantly higher radiation exposure dose than the technetium-99m–labeled radiopharmaceuticals, and it should not be used routinely unless there are specific reasons for its use. Because of its redistribution, thallium-201 is recommended can be used when the purpose of the examination is to assess for myocardial viability; however, the use of fluorodeoxyglucose (FDG)-
positron emission tomography (PET) or cardiac magnetic resonance imaging (MRI) is preferred. Thallium is injected intravenously in administered activity of 2.0 to 4.0 mCi (74-148 MBq). For an exercise examination, radiopharmaceutical injection should occur 1 minute prior to cessation of stress. Imaging is routinely started within 10 minutes after injection. Redistribution images are obtained 3 to 4 hours after injection, with or without the additional reinjection of 1.0 mCi (37 MBq) of thallium. If reinjection of 1.0 mCi of thallium is planned prior to redistribution imaging, the administered activity used for stress imaging may be limited to 3 mCi. When assessing myocardial viability, additional information may be gained by obtaining 24-hour delayed images. Other protocols, such as rest and delayed redistribution imaging, may also give useful information about myocardial viability.

c. PET agents (13N-ammonia, or rubidium-82 Chloride)

PET perfusion agents, when equipment and radiopharmaceuticals are available, are preferred imaging agents because of their improved resolution, fast scan times, quantitative myocardial perfusion with flow reserves, and reduced patient radiation exposure compared with technetium-99 perfusion agents. The studies are generally performed with pharmacologic stress. The stress and rest rubidium-82 portions of the examination are done in rapid sequence, usually during one positioning on the gantry, whereas for 13n-ammonia, a 50-minute period of decay is necessary between the rest and stress portions of the examination. PET/CT allows for routine CT attenuation correction image sets as well as coronary calcium scoring if desired. Studies with 13n-ammonia require proximity to a cyclotron because of the short physical half-life. Rubidium-82 chloride studies require a generator system that is available commercially and must be replaced monthly. The very short physical half-life of rubidium-82 requires that the generator and the delivery system be placed adjacent to the scanner.

2. Patients

Patients should be evaluated prior to the examination for their ability to undergo physical or pharmacologic stress safely. Patients who are unable to exercise may be stressed pharmacologically. If a patient is unable to tolerate physical stress for cardiac reasons, pharmacologic stress may also be contraindicated. All patients undergoing stress should have intravenous access and should wear comfortable clothing and shoes. External attenuating objects should be removed, if possible. Patients should fast for at least 4 hours prior to exercise or pharmacologic stress. They may have sugar-free beverages prior to the redistribution phase of a thallium examination but otherwise should remain fasting and not exercise more than is absolutely necessary.

3. Stress

For SPECT myocardial perfusion imaging, stress may be performed by physical or pharmacologic means. For PET myocardial perfusion imaging, pharmacologic stress is preferred because of the short physical half-life of the tracers. Exercise is feasible with 13n-ammonia but has many practical challenges and may have adverse effects on image quality that are due to patient motion.

A brief summary of the level and method of stress and level (if exercise or dobutamine) of stress, hemodynamic measurements, electrocardiographic (ECG) findings, and symptoms should be included in the imaging report.

a. Physical

For patients who are physically able to exercise, the desired endpoint is the presence of ischemic symptoms or ECG changes, a heart rate of at least 85% of the age-predicted maximum predicted heart rate (MPHR) or a workload of at least five metabolic equivalents (METS). One hundred percent of
MPHR is calculated as 220 minus the patient’s age in years; 1 MET = amount of energy expended at rest or 3.5 mL oxygen/kg/min; carrying out activities of daily living requires 5 METS, which is achieved by walking at 1.7 mph (2.7 km/hour) up a 10% incline. The patient must be monitored closely by a physician or other qualified personnel experienced in cardiac stress testing. For further information see the ACR Nuclear Medicine and PET Accreditation Program Requirements. With development of angina, stress may be discontinued and the reason so noted. Stress is discontinued before achieving the desired workload if the patient develops angina, specific ECG changes suggestive of ischemia, certain arrhythmias, significant increase or decrease in blood pressure, or signs of hypoperfusion. The reason for premature termination should be recorded. If exercise is terminated prior to the achievement of 85% of the age-predicted MPHR because of noncardiac limitations, such as musculoskeletal, neurological, or pulmonary symptoms, abnormalities associated with coronary stenosis may be underestimated or missed. Beta-blocking and calcium channel–blocking medications often prevent the patient from achieving the desired heart rate and may reduce the sensitivity of the examination [9]. Depending on the clinical necessity or the clinical question, these medications may need to be discontinued by the patient’s physician prior to examination for a time sufficient to obviate their pharmacologic effect. Contraindications to exercise testing include high-risk acute coronary syndrome, uncontrolled acute cardiac conditions, such as arrhythmias, heart failure, myocarditis, and pericarditis, aortic dissection, severe symptomatic aortic stenosis, and acute medical illness. Alternatively, pharmacologic stress may be used.

b. Pharmacologic

The heart may be stressed using one of a variety of pharmaceutical medications, but a vasodilator stress agent (eg, dipyridamole, ie, adenosine, dipyridamole, or regadenoson) is preferred for radionuclide myocardial perfusion imaging unless a contraindication exists, in which case dobutamine should be considered. Depending on the clinical necessity or the clinical question, beta-blocking and calcium channel–blocking medications may need to be discontinued by the patient’s physician prior to examination for a time sufficient to obviate their pharmacologic effect.

i. Dipyridamole is infused intravenously in a dosage of 0.14 mg/kg/min for 4 minutes (total dosage = 0.56 mg/kg). Its duration of action is between 30 minutes and 1 hour. The radiopharmaceutical should be injected 2 to 4 minutes after the end of the dipyridamole infusion. Dipyridamole has numerous side effects, including chest pain, headache, dizziness, hypotension, nausea, flushing, and dyspnea. Severe reactions have included fatal and nonfatal myocardial infarctions and severe bronchospasm. Aminophylline (1-2 mg/kg) must be immediately available for intravenous injection and should be given to reverse significant side effects. Because all xanthines (eg, caffeine and theophylline) interfere with the pharmacologic effect of dipyridamole, they must be discontinued for 24 to 48 hours prior to the examination. Patients who have unstable angina, bronchospastic airway disease, and second-degree or third-degree atrioventricular (AV) block without a functioning pacemaker are at increased risk for complications of dipyridamole administration, and these conditions should be considered at least relative contraindications to use of the medication. As with physical stress, clinical, blood pressure, and ECG monitoring are mandatory during the dipyridamole infusion and for a period of time following the infusion.

ii. Adenosine may also be given intravenously in a dosage of 0.14 mg/kg/min over 6 minutes (3 minutes prior to injection of the radiopharmaceutical and continued for 3 minutes thereafter). Shorter infusion protocols (4-5 minutes) have been used successfully with adenosine. While using shorter infusion protocols, the radiopharmaceutical should be injected at least 2 to 2.5 minutes prior to termination of adenosine infusion. Because of the extremely short duration of the pharmacologic action of adenosine, injection of the radiopharmaceutical must occur during the adenosine infusion. Side effects are similar to those of dipyridamole but are very short-lived, often eliminating the need for aminophylline. Adenosine is vulnerable to the same interference from xanthine-containing foods, beverages, and medications as is dipyridamole, so all must be discontinued for 24 to 48 hours prior to examination. Significant bronchospastic airway disease, second- or third-degree atrioventricular block or sinus node disease without a functioning pacemaker, systolic blood pressure less than 90 mmHg, and recent (less than 48 hours) use of dipyridamole-containing
omedications are contraindications to adenosine administration. Caution should be used in patients who have had unstable angina and acute coronary syndromes in the last 2 days. Hemodynamic, ECG, and clinical monitoring must be carried out with any other form of stress.

iii. Regadenoson is an A2A adenosine receptor agonist administered as a rapid intravenous injection in a dosage of 0.4 mg over 20 seconds; there is no dosage adjustment for body weight/body mass index. Unlike other vasodilator agents, regadenoson can be used in stable bronchospastic airway disease. It should not be administered to patients with a second- or third-degree atrioventricular block or sinus node dysfunction who do not have a functioning artificial pacemaker. Systolic blood pressure less than 90 mmHg and recent (less than 48 hours) use of dipyridamole-containing medications are contraindications to regadenoson administration. Caution should be used in patients with unstable angina and acute coronary syndromes in the last 2 days and in patients with significant renal impairment.

iv. Both all three vasodilator stress agents (adenosine, dipyridamole, and adenosine regadenoson) can be combined with simultaneous low-level exercise for SPECT myocardial perfusion imaging in patients who are ambulatory to reduce the side effects of these agents, reduce to decrease subdiaphragmatic radiopharmaceutical uptake, and to improve image quality. While using dipyridamole, exercise should start after the completion of dipyridamole infusion and should last 4 to 6 minutes. While using adenosine, exercise should be simultaneous with the adenosine infusion. Its duration of effect is short (biologic half-life of approximately 2 minutes). Low-level exercise, such as the first two stages of the modified Bruce protocol, suffices. Patients who are ambulatory may also undergo low-level exercise (eg, treadmill at 1.7 mph, 0% grade) for 1.5 minutes followed by regadenoson administration, tracer injection, and an additional 2 minutes of exercise.

v. Dobutamine is infused intravenously. A number of protocols are available. One involves the graduated infusion of increasing amounts of dobutamine over time, beginning with 5 to 10 mcg/kg/min over 3-minute increments, rising by 5 to 10 μg/kg/min each step, with a maximum dosage rate of 40 μg/kg/min. Atropine may be needed to achieve the target heart rate. The endpoint is 85% of MPHR or side effects similar to those listed in sections IV.3.a. and IV.3.b.i. It is not necessary to withhold β blockers and calcium channel blockers must be withdrawn far enough in advance of the test if the patient is eligible for atropine to eliminate their effect. Dobutamine stress is an alternative in patients who have bronchospastic airway obstructive pulmonary disease or certain conduction system disorders. Dobutamine is associated with an increased incidence of cardiac arrhythmia and should be given with extreme caution avoided in patients prone to arrhythmias or in the postmyocardial infarction period.

4. Safety
When exercise or pharmacologic stress is performed or when hemodynamically unstable patients are studied, life support instruments, medications, and appropriately trained personnel (advanced cardiac life support [ACLS] or pediatric advanced life support [PALS]) must be available in the immediate vicinity of the stress laboratory. Baseline blood pressure measurement and ECG tracing should be obtained before performing either a stress test using exercise or a pharmacologic stimulation. ECG and blood pressure monitoring must be performed during stress and recovery.

5. Imaging
For most applications, SPECT, or SPECT/CT, PET, or PET/CT should be performed [10,11]. Planar imaging may be performed when the patient is unable to undergo SPECT (eg, body habitus, claustrophobia, or inability to lie recumbent or remain immobile).
a. SPECT or SPECT/CT

In most SPECT systems, the patient is placed supine on the imaging table. In some cardiac-specific systems, the patient may sit upright or semi-upright. and should The patient should be instructed to stay as motionless as possible, and care should be taken to provide for his/her comfort. It is possible to image with the patient in the prone position, especially in those patients with suspected when inferior wall attenuation defects are suspected, but the prone position may also introduce anterior wall artifacts. In one system, two-position supine and semi-upright imaging is performed to resolve possible attenuation artifacts. Depending on the system, either the left arm or both arms for some multihead systems should be raised above the head to reduce attenuation, permit a smaller radius of rotation, and prevent inadvertent contact with the detector. In rare instances, strapping the arm over the head can result in nerve or dialysis shunt injury. Patients should wear similar, loose-fitting clothing for both sets of images. To avoid inconsistent attenuation artifacts in a woman, special care should be taken to position the woman’s breasts as identically as possible between the stress and rest images.

The imaging and reconstruction protocol should be chosen for optimum quality and should be used consistently from patient to patient.

Patient motion and attenuation artifacts may create defects on the reconstructed tomographic filtered images. Cinematic raw data (projection files), sinograms, and/or linograms, if available, should be reviewed to evaluate the examination for overall quality, patient motion, and attenuation artifacts during image acquisition. Attenuation correction is available on some commercial SPECT or SPECT/CT systems; both the attenuation-corrected and the non–attenuation-corrected images should be reviewed when available [12]. Other useful quality control images are the sinogram and summed projection images. Improper reconstruction techniques can also produce artifacts [13,14]. When attenuation correction is used, care should be taken to ensure correct alignment of the SPECT and CT data sets.

With the high count rates achievable with technetium-99m–based radiopharmaceuticals, gated acquisition of images should be carried out routinely. Gated images can be used to calculate ejection fraction and end-diastolic and end-systolic volumes and to assess regional wall thickening and wall motion.

New technology instrumentation, such as solid-state detectors, specialized cardiac collimators, or wide beam reconstruction techniques, may allow for more rapid acquisitions or lower administered activities than described elsewhere in this document [15-18]. In such cases, manufacturers’ suggested protocols should be followed [10-12].

b. PET and PET/CT

The patient is placed supine on the imaging table and should be instructed to stay as motionless as possible. Care should be taken to maximize patient comfort. Both arms should be raised above the head to reduce attenuation. Patients should wear loose-fitting comfortable clothing. The imaging and reconstruction protocol should be chosen for optimum quality and should be consistent from patient to patient and between rest and stress images.

Both the attenuation-corrected and the non–attenuation-corrected images should be reviewed when available. When CT attenuation correction is used, care should be taken to ensure correct alignment of the PET and CT data sets.
c. Planar
At a minimum, images should be obtained in the anterior, shallow left anterior oblique, and left lateral
and/or steep left anterior oblique (LAO) projections. When stress and rest/redistribution images are
obtained, each pair of images should be as closely matched in positioning as possible.

6. Interpretation

For both SPECT and PET myocardial perfusion imaging, myocardial perfusion images are usually
reconstructed and displayed in three standard views (horizontal long axis, vertical long axis, and
short axis). Myocardial perfusion is generally graded in a semiquantitative manner using a five-point
scale, where 0 = normal uptake, 1 = mildly reduced uptake, 2 = moderately reduced uptake, 3 =
severely reduced uptake, and 4 = no uptake. A standard 17-segment myocardial model is commonly
used. Global left ventricular systolic function and left ventricular size are generally assessed
quantitatively and qualitatively. Regional wall motion is assessed using a combination of visually
assessment of thickening and brightening of the segment. Evaluation for coronary artery calcification
(for SPECT/CT and PET/CT) and extra cardiac findings are also integral components of the
interpretation.

7. Quantification
A number of strategies are available for quantitative analysis of planar, PET, and SPECT myocardial
perfusion studies. Quantitative analysis requires comparison with a normal database. Whether the database
is commercially supplied or developed from one’s own experience, the interpreting physician is responsible
for ensuring the quality of the database. Quantitative analysis only supplements a careful visual analysis of
the raw images and reconstructed images.

Quantification of myocardial blood flow and calculation of myocardial flow reserve with PET is
gaining momentum, with the recent addition of a new category III code for PET absolute
quantification of myocardial blood flow by the Centers for Medicare and Medicaid Services (CMS
in 2018. Although the benefits of PET-based myocardial blood flow and flow reserve are growing,
investigations are ongoing in this area for SPECT.

V. EQUIPMENT SPECIFICATIONS

1. Planar
For technetium-99m sestamibi or tetrofosmin, a high-resolution collimator may be used, and up to
1,000,000 counts per view may be achieved quite easily. Imaging may be started as soon as is convenient
after heart rate and respirations slow adequately (to avoid motion artifacts), although a delay of 30 minutes
may improve images by allowing clearance of hepatic activity.

For thallium 201, a gamma camera with a detector size of 250 to 400 mm and a low energy all purpose
(LEAP) collimator may be used. A high-resolution collimator may improve resolution, but longer imaging
times will be required to obtain the same number of counts. For thallium 201, imaging is routinely started
within 10 minutes after injection. Images should be acquired for 6 to 10 minutes per view. This represents
the best compromise between image quality and the need to acquire the images before redistribution occurs.
Redistribution images obtained 3 to 4 hours after injection should be acquired for duration of time similar
to that for poststress views. Cardiac and respiratory motion reduces the spatial resolution of cardiac
examinations.

Currently, planar imaging has largely been replaced by SPECT and PET imaging. Planar imaging is only
used in cases where SPECT or PET imaging cannot be carried out.
2. SPECT

SPECT acquisition parameters depend on the radiopharmaceutical and instrument [10,11]. For single-head cameras, low-energy all-purpose (LEAP)/general all-purpose (GAP) collimators and a circular orbit are acceptable. When thallium-201 is used, LEAP/GAP collimators should be used. With sestamibi and tetrofosmin, high-resolution collimators enhance image quality. With dual-radiopharmaceutical imaging, the same collimator should be used for both radiopharmaceuticals. At a minimum, 32 images in a 180° arc, from right anterior oblique to left posterior oblique (LPO), should be obtained.

For multidetector systems, data can be acquired from either a 180° or a 360° arc, and images can be reconstructed from the complete orbit (whether circular or ellipse) or from the 180° arc. Two-detector camera systems in which the detectors may be positioned at approximately 90° angles allow efficient acquisition of data over a 180° arc. Smaller imaging intervals (3° rather than 6°) are feasible with triple-head systems and two-head 90° systems.

Multihead camera systems are the preferred imaging systems. They decrease image acquisition time compared with single-head systems, which helps to improve patient comfort and reduce patient motion.

SPECT/CT cameras have evolved are being used more frequently. In addition to attenuation correction, the CT images may detect the presence allow detection of coronary artery calcification, which may be clinically significant and should be reported [19-21].

The majority of conventional SPECT systems described above are based on Anger camera technology where one or more large-area detectors rotate around the body of the patient. Conventional Anger cameras consist of a single scintillation crystal that absorbs incident gamma rays and scintillates (emits light in response), a bank of photomultiplier tubes and electronics to compute gamma-ray energy and the location of scintillation within the crystal.

More recently, dedicated cardiac SPECT systems that are based on small semiconductor detector modules have been introduced, which detect the gamma rays without the use of the scintillation crystal. In these solid-state detectors, gamma rays are absorbed into the semiconductor material, which generates electron-hole pairs that are pulled to the end plates through an applied electric field. The collected charge from the electron-hole pairs is used to determine the location and energy of the gamma ray. The small size of these detector modules has made a number of innovative camera designs possible. In one system, multiple pixelated cadmium zinc telluride detector arrays are mounted in vertical columns and placed in gantry over a 90° arc around the patient. Each detector is configured with a high-sensitivity parallel-hole collimator, which restricts its field of view to a small volume. To cover the entire myocardial region, each detector pivots about its own axis, sweeping its field of view across the entire imaging volume. By spending more time imaging the myocardium and less time imaging the rest of the chest, data collection is more efficient and allows reduced scan time or administered tracer activity. During image acquisition, the moving detectors are covered with no visible movement externally, and imaging is performed in a chair to maximize patient comfort, with two-position imaging in the supine and semiupright positions to resolve possible attenuation artifacts.

3. PET

Acquisition can either be in 2-D or 3-D mode. ECG-gated images yield a good-quality ventricular function examination and are acquired in 8 to 16 time frames per R-R interval, in a manner similar to SPECT-gated perfusion studies but at higher spatial resolution. List-mode acquisitions are now available with nearly all cameras, which enable simultaneous dynamic and ECG-gated acquisitions (see ASNC/SNMMI Position Statement [22]). With PET/CT the reconstructed PET and CT image sets must be accurately aligned for fusion and subsequent attenuation correction.
PART II
GATED BLOOD-POOL IMAGING AND FIRST-PASS CARDIAC IMAGING, INCLUDING LEFT-TO-RIGHT SHUNT EVALUATION

VI. INDICATIONS AND CONTRAINDICATIONS

Cardiac scintigraphy includes gated cardiac blood-pool imaging (rest and/or stress), first-pass cardiac imaging, and left-to-right shunt evaluation. Indications for these examinations include, but are not limited to, the following:

A. Gated Cardiac Blood-Pool Imaging

Quantifying parameters of ventricular function (eg, ejection fraction, wall motion, ventricular volume, cardiac output, diastolic function), including monitoring cardiac effects of chemotherapy

B. First-Pass Cardiac Imaging Including Left-to-Right Shunt Evaluation

1. Calculating left and right ventricular ejection fractions
2. Quantifying left-to-right cardiac shunts

Note: Detecting and quantifying right-to-left shunts using radiolabeled particles are covered in the ACR–SPR–STR Practice Parameter for the Performance of Pulmonary Scintigraphy [23].

VII. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

VIII. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for cardiac scintigraphy 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

A. Gated/Multigated Acquisition, MUGA Cardiac Blood-Pool Imaging (Radionuclide Angiocardiography or Ventriculography)

1. Radiopharmaceutical [24-27]

Technetium-99m–labeled autologous red blood cells, labeled by the in vivo, in vivo/in vitro, or in vitro technique, are most commonly used. The adult administered activity is usually 15 to 25 mCi (555-925 MBq) administered intravenously, and the examination may commence immediately thereafter. Administered activity for children should be determined based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality. For children, the recommended administered activity for a gated blood-pool examination including left-to-right shunt is 5 to 20 mCi (185-740 MBq)
[1,2]. If a patient has received a recent blood transfusion, is in renal failure, or is on heparin or doxorubicin, the in vivo technique may result in unacceptably high levels of unbound technetium-99m. Other medications may have similar effects.

2. Patient
Except for those patients undergoing stress-gated ventriculography, few restrictions apply. Patients requiring exercise should be evaluated for their ability to undergo the physical stress safely.

3. Stress
Exercise, when performed, usually consists of graded levels of work performed on a bicycle ergometer with simultaneous acquisition of gated images. These are commonly obtained for 2 to 3 minutes during each level of exercise by imaging after heart rate equilibration, which usually occurs in 1 to 2 minutes. The endpoint may be achievement of a desired predefined work level or percentage of MPHR, anginal symptoms, significant ST segment depression or other electrocardiogram abnormality, or physical inability to continue.

4. Safety
When hemodynamically unstable patients are studied or when exercise is performed, life support instruments, medications, and appropriately trained personnel (ACLS or PALS) must be available in the immediate vicinity of the stress laboratory. Baseline blood pressure measurement and ECG tracing should be obtained before performing a stress test using exercise. ECG and blood pressure monitoring must be performed during stress and recovery.

5. Imaging
a. Rest
At least 16 frames per R-R interval are needed for accurate measurement of the ejection fraction. The ECG tracing on the monitor should be inspected before imaging starts to be certain that the R wave is properly triggering the acquisition. The angle for the LAO view should be chosen to obtain the best separation of the right and left ventricles. The anterior view should be obtained at an angle that is 45° shallower than the LAO (best septal) view. The left lateral view should be obtained at an angle that is 45° steeper than the LAO view. An LPO view may be substituted for, or can be obtained in addition to, the left lateral view. Caudal angulation (up to 30° if using a slant-hole collimator) may help to separate the ventricular blood pool from the atrial blood pool. The matrix size should be 64 × 64. Each set of images should be acquired for at least 5 minutes or 300,000 counts per frame, whichever occurs first. Recent advances in hardware and software allow SPECT acquisition of gated blood-pool images. SPECT acquisition allows a more detailed evaluation of left and right ventricular regional wall motion and calculation of both right and left ventricular ejection fractions.

b. Stress
Patients should exercise at each new level of exercise for 1 to 2 minutes to achieve a stable heart rate. Once a stable heart rate is obtained, 2- to 3-minute images are acquired using the best septal view and approximately 16 frames per cardiac cycle. One examination should be acquired at the maximum level of exercise. Studies at other levels of exercise can also be obtained.

6. Quantification
a. R-wave histogram ("beat histogram")
Inspection of the R-wave histogram provides information on the regularity of the cardiac rhythm during the acquisition. Because the gated examination averages hundreds of heartbeats, wall-motion evaluation and ejection fraction calculations are optimal with a regular rhythm. Less than 10% of beats rejected is optimal. If more than 30% of beats are rejected, quantitative results may be unreliable.
b. Wall motion
Wall motion can be assessed quantitatively or qualitatively. Functional images, such as stroke volume, paradox, regional ejection fraction, amplitude, and phase images, may be helpful.

c. Left ventricular ejection fraction
All computer programs calculate an ejection fraction using the difference between background-corrected end-diastolic counts and background-corrected end-systolic counts divided by background-corrected end-diastolic counts. The background region of interest should avoid the stomach or the spleen, which can result in erroneously low or high ejection fractions, respectively. Manual, semiautomatic, or fully automatic algorithms for calculating ejection fractions are available. In addition to the R-wave histogram, region of interest and the ejection fraction curve should be inspected to be certain the quantitative results are consistent with the acquired data. The user of these programs should have a quality control program in place to maximize the precision of the measurement. The user should understand the strengths and limitations of the algorithms used. Computer-generated left ventricular ejection fractions should be compared with the visual estimation of ejection fractions to ensure reliability.

B. First-Pass Cardiac Imaging (First-Pass Ventriculography), Including Left-to-Right Shunt Evaluation

1. Radiopharmaceutical [24-27]
If the examination is performed in conjunction with a gated blood-pool examination, technetium-99m–labeled red blood cells in an administered activity of 15 to 25 mCi (555-925 MBq) may be used. Other technetium-99m–labeled radiopharmaceuticals (eg, pertechnetate, diethylene-triamine penta-acetic acid, or sestamibi) may be used if the study examination is done alone or with another unrelated examination. Administered activity for children should be determined based on body weight and should be ALARA for diagnostic image quality. For children, the recommended administered activity for first-pass cardiac imaging including left-to-right shunt is 5 to 20 mCi (185-740 MBq). Injection technique is critically important. Rapid injection of a small volume of the radiopharmaceutical into a large proximal vein (eg, external jugular) or through a large-gauge intravenous access in an antecubital vein followed by an instantaneous saline flush is necessary for optimal results, especially when measuring left-to-right shunts. If the bolus is suboptimal, the results may not be valid. Bolus adequacy can be measured by superior vena cava (SVC) bolus analysis.

2. Patient
No patient preparation is required unless the procedure is performed as part of an exercise examination.

3. Imaging
Depending on the information desired, the imaging device is positioned over the patient’s chest in the anterior or right anterior oblique projection. Data are acquired in list or fast-frame mode for up to 1 minute. A 64 × 64 matrix is preferred. A LEAP/GAP or high-sensitivity collimator is used.

4. Quantification of right and left ventricular ejection fraction(s)
The user must understand the limitations of the quantitative techniques used to avoid errors. A quality control program should be in place to maximize the value of this examination.

5. Evaluation of left-to-right shunt
The size of cardiac and extracardiac left-to-right shunts also may be measured by assessing first-transit pulmonary time-activity curves. The technique is used more commonly in children than in adults. The injection technique must ensure delivery of the radiopharmaceutical in as tight a bolus as possible. Computer programs, such as gamma variate analysis, are applied to pulmonary curves to determine the pulmonary-to-systemic blood-flow ratio (QP/QS).
Note: Right-to-Left Shunt Detection: For further information see the ACR–SPR–STR Practice Parameter for the Performance of Pulmonary Scintigraphy [23].

IX. EQUIPMENT SPECIFICATIONS

A. Gated Cardiac Blood-Pool Imaging

A gamma camera equipped with a LEAP/GAP collimator is required, although a high-resolution collimator provides sharper images on a rest examination if the count rate is adequate. An electronic cardiac monitor with an R-wave trigger signal compatible with the camera/computer system used is required. Recently, gated SPECT imaging has been used quite successfully in place of planar imaging for gated blood pool imaging. With the wider availability of appropriate software and computer programs for SPECT blood pool imaging, this is likely to be used increasingly in the future.

B. First-Pass Cardiac Imaging, Including Left-to-Right Shunt Evaluation

Any standard gamma camera may be used. A LEAP/GAP collimator or a high-sensitivity collimator is recommended.

PART III
FDG-PET Viability Imaging

X. INDICATIONS

Evaluation of viable myocardium in cases of suspected stunned or hibernating myocardium.

XI. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

XII. SPECIFICATIONS OF THE EXAMINATION

Two sets of images are required for viability assessment: a perfusion image and an FDG image. Perfusion imaging is first performed with either rubidium-82 chloride or 13N-ammonia using procedures described in the PET myocardial perfusion section. If these radionuclides are not available, standard SPECT myocardial perfusion can be performed. The two sets of images are required to assess regional concentrations of FDG relative to regional distribution of myocardial perfusion to differentiate between the various myocardial states. For example, hibernating myocardium is identified by a perfusion-metabolism mismatch (ie, a regional increase in FDG relative to regional perfusion), whereas myocardial scar is identified by a perfusion-metabolism match (ie, a regional reduction in FDG uptake in proportion to regional reductions in myocardial perfusion). Regional wall motion assessment with gating assists with this interpretation.

FDG imaging for myocardial viability assessment requires patient preparation and metabolic manipulation to shift the myocardial energy substrate utilization to glucose. A number of protocols to accomplish this are available, including glucose loading and/or the use of insulin, or the hyperinsulinemic clamp [28]. Diabetic patients may require the latter [29] (see ASNC/SNMMI Position Statement [22]). Once the patient has been appropriately prepped, 5 to 15 mCi of FDG is then injected, and after a 45 to 60 minute delay, imaging of the heart is performed using either 2-D or 3-D mode. The resulting scan of metabolically active myocardium is compared with the perfusion images generally using standard views, a semiquantitative approach, and a 17-segment model.
PART IV
FDG-PET Inflammation/Infection Imaging

XIII. INDICATIONS

FDG-PET is becoming a useful tool in the evaluation of myocardial inflammation and especially in cases of cardiac sarcoid. Other uses include myocarditis (especially viral Coxsackie) and various arteritides. FDG-PET assessment of cardiac disease can be challenging because the radiopharmaceutical accumulates in normal myocardium [30], thus obscuring visualization of myocardial uptake that is due to inflammation.

XIV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

XV. SPECIFICATIONS OF THE EXAMINATION

Physiologic FDG uptake in normal myocardium can range from none to focal or even diffuse uptake in the same person under varying physiologic conditions because uptake in the normal myocardium depends on the patient’s fasting state and shift of myocyte metabolism from glucose to fatty acid [31]. A variety of patient preparations have been utilized with varying success for suppression of physiologic myocardial FDG uptake, including, but not limited to, prolonged fasting, dietary manipulations with high-fat, low-carbohydrate meals, or intravenous heparin. An acceptable approach to patient preparation is the use of combined low-carbohydrate meals the day before the PET examination followed by at least 12-hour fasting before PET can be used to suppress physiologic FDG uptake by normal myocytes. The success rate of this approach is not known but is estimated to be 80% to 90%. Exercise should be avoided for 24 hours before the PET examination. Following injection of the FDG (5 to 15 mCi), acquisition can be performed after a 60 to 90-min delay in either 2-D or 3-D mode but without gating, as images may have no or minimal myocardial FDG uptake for tracking of myocardial contours.

If there is clinical desire to assess for the presence of extracardic sarcoid, a limited whole-body PET study using the same fludeoxyglucose FDG, or 18F-FDG, injection can be performed immediately following the dedicated cardiac 18F-FDG study.

To differentiate the spectrum of cardiac sarcoidosis and improve diagnostic accuracy, rest myocardial perfusion imaging is recommended in conjunction with FDG imaging. The perfusion images are generally performed prior to the FDG, using either 13N-ammonia or rubidium-82 and, as previously outlined, SPECT myocardial perfusion with either sestamibi or tetrofosmin, if 13N-ammonia or rubidium-82 are not available.

With PET/CT, the reconstructed PET and CT image sets must be accurately aligned for fusion and subsequent attenuation correction. A normal PET examination for cardiac sarcoidosis will show complete suppression of FDG from the myocardium and normal resting myocardial perfusion. Incomplete suppression of FDG from normal myocardium, as might occur because of inadequate patient preparation, may be accompanied by diffuse FDG uptake, usually with normal resting perfusion. In the presence of active inflammation, focal areas of FDG uptake may be present without or with perfusion defects. In the case of scarring/fibrosis, a resting perfusion defect without FDG uptake is present. Inflammation and scarring/fibrosis may coexist in the same patient and may lead to several patterns of perfusion and metabolism in the left ventricle.
XVI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [32].

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

XVII. RADIATION SAFETY [33,34]

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). Please consult 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.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).

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance of Gamma Cameras [35].

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 – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and by the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the NASCI, the SNMMI, the SPR, and the STR.

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

ACR
David C. Wymer, MD, FACR, Chair
Twyla B. Bartel, DO, MBA
Helen R. Nadel, MD

SNMMI
Panithaya Chareonthaitawee, MD
Sharmila Dorbala, MD

STR
Joanna Ewa Kusmirek, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Richard K. J. Brown, MD, FACR, Co-Chair
Alexandru C. Bageac, MD, MBA
Twyla B. Bartel, DO, MBA
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH
Joanna R. Fair, MD
Erin C. Grady, MD
Edward D. Green, MD
Jeffrey S. Kempf, MD, FACR
Jennifer J. Kwak, MD
Charito Love, MD
Syam P. Reddy, MD
Levi Sokol, MD
Rathan M. Subramaniam, MD, PhD, MPH
Stephanie P. Yen, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Committee on Practice Parameters – Pediatric Radiology

Kassa Darge, MD, PhD  Helen R. Nadel, MD
Monica S. Epelman, MD  Sumit Pruthi, MBBS
Dorothy L. Gilbertson-Dahdal, MD  Pallavi Sagar, MD
Safwan S. Halabi, MD  Richard B. Towbin, MD, FACR

720
Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
721
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
722
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
723
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
724
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards
725

Comments Reconciliation Committee
Gregory N. Nicola, MD, FACR, Chair  Matthew Lungren, MD
Samir B. Patel, MD, FACR, Co-Chair  Alan H. Matsumoto, MD, FACR
Richard A. Barth, MD, FACR  Mehran Midia, MD
Jacqueline A. Bello, MD, FACR  Jason W. Mitchell, MD
Lynn A. Brody, MD  Mary S. Newell, MD, FACR
Drew M. Caplin, MD  Beverley Newman, MB, BCh, BSc, FACR
Mandep S. Dagli, MD  Manish N. Patel, DO
Kassa Darge, MD, PhD  Matthew S. Pollack, MD, FACR
Sean R. Dariusnia, MD  Michael S. Stecker, MD
Richard Duszak, Jr., MD, FACR  Timothy L. Swan, MD, FACR
Clair Kaufman, MD  Clayton K. Trimmer, DO, FACR
Paul A. Larson, MD, FACR  Ranjith Vellody, MD

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 2009 (Resolution 14)
Sunset 2014 (Resolution 29)
2015 (Resolution 44)
BE IT RESOLVED, that the American College of Radiology adopt the ACR–ACNM–ASTRO–SNMMI–SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I-131 Sodium Iodide

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–SPR PRACTICE PARAMETER FOR TREATMENT OF BENIGN AND MALIGNANT THYROID DISEASE WITH I-131 SODIUM IODIDE

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

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (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.
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 developed collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to guide appropriately trained and licensed physicians treating thyroid disease with I-131 Sodium Iodide.

Therapy with I-131 Sodium Iodide takes advantage of the fact that benign and malignant thyroid tissue is capable of producing thyroid hormone and trapping and organifying iodine to include its radioactive isotopes. Once taken up by functioning thyroid tissue, the therapeutic effect of I-131 Sodium Iodide is achieved by the emission of ionizing radiation in the form of high-energy beta particles, which results in cell death.

I-131 Sodium Iodide is both a beta particle and gamma ray emitter, with a physical half-life of 8.02 days. Its primary means of decay is via beta particle emission, which provides cytotoxic properties. The principle beta particle emitted by I-131 Sodium Iodide has a maximum energy of 0.61 MeV, an average energy of 0.192 MeV, and a tissue range of 0.6 to 2 mm [1]. I-131 Sodium Iodide also emits gamma rays, with its principle gamma ray having an energy of 364 KeV, which allows for imaging.

Therapy requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient and those who administer radiopharmaceutical therapy and 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 as that standard relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public [2]. There must also be compliance with applicable laws and regulations.

II. DEFINITION

Therapy with I-131 Sodium Iodide involves its oral administration for the treatment of benign and malignant thyroid diseases.

III. INDICATIONS

Examples of therapy with I-131 Sodium Iodide for disease include the following:

1. Benign Disease:
a. Treatment of Graves disease (primary or recurrent)
b. Treatment of toxic autonomous functioning nodule
c. Treatment of autonomous functioning multinodular goiter
d. Treatment of nontoxic nodular goiter

2. Malignant Disease:
   a. Treatment of Iodine-avid papillary and follicular thyroid cancer metastases
   b. Thyroid remnant ablation
   c. Treatment of recurrent thyroid cancer (to include suspected recurrence based upon elevated thyroglobulin levels)

IV. 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 [2,3]. In addition, training and experience must be in compliance with the applicable laws and regulations.

V. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

The written or electronic request for a radiopharmaceutical 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 - revised in 2016, Resolution 12-b)

For further information on benign thyroid disease, thyroid uptake measurement, and thyroid scintigraphy see the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [4].

A. General Procedures

1. Clinical evaluation
   In concordance with the ACR–ASTRO Practice Parameter for Radiation Oncology and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [3,5], the treating physician’s initial evaluation of the patient must include review of the patient’s history, including medications, physical examination, pertinent diagnostic studies, laboratory and pathology reports that include a complete history of all previous radiotherapy and radiopharmaceutical therapy. These findings should be communicated to the referring physician and other physicians involved in the patient’s care. Evaluation of pregnancy test (serum preferred) should be performed in those of reproductive potential. Likewise, inquiring about breastfeeding is recommended. The patient should have discontinued breastfeeding long enough to result in the cessation of lactation, which is generally 6 to 12 weeks prior to therapy, to mitigate ill effects to the child and reduce radiation dose to the maternal breasts.

2. Quality Management
In order to use radiopharmaceuticals as unsealed sources for therapy, a “quality management” program must be in place as required by the United States Nuclear Regulatory Commission (NRC) or by Agreement State regulations (an Agreement State is any state with which the NRC or the U.S. 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 relevant to I-131 therapies include written directives; duplicative procedures for identifying patients; careful record keeping to ensure prescribed administered activity; procedures for minimizing radiation exposure or radiopharmaceutical contamination of personnel, family members of patients, and the public (eg, instructions regarding possible current or future pregnancy); procedures for containment of radioactivity; and an audit mechanism to ensure compliance with the program.

3. Treatment
The procedure and follow-up should be performed according to an established system of procedural steps specific for treatment of benign and malignant conditions. The treating physician must discuss the risks, benefits, and alternatives of I-131 treatment with the patient in detail and obtain an informed consent and reconfirm the ability of the patient to comply with the prescribed radiation precautions. Specific precautions and caution should be used when treating patients with ophthalmopathy, large thyroid glands, or significant postthyroidectomy residual or metastatic disease to the brain or spine. The patient must not be pregnant, breastfeeding, or lactating at the time of I-131 sodium iodide therapy. Pregnancy must be excluded prior to radiopharmaceutical administration by one of the following: negative human chorionic gonadotropin (hCG) test within 24 hours of treatment, documented hysterectomy, postmenopausal state (absence of menstrual bleeding for 2 years), or by premenarche (child age 10 years or younger). Providing that the patient remains sexually abstinent, this can be done within 72 hours. Caution is advised for patients who have had recent unprotected intercourse as pregnancy testing may remain negative for 7 to 10 days. The patient should be advised against planning future pregnancy for 6 to 12 months after treatment. Breastfeeding should be stopped long enough to cease lactation prior to radiiodine therapy and not resumed after treatment for that infant, but may be undertaken for subsequent pregnancies. Education and prevention strategies for early complications, such as nausea and vomiting, sialadenitis, loss or alteration of taste, neck pain and swelling, and oral mucositis, should be discussed and provided to the patient. Written radiation safety instructions and a letter confirming treatment will be provided with contact details of the treating facility radiation safety officer (RSO).

4. 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 RSO, medical physicist, or health physicist for the local facility should 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 CFR 35.75 [8,9] and key sections of NUREG 1556 [10], the patient may be released 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). However, 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 maintain doses 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. 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 connection to the patient and for whom there is 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/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. The patient should be compliant with all radiation safety precautions and instructions. Inability to comply with the precautions might require an admission, as determined by the authorized user. Urinary incontinence, if present, would require catheterization to prevent radiation contamination. Peritoneal and hemodialysis are not contraindications for treatment but may impact the administered activity of I-131 given the prolonged residence time within the patient. These procedures should be performed within NRC guidelines and comply with state requirements and hospital practices.

All routine blood work and laboratory specimens should be obtained prior to treatment with the radiopharmaceutical. If confinement in a health care facility is needed, it is not usually necessary to store body effluents, such as urine, stool, or vomitus. For effluent disposal where acceptable under State or Federal regulations, the toilet should be flushed two or three times after each use to ensure sufficient dilution of radioactivity. Food trays and linens should 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 must be limited. All trash and residual nondisposable items must 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, or when 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. 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.

B. Malignant Thyroid

1. Clinical evaluation

There are multiple imaging studies that increase the suspicion for the presence of thyroid carcinoma, including features on thyroid ultrasound, abnormalities on thyroid uptake and scan, and fluorodeoxyglucose (FDG)-positron emission tomography (PET), or F-18 FDG PET imaging. Less commonly, incidental nodular abnormalities demonstrated on standard diagnostic computed tomography (CT) imaging of the thorax or neck may prompt further workup for thyroid carcinoma.

Suspicion for locally advanced thyroid carcinoma may also be suggested by lymphadenopathy in the neck on soft-tissue neck ultrasound imaging, CT, or magnetic resonance imaging (MRI) or as detected by physical examination.

As the use of F-18 FDG PET/CT increases, incidental thyroid carcinomas are increasingly detected by this method. In one study of 285 patients with incidental thyroid hypermetabolism, the overall cancer risk in this population was 23.2%, with focal thyroid hypermetabolism yielding a risk of 30.9% [6].

Some studies have suggested that F-18 FDG standardized uptake values (SUV) max of >6.2 can be relatively specific for the differential identification of malignancy from benign thyroid hypermetabolism in incidental thyroid nodules [7]. Using this cutoff value as suggested in this study of 34 patients with
A variety of ultrasound features help to characterize the risk of malignancy. Highly suspicious features include a solid hypoechoic nodule or a solid hypoechoic component of a partially cystic nodule that also contain either one or more of the following: irregular margins (infiltrative, microlobulated), microcalcifications, taller-than-wide shape, rim calcifications with small extrusive soft-tissue component, and/or evidence of extrathyroidal extension.

The following link, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4739132/figure/f2/, is from the 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer and demonstrates a stratification of malignancy risk by feature, illustrated with ultrasound appearance examples [8].

This next link, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854274/, is from the 2015 Management Guidelines for Children with Thyroid Nodules and Differentiated Thyroid Cancer, the American Thyroid Association guidelines task force on pediatric thyroid cancer, and it demonstrates a stratification of malignancy risk by feature, illustrated with ultrasound appearance examples [9,10].

2. Indications for ultrasound evaluation of the thyroid and/or soft-tissue neck [8,11-16]

Some of the indications for performing diagnostic ultrasound related to thyroid carcinoma are listed in the ACR–AIUM–SPR–SRU Practice Parameter for Performing and Interpretation of Diagnostic Ultrasound of the Extracranial Head and Neck [17]. Indications for a thyroid head and neck ultrasound (US) examination include, but may not be limited to:

a. Evaluation of the location and characteristics of palpable neck masses.

b. Evaluation of abnormalities detected by other imaging examinations (eg, a thyroid nodule or other neck mass detected on CT, PET-CT, MRI, or seen on other ultrasounds (eg, carotid ultrasound)).

c. Evaluation of patients at high risk for thyroid malignancy.

d. Imaging of previously detected thyroid nodules that meet criteria for follow-up imaging.

e. Evaluation for regional nodal metastases in patients with proven or suspected thyroid carcinoma prior to thyroidectomy.

f. Evaluation for recurrent disease or regional nodal metastases after total or partial thyroidectomy for thyroid carcinoma.

g. Evaluation of the thyroid gland for malignancy prior to neck surgery for nonthyroid disease.

h. Evaluation of the thyroid gland for malignancy prior to radioiodine ablation of the gland.

i. Guidance for aspiration or biopsy of thyroid abnormalities or other masses of the neck.

Ultimate detection and confirmatory diagnosis of the presence of primary thyroid carcinoma is by ultrasound-guided needle biopsy and/or fine-needle aspiration, with pathologic confirmation. Diagnosis of metastatic thyroid carcinoma is typically made by an excisional biopsy or surgical specimen evaluation of the metastatic lymph node or organ.

3. Quality Control and Improvement, Safety, Infection Control, Patient Education Concerns [18-24]

a. Clinical Use of Radiopharmaceutical
i. All radiopharmaceuticals dispensed and administered must be pursuant to an order (eg, prescription) by an authorized physician;

ii. Prescribing physicians are ultimately responsible for the safety, quality, and correctness of all radiopharmaceuticals prepared and dispensed for administration under their direction;

iii. Nuclear pharmacists are ultimately responsible for the safety, quality, and correctness of radiopharmaceuticals prepared and dispensed under their supervision;

iv. The preparation, quality control, dispensing, and administration to patients of radiopharmaceuticals and adjunctive drugs may be delegated to qualified personnel, in accordance with applicable state and local laws;

v. There must be a signed and dated written directive for each patient for I-131 sodium iodide in quantities of 1.1 MBq (30 μCi) or more and for all therapeutic doses.

vi. The identity of the radiopharmaceutical and patient and the route of administration must be verified before administration. Syringes and outer shields or containers must be labeled for verification of contents.

vii. Female patients who are postmenarcheal and premenopausal should be asked about pregnancy, lactation, and breastfeeding before administration. Pregnancy testing in females of child-bearing capability should be performed before administration.

viii. The quantity of each radiopharmaceutical dose must be determined before administration to patients and must be consistent with that ordered by the physician or as stipulated in the applicable standing orders in the nuclear medicine procedure manual. The quantity of radioactivity dispensed should be within 10% of the prescribed dose or dose range, and the actual quantity administered should be within 20% unless otherwise directed by the authorized physician and recorded in the patient’s medical record.

ix. Radiopharmaceuticals should not be used beyond the expiration date or time recommended by the manufacturer unless quality control testing demonstrates that the product still meets the specifications of the U.S. Pharmacopeial Convention at the time of use.

x. Any discrepancies must be resolved before administration.

b. Radiation precautions

Radiation safety issues for pregnancy, breastfeeding, and lactation are discussed under section V.A.3-4.

Regulatory requirements for hospitalization and other radiation protection vary among states and countries. Many of those guidelines are more stringent than those of the Nuclear Regulatory Commission (NRC). The NRC has three alternate criteria for allowing patient release from the hospital after I-131 Sodium Iodide therapy. They are:

i. When no individual member of the public is likely to receive more than 5 mSv (500 mrem) from that patient, assuming all other regulatory requirements for patient instructions and record keeping are met. NUREG-1556, volume 9, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (500 mrem). This guidance is not a regulation. Realistic and scientifically valid, less
conservative calculations on patient release, based on the realities of patient life at home, have been published (105–107).

ii. When the survey meter reading is less than 0.07 mSv/h (7.0 mrem/h) at 1 m. Some radiation meters measure exposure rates in milliroentgens per hour, but for low LET radiation (including b-particles and most x-rays and gamma rays), the exposure rate at 7 mR/h will be equivalent to the dose rate at 0.07 mSv/h (7 mrem/h) (108).

iii. When the administered activity is 1.22 GBq (33 mCi) or less.

If the patient is to be treated as an inpatient, nursing personnel must be instructed in all relevant radiation safety procedures. Selected nursing personnel should be provided with appropriate radiation monitors (film badge, direct-reading dosimeters, etc). Nurses who are or may be pregnant are excluded from direct patient care. Any significant medical conditions should be noted and contingency plans made in case radiation precautions must be breached for a medical emergency, as concern about radiation exposure should not interfere with prompt, appropriate medical treatment of the patient should an acute medical problem develop.

Written instructions describing methods to limit the dose to others must be given to the patient if an individual member of the public is likely to receive a radiation dose exceeding 1 mSv (100 mrem) from that patient and if the administered dosage is greater than 0.26 GBq (7 mCi) (17). Individual Agreement States may have specific rules and regulations regarding the release of patients with significant residual activity. Details on the relevant federal regulations can be obtained at the NRC website (https://www.nrc.gov) or by telephone (301-415-7000).

As a precaution, before releasing the patient, the licensee should instruct the patient on how to reduce unnecessary radiation exposure to family members and members of the public. Written instructions must be provided to reduce the radiation dose both to the patient and to members of the public and may be required in some jurisdictions (109). With simple precautions, the radiation dose to family members is low (considerably less than the NRC upper limit of 5 mSv [500 mrem]) even when patients are not admitted to a hospital (110). In a study where the patients were to sleep alone and avoid prolonged personal contact for 2 days after therapy, 65 household members received a mean dose of 0.24 mSv (24 mrem) (range, 0.01–1.09 mSv [1–109 mrem]) (111).

Radiation safety precautions should be provided to the patient to minimize the radiation exposure of other individuals who may be in close contact with the patient following a therapeutic administration of I-131 Sodium Iodide, with the goal of limiting the exposure of other individuals to a total of < 5mSv (500mR). Although these procedures may vary somewhat from institution to institution, typical precautions would include limiting close contact of less than 1 yard away to less than 1 hour per day, especially for any pregnant women or young children the patient may encounter. The patient should use a separate bathroom at home if possible if living with others and flush the toilet twice when using the bathroom for the first week, wash their hands carefully after going to the bathroom or preparing food for others, and use paper plates and plastic silverware.

There is no hazard to any member of the family arising from sites where the patient sits, what the patient has touched, or what the patient cooks. Internal exposure of family members from items contaminated by patient saliva or urine must be prevented. Although telephone mouthpieces and other devices touched frequently may have minimal I-131 Sodium Iodide contamination detected on them, this is not a health hazard because of the minute amount of radiation present compared with ambient background radiation. Disposable plates and utensils are not only unnecessary but, if used, can trigger sensitive waste facility alarms; dishes and utensils should not be shared before washing. It is unnecessary to wash the patient’s laundry separately. Patients should flush the toilet twice after use.
and wash their hands for 20 s. Men should urinate sitting down to avoid contamination in the toilet area. Although certain proprietary products are advertised for specifically decontaminating I-131 Sodium Iodide in the home, such products are not necessary in the typical home situation.

Prolonged use of public transportation is discouraged for the first 24 h after I-131 Sodium Iodide therapy. Although Title 10 of the Code of Federal Regulations, part 35.75, does not expressly prohibit the 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 Title 10 of Code of Federal Regulations, part 35.75(a) and may result in doses that are not ALARA [(112) NRC Policy on Release of I-131 Sodium Iodide Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences. Rockville, MD: Nuclear Regulatory Commission; January 25, 2011.].

Most experts recommend that both men and women wait 6 to 12 months after I-131 Sodium Iodide therapy before trying to conceive a child, although there are no reliable data on the validity of this suggested interval. A 12-month interval also allows for follow-up imaging to evaluate the effectiveness of the treatment (113) and for retreatment if deemed appropriate.

Patient-specific calculations of radiation exposure to others can be performed using several assumptions and specific recommendations given to each patient about the time and distance to stay away from others. Radiation surveys of the thyroid gland on personnel administering I-131 Sodium Iodide are performed periodically, depending on local regulations and institutional policy. Patients should be provided with a written document stating they have been given a radioactive substance, the date of administration, the name of the radiopharmaceutical, and the activity administered in the event that it is detected by monitoring devices during travel.

4. Treatment
Therapy for Thyroid Remnant Ablation, Residual Thyroid Cancer, or Metastases from Thyroid Cancer

a. Background

Iodine-avid thyroid cancers frequently take up radioiodine in the absence of significant amounts of residual normal thyroid tissue. In selected patients following near-total thyroidectomy, the thyroid remnant may be ablated by radioiodine. A large thyroid remnant (eg, following a hemithyroidectomy) may require a completion thyroidectomy prior to radioiodine ablation. To optimize radioiodine therapy for locoregional or distant disease, the remnant normal thyroid must be eliminated and can be detected on a pretherapy diagnostic whole-body scan, the latter of which can also aid in assessing the extent of the disease. Details regarding risk stratification of patients with thyroid cancer, appropriateness of radioiodine therapy in various clinical situations, and the overall management of patients with thyroid cancer are covered extensively elsewhere.

b. Summary of selected data

i. A study evaluating thyroid cancer over a 40-year period reported that, for patients with cancers greater than or equal to 1.5 cm in diameter postthyroidectomy and without distant metastases, the addition of I-131 Sodium Iodide therapy alone for remnant thyroid ablation reduced the rate of recurrence and cancer death by at least one-half and reduced the risk of recurrence by more than two-thirds [23].

ii. In two phase III trials comparing results of I-131 Sodium Iodide therapy in patients with low-risk thyroid cancer postthyroidectomy using thyroid hormone withdrawal versus use of recombinant human thyrotropin, the ablation rate was found to be equivalent between I-131 Sodium Iodide activities of 1.1 GBq (30 mCi) and 3.7 GBq (100 mCi) [25,26]. There was also no difference in the ablation rate between patients withdrawn from thyroid hormone versus those who received recombinant human thyrotropin. A retrospective study raised some concerns about the effectiveness of activities lower than 2 GBq (54 mCi) in patients older than 45 years [27].
c. Treatment recommendations

I-131 Sodium Iodide has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation, which is suitable for imaging. Because of increased sensitivity afforded by the therapeutic dosage of I-131 Sodium Iodide, posttherapy imaging (usually performed 2 to 10 days after treatment) is useful and usually recommended to identify sites of disease not detected on pretherapy iodine imaging.

d. Patient preparation

The serum thyroid-stimulating hormone (TSH) must be elevated, usually to a level in excess of 30 µIU/mL. Traditionally, this TSH elevation is achieved either by not administering thyroid hormone following thyroidectomy for 2 to 4 weeks or by withholding thyroid hormone from a patient at a more remote time after surgery to induce an endogenous TSH elevation. Recently, an alternative practice of administering recombinant human TSH (rhTSH) to raise the patient’s blood level of this hormone before therapy has become more commonly used. If a remnant is suspected, scintigraphy may be performed to determine how avidly the thyroid remnant is accumulating radioiodine. If a large thyroid remnant is present, performing a completion thyroidectomy before the I-131 Sodium Iodide therapy should also be considered. Documentation of an elevated TSH level as well as adherence to a low-iodine diet for 1 to 2 weeks prior to treatment is recommended. Optimally, the patient’s system should be free of iodide-containing medications, iodinated contrast, and exogenous thyroid hormone (for withdrawal therapy). For further information, please refer to the Compounds That May Decrease Thyroid Iodine Uptake table in the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [4]. The patient should be fasting and abstain from eating 2 to 4 hours before and 1 to 2 hours after therapy.

e. Administered activities

I-131 Sodium Iodide may be administered to all ages in the management of thyroid cancer, but pediatric dosages should be weight adjusted [9,10]. The patient may need to be placed on radiation precautions.

i. Ablation of thyroid remnant

Activities of 1.1 to 3.7 GBq (30-100 mCi) of I-131 Sodium Iodide (sodium iodide) administered orally are most often used. Higher dosages may be used for more extensive disease.

ii. Known or suspected residual thyroid cancer (adjuvant treatment)

For residual tumor in the thyroid bed or in the setting of local lymph node metastases in the neck without evidence of distant metastasis, activities of 3.7 to 5.55 GBq (100-150 mCi) are usually administered.

iii. Known or suspected distant metastases will usually require administered radioiodine activities equal to or greater than 5.55 to 7.4 GBq (150-200 mCi).

f. Residual or recurrent disease

After successful remnant ablation, a measurable serum thyroglobulin level suggests functioning thyroid tissue and the possibility of recurrent disease and may be an indication for additional treatment. However, both high and low thyroglobulin levels are unreliable in the presence of antithyroglobulin antibodies. In particular, falsely low thyroglobulin levels may occur in antibody-positive patients; therefore, antibody assays should accompany all thyroglobulin measurements. Even when a diagnostic whole-body scan is negative, if the stimulated thyroglobulin level is greater than 10 ng/mL or there is other evidence of disease in a patient with a high risk of recurrence, empiric therapy with 3.7 to 7.4 MBq (100-200 mCi) can be considered. Typical treatment doses would include 150 mCi for lymph node involvement, 175 mCi for pulmonary involvement, and 200 mCi for skeletal involvement. If dosimetry is performed, single treatment dosages of greater than 200 mCi (7.4 GBq) may be administered to selected patients with advanced metastatic disease.
In the setting of a negative whole-body scan and suspected metastatic disease, an FDG-PET/CT scan may be helpful to identify and localize non-iodine-avid disease. (See the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [4].)

g. Interactions with other forms of treatment:
Patients with a high risk of local/regional recurrent disease or distant metastatic lesions may be treated with I-131 Sodium Iodide, external beam irradiation, surgery, systemic therapy, and/or other treatments as clinically indicated.

5. Radiation precautions

Discussion of fertility should be considered, particularly in young patients who may need multiple treatments. Most experts recommend that pregnancy should be delayed by at least 6 to 12 months after radioiodine therapy to complete follow-up evaluation of therapeutic effectiveness and completion of therapy.

6. Complications

a. Side effects/complications

The use and protocol for administering sour candy or other sialagogues following high-dose I-131 sodium iodide therapy is somewhat controversial, but the administration of such agents beginning within 24 hours following therapy is commonly done to minimize salivary gland uptake and the subsequent development of sialadenitis. Permanent xerostomia following I-131 sodium iodide therapy is rare.

Following radioiodine therapy, hydration is recommended; however, the use of sialagogues is debatable. Acute sialadenitis is often transient. Permanent xerostomia is rare and reported in 2% to 4% of affected patients and is generally associated with a history of single or multiple high administered activities of radioiodine.

Reports of pulmonary fibrosis and/or pneumonitis have been described. A whole-body retention threshold of 2.96 GBq (80 mCi) at 48 hours has been used for intense iodine-avid diffuse pulmonary metastases to avoid lung injury. This administered activity is approximately 7.4 GBq (200 mCi; ie, the upper limit of the administered activity should be 200 mCi unless dosimetry is performed). Pulmonary function studies should be considered prior to treatment if there are widespread pulmonary metastases.

The potential for the development of secondary primary malignancies (SPMs) is low, mainly found with leukemia following high administered activities of therapeutic radioiodine, and is controversial. No increased risk of secondary primary solid tumors has been identified. A large European study of 6,871 patients reported an increase in solid tumors and leukemia after radioiodine therapy. A recent literature review, however, reassessed the data and reported a nonlinear dose effect. Review of the Surveillance, Epidemiology, and End Results (SEER) program with a database of 18,882 patients and a mean follow-up of 61.8 months concluded that radioiodine therapy slightly increased the risk of SPM. However, a significantly greater risk of leukemia or other SPM was reported for patients treated with cumulative activities of 22 GBq (600 mCi) of radioiodine, particularly if combined with external beam radiotherapy. Almost all cases of SPM have occurred in patients who received cumulative administered activities in excess of 29.6 GBq (800 mCi). Significant bone marrow depression is likely when cumulative administered activities exceed 29.6 GBq (800 mCi).
b. Interactions of I-131 Sodium Iodide with other forms of diagnosis or treatment (combinations and/or interactions with clinical external-beam radiation therapy)

Patients with advanced local or regional recurrent disease or distant metastases, such as those with involvement of the central nervous system or aerodigestive tract, may be treated with both I-131 Sodium Iodide and external-beam radiation postthyroidectomy. The toxicity, acute and late, is likely to be additive within the field of irradiation.

To avoid potential radiation-induced spinal cord damage in patients with spinal metastases where I-131 Sodium Iodide therapy and external-beam radiotherapy are to be used in combination, dosimetry calculations are particularly important. A treatment planning method for combination external-beam therapy with radiopharmaceutical therapy is described by Hobbs et al. [28].

C. I-131 Sodium Iodide (sodium iodide)

1. Therapy for Hyperthyroidism
   a. Background

   I-131 Sodium Iodide has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation that allows imaging, though imaging of the dose administered for treatment of hyperthyroidism is not performed in clinical practice.

   b. Summary of selected data

   i. Fifty percent to 90% of hyperthyroid patients reach a euthyroid or hypothyroid state within 1 year of treatment with I-131 Sodium Iodide [13].

   ii. In a study of 1,278 patients seen over an approximate 20-year time period, hyperthyroid patients were rendered euthyroid or hypothyroid after a single dose of 600 MBq (16.2 mCi), 370 MBq (10 mCi), or 185 MBq (5 mCi) in 84.1%, 74.9%, and 63% of cases, respectively [14].

   iii. Failure rates for I-131 Sodium Iodide treatment for Graves disease as a cause for hyperthyroidism are higher in patients with large thyroid volumes, high iodine uptake, and high iodine turnover [15].

   c. Treatment recommendations

     Patient preparation—A recent radioiodine thyroid uptake should be available (See the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [4].) The size of the thyroid gland should be noted. Optimally, the patient should be free of iodide-containing medications, iodinated contrast, exogenous thyroid hormone, and antithyroid medications. The patient should avoid foods containing very large amounts of iodine for the week prior to therapy; however, a strict low-iodine diet is usually unnecessary. Ideally, patients should not receive thioamide medications (eg, propylthiouracil or methimazole) for at least 2 to 7 days prior to therapy.

   d. Administered activities

   i. Diffuse hyperfunctioning thyroid/Graves disease

     Initial activity of 3.0 to 7.4 MBq (80-200 μCi) per gram of thyroid (after adjusting for current 24-hour radioiodine uptake) may be administered. Rarely, it may be necessary to administer an activity greater than 1.22 GBq (33.0 mCi). Alternatively, an empiric adult administered activity of 185 to 555 MBq (5-15 mCi) may be given. The measurement of radioiodine uptake before therapy is necessary to establish the cause of the patient’s hyperthyroid state, to avoid the inappropriate administration of radioiodine in the setting of subacute thyroiditis or factitious hyperthyroidism, and to provide information on the radiation emanating from the patient for purposes of counseling the patient on radiation safety matters.
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ii. Toxic nodular goiter and solitary toxic nodule

These conditions tend to be more resistant to radioiodine therapy. Activity of up to 1.22 GBq (33 mCi) or more may be administered.

Administered activity for pediatric patients can be empiric, weight-based, or based on dosimetry [20].

e. Side effects/complications

Side effects are usually minor. Patients may occasionally experience neck tenderness and/or odynophagia from radiation thyroiditis. Sialadenitis is a common side effect with higher administered activities that may be managed by the oral administration of sialagogues and/or anti-inflammatory medications. Serious complications are rare. However, on occasion, patients with severe hyperthyroidism may experience exacerbation of symptoms within the first 2 weeks following I-131 Sodium Iodide therapy. These symptoms usually respond to short-term beta blocker therapy but rarely may progress to frank thyroid storm. Patients should be instructed to contact their referring physician or seek immediate medical care should such symptoms occur.

Hypothyroidism is often considered to be a likely or even desired outcome of successful therapy of Graves disease or toxic nodular goiter and can occur within the first few months following therapy or even decades later, with a small, ongoing annual incidence. If a solitary toxic nodule has fully suppressed the function of the remaining thyroid, the risk of resulting hypothyroidism is decreased, but hypothyroidism may still occur. Hypothyroidism is treated with carefully monitored hormone-replacement therapy. Based on previous multicenter trials, there is no evidence of increased risk of thyroid carcinoma or other malignancy, infertility, or increased incidence of birth defects following I-131 Sodium Iodide therapy for hyperthyroidism.

f. Treatment failures and subsequent therapies

In 20% of patients, the initial therapeutic dosage of I-131 Sodium Iodide fails to sufficiently control hyperthyroidism [29]. In patients who have not adequately responded to prior I-131 Sodium Iodide therapy, subsequent radioiodine treatments may be given. An equal or higher treatment dosage is generally used for retreatment. To achieve the maximal therapeutic effect, repeat therapies are usually not recommended until at least 6 months after the most recent radioiodine therapy. In the setting of diffuse hyperthyroidism, the likelihood of residual hyperthyroidism is greater for lower initial radioiodine administered activities.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR-ASTRO Practice Parameter for Communication: Radiation Oncology [5].

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

VII. ACR 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 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 therapies using unsealed radioisotopes. 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 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 therapy with I-131 Sodium Iodide (oral and parenteral administration) under the supervision of an AU for the specific therapeutic radiopharmaceutical. Although they may not issue written directives for I-131 Sodium Iodide therapy, they may administer such a dosage as designated by an AU;

- Physicians who are board-certified in DR, NR, NM, or RO and hold AU status based on that certification and site-specific credentialing: These physicians may practice I-131 Sodium Iodide radioisotope therapy consisting of oral radioiodine at all dosage levels under their own AU qualifications;

- Physicians who are board-certified in DR, NR, NM, or RO and hold the appropriate AU statuses and site-specific credentialing: These physicians may practice parenteral I-131 Sodium Iodide radioisotope therapy(ies) as permitted by their own specific training leading to such AU statuses.

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 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.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
IX. 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras [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—Nuclear Medicine and Molecular Imaging of the ACR Commissions on Nuclear Medicine and Molecular Imaging, the Committee on Practice Parameters—Radiation Oncology of the ACR Commission on Radiation Oncology, the Committee on Practice Parameters—Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the ASTRO, the SNMMI, and the SPR.

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

ACR
Perry Grigsby, MD, Co-Chair
William G. Spies, MD, FACR, Co-Chair
Kevin P. Banks, MD
Rathan M. Subramaniam, MD, PhD, MPH
Bassem I. Zaki, MD

ACNM
Anca Avram, MD
KG Bennet, MD

ASTRO
Tod W. Speer, MD
Richard W. Tsang, MD

Murthy RK Chamarthy, MD
Bennett S. Greenspan, MD, MS, FACR
Ravinder K. Grewal, MD
Michael G. Stabin, PhD, CHP

SPR
Adina Alazraki, MD
Helen R. Nadel, MD, FRCPC
Victor Segher, MD

SNMMI

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging (ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Edward D. Green, MD
Committee on Practice Parameters — Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Richard K. J. Brown, MD, FACR, Co-Chair
Alexandru C. Bagace, MD, MBA
Twyla B. Bartel, DO, MBA
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH
Joanna R. Fair, MD
Erin C. Grady, MD

Jeffrey S. Kempf, MD, FACR
Jennifer J. Kwak, MD
Charito Love, MD
Syam P. Reddy, MD
Levi Sokol, MD
Rathan M. Subramaniam, MD, PhD, MPH
Stephanie P. Yen, MD

Committee on Practice Parameters — Radiation Oncology
(ACR Committee responsible for sponsoring the draft through the process)

Alan C. Hartford, MD, PhD, FACR, Chair
Naomi R. Schechter, MD, Vice Chair
Nathan H. J. Bittner, MD
Samuel T. Chao, MD
Chee-Wai Cheng, PhD, FAAPM
Neil B. Desai, MD
Nancy A. Ellerbroek, MD, FACR
Beth A. Erickson, MD, FACR
Mark Hurwitz, MD
Lesley A. Jarvis, MD, PhD

Join Y. Luh, MD
Matthew Poggi, MD
Helen A. Shih, MD
Nikhil Thaker, MD
Paul E. Wallner, DO, FACR
Kristina L. Woodhouse, MD
Ying Xiao, PhD
Sue S. Yom, MD, PhD
Bassem I. Zaki, MD

Committee on Practice Parameters — Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACR

Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Seth A. Rosenthal, MD, FACR, Chair, Commission on Radiation Oncology
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Darlene F. Metter, MD, FACR, Chair
Samir B. Patel, MD, FACR, Co-Chair
Adina Alazraki, MD
Kevin P. Banks, MD
Jacqueline A. Bello, MD, FACR
KG Bennett, MD

Helen R. Nadel, MD, FRCPC
Mary S. Newell, MD, FACR
Matthew S. Pollack, MD, FACR
Lee Rogers, MD
Seth A. Rosenthal, MD, FACR
Naomi R. Schechter, MD

PRACTICE PARAMETER I-131 Sodium Iodide
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Comments Reconciliation Committee
Richard KJ Brown, MD, FACR
Murthy RK Chamarthy, MD
Richard Duszak, Jr., MD, FACR
Saeed Elojeimy, MD
Erin C. Grady, MD
Bennett S. Greenspan, MD, MS, FACP
Perry W. Grigsby, MD
Alan C. Hartford, MD, PhD, FACR
Paul Larson, MD
Alan K. Klitzke, MD
Victor Segher, MD
Tod W. Speer, MD
William G. Spies, MD, FACR
Michael G. Stabin, PhD, CHP
Rathan M. Subramaniam, MD, PhD, MPH
Timothy L. Swan, MD, FACR
Mark Tulchinsky, MD
Don C. Yoo, MD, FACR
Bassem I. Zaki, MD

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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RESOLUTION NO. 38

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SPR Practice Parameter for the Performance of Parathyroid Scintigraphy

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 32)*

ACR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF PARATHYROID 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 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, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR). It is intended to guide physicians performing and interpreting parathyroid scintigraphy in adult and pediatric patients.

The goal of parathyroid scintigraphy is to produce images of diagnostic quality to assist in the detection and localization of enlarged and hyperfunctioning parathyroid tissue in normal or ectopic locations in patients with clinical hyperparathyroidism as shown by elevated levels of serum-ionized calcium and parathyroid hormone (PTH). When properly performed, imaging with radiopharmaceuticals that localize in parathyroid tissue is a sensitive means of detecting parathyroid adenomas. These examinations may also detect parathyroid carcinomas in patients with known hyperparathyroidism. Although multigland hyperplasia may also be detected on this examination, it is more often associated with negative or equivocal examination results [1,2]. As with all nuclear medicine examinations, scintigraphic findings must be correlated with clinical information and other imaging modalities.

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

II. DEFINITIONS

**Single Radiopharmaceutical Dual-Phase Imaging**
Utilization of a single radiopharmaceutical with imaging at two time points (early and delayed).

**Dual Radiopharmaceutical Imaging**
Imaging of two different radiopharmaceuticals at a single time point, which is achievable by utilizing the differences in photopeaks.

III. INDICATIONS AND CONTRAINDICATIONS

Parathyroid scintigraphy is used to identify and localize hyperfunctioning parathyroid tissue prior to surgery in a patient with clinically proven hyperparathyroidism (persistently elevated serum calcium and PTH) in the proper clinical setting, and in so This helps to facilitate and expedite surgical excision, shorten hospital stay for the patient, and is more cost effective. It may also be used in postoperative patients with persistent or recurrent hyperparathyroidism to detect residual or ectopic parathyroid tissue. This imaging examination is not intended as a screening test for hyperparathyroidism, and to help reduced surgical time at the time of repeat excisional surgery.

Parathyroid imaging is not to be used but is used to localize the source of excess parathyroid hormone production in a patient with clinically proven hyperparathyroidism (persistently elevated serum calcium and parathyroid hormone in the appropriate clinical setting).

Technetium-99m sestamibi is the universally accepted radiopharmaceutical for this purpose. However, uptake is not specific for parathyroid adenoma or hyperplasia but may also localize to benign or malignant tumors in any organ or tissue, including adenoma (thyroid or parathyroid), carcinoma, lymphoma, sarcoma, benign bone
tumor benign (brown tumor, osteitis fibrosa cystica), and malignant malignancy (primary or metastatic, including breast cancer and multiple myeloma). and plasmacytoma.

The ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [4-6].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [3].

V. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for parathyroid scintigraphy 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’s scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

A. Patient Preparation

There is no specific patient preparation. Elevated PTH and serum calcium levels should be documented.

B. Radiopharmaceuticals

1. Radiopharmaceuticals localizing in both thyroid and parathyroid tissues

- The principal agent for parathyroid scintigraphy is currently technetium-99m sestamibi. Although technetium-99m tetrofosmin and thallium-201 chloride historically have been used for this purpose historically parathyroid tissue localization, technetium-99m sestamibi is now the more widely accepted radiopharmaceutical of choice [7-10].

  a. Technetium-99m sestamibi given intravenously in an administered activity of 20 to 30 mCi (740 to 1,110 MBq) that localizes in both thyroid and parathyroid tissues in proportion to local blood flow and percentage of mitochondria in oxyphil cells [11]. metabolism The rate of radiopharmaceutical clearance (also called washout) from hyperplastic and/or neoplastic parathyroid tissue is usually slower than from the normal thyroid and parathyroid tissues. [5-8]

  b. Thallium-201 chloride should no longer be used for parathyroid scintigraphy [5-7].

  b. Administered activity for children should be determined based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality. For children, the recommended administered activity of technetium-99m sestamibi is 0.3 mCi/kg, with a minimum administered activity of 1 mCi and maximum administered activity of 20 mCi [12].
2. Radiopharmaceuticals localizing in the thyroid in proportion to thyroid function can help outline the thyroid anatomy (see the ACR-SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease) [13].

a. Technetium-99m pertechnetate is given intravenously in an administered activity of 1 to 10 mCi (37-370 MBq) and is trapped by the follicular cells of the thyroid.

b. Iodine-123 sodium iodide is given orally in an administered activity of 200 to 600 μCi (7.5-22 MBq) and is trapped and organized by the follicular cells of the thyroid.

C. Imaging Protocols

There are two different strategies for imaging: (1) single radiopharmaceutical dual-phase imaging (early and delayed) and, less commonly, (2) dual radiopharmaceutical imaging (two different radiopharmaceuticals). For both strategies, it is important to image the neck and mediastinum (at least through the mid heart) to evaluate for possible ectopic parathyroid tissue. Single photon emission computed tomography (SPECT) imaging separately or together with computed tomography (SPECT/CT) has been shown to increase sensitivity and greatly improve anatomic localization for the surgeon, especially in cases of ectopic parathyroid tissue. SPECT or SPECT/CT imaging is most sensitive and accurate when performed immediately after the initial planar images [6,8].

1. Single radiopharmaceutical with single-phase or dual-phase imaging

After intravenous administration of technetium-99m sestamibi, is given intravenously anterior, right anterior oblique, and left anterior oblique planar images of the thorax are obtained at 10 to 30 minutes (early images) and again at 90 to 180 minutes (delayed images). Because abnormal parathyroid tissue usually retains the radiopharmaceutical for a longer period of time than normal thyroid or parathyroid tissue, abnormal tissues appear as persistent foci of increased activity on the delayed images. Although the single radiopharmaceutical dual-phase imaging technique relies on differential washout, some parathyroid lesions with more rapid radiopharmaceutical washout may be difficult to detect. Single-photon emission computed tomography (SPECT)/CT, SPECT, and dual radiopharmaceutical imaging have increased sensitivity and may improve detection of abnormal parathyroid tissue with rapid washout [14]. If SPECT or SPECT/CT is not performed as part of the protocol, pinhole-collimated images of the neck can improve resolution and permit anterior oblique images for lesion depth estimation.

2. Dual radiopharmaceutical imaging

In this strategy, an image acquired after the administration of a radiopharmaceutical that accumulates only in thyroid tissue (technetium-99m pertechnetate or iodine-123 sodium iodide) is subtracted digitally or by qualitative visual comparison from an image acquired after administration of a radiopharmaceutical that localizes in both thyroid and parathyroid tissue (technetium-99m sestamibi). Imaging relies on using appropriate photopeaks of the two radiopharmaceuticals administered or different administered activities of the two radiopharmaceuticals. Two approaches are used: (1) the thyroid-seeking radiopharmaceutical is given first or (2) the parathyroid radiopharmaceutical is given first.

3. SPECT or SPECT/CT imaging

SPECT imaging, separately or together with SPECT/CT, has been shown to increase sensitivity and greatly improve anatomic localization for the surgeon, especially in cases of ectopic parathyroid tissue. SPECT or SPECT/CT imaging is most sensitive and accurate when performed immediately after the initial planar images with the field of view matching that of the planar images.
Various protocols for SPECT/CT and SPECT imaging with single- and dual-phase technetium-99m sestamibi parathyroid scintigraphy are in clinical use. These include performing SPECT/CT (or SPECT) immediately after the early planar images, after the delayed planar images, or after both sets of images. One large investigation showed that early SPECT/CT (or SPECT) imaging in combination with any delayed imaging method (planar, SPECT, or SPECT/CT) had the highest accuracy for parathyroid adenoma localization. This is thought to be related to the rapid sestamibi washout from some parathyroid adenomas and many hyperplastic parathyroid glands [8,10].

VI. EQUIPMENT SPECIFICATIONS

A. Gamma Camera

Any gamma camera may be used. A low-energy, high-resolution parallel-hole collimation collimator is the standard for imaging the neck and mediastinum. Pinhole collimation may improve resolution of the neck and permit 35° right and left anterior oblique and lateral images for lesion depth determination [15]. A 20% window centered around a 140-keV photopoint should be used [8].

B. SPECT, SPECT/CT

Various methodologies for SPECT/CT and SPECT imaging with single- and dual-phase technetium-99m parathyroid scintigraphy are in clinical use. These include performing SPECT/CT (or SPECT) immediately after the early planar images, after the delayed planar images, or after both sets of images. One large investigation showed that early SPECT/CT (or SPECT) imaging in combination with any delayed imaging method (planar, SPECT, or SPECT/CT) had the highest accuracy for parathyroid adenoma localization. This is thought to be related to the rapid sestamibi washout from some parathyroid adenomas and many hyperplastic parathyroid glands [6,8].

SPECT data are optimally acquired over a 360° elliptical body-contouring orbit. The SPECT acquisition requires approximately 25 minutes and ranges from 120 to 60 projections obtained at 15 to 25 seconds per projection at 3°- to 6° angles, depending on the sensitivity of the detector and number of projections. The SPECT data are acquired into a 128 × 128 matrix corrected for attenuation and reconstructed using an ordered subset expectation maximization iterative technique. A 3-D postprocessing filter is usually applied to the SPECT data as per the manufacturer’s specifications.

CT acquisition parameters vary according to individual patient, laboratory, and equipment manufacturer. Typically, a tube current ranging from 100 to 200 mAs and a voltage of 120 kVp (ranging from 100-140 kVp) are used. Also, 10-mm slices are typically reconstructed in a 256 × 256 matrix. Intravenous contrast is usually not administered for SPECT/CT parathyroid scintigraphy [8].

The reconstructed data are ideally displayed as separate SPECT, CT, and fusion image sets in the three standard projections (axial, coronal, and sagittal). These image sets should be coregistered so that the body regions are displayed by the number slices of any given projection.

At some centers, surgeons increasingly utilize handheld gamma probe devices to enhance their intraoperative identification of parathyroid lesions after administration of technetium-99m sestamibi at the same administered activity used for preoperative diagnostic examination. In such cases, skin marking may be done by the radiologist preoperatively, ie, within a few hours before the patient goes to surgery [7].

VII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [16].
The report should include the radiopharmaceutical, administered activity, and route of administration, as well as any other pharmaceuticals administered, also with dosage and route of administration.

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

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

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [17].
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 and the SPR.

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

**ACR**
- Twyla B. Bartel, DO, MBA, Chair
- Shane B. Anderson, MD
- Richard K. J. Brown, MD, FACP
- Marguerite T. Parisi, MD, MS

**SPR**
- Nadia F. Mahmood, MD
- Helen R. Nadel, MD, FRCPC

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

- Kevin P. Banks, MD, Co-Chair
- Richard K. J. Brown, MD, FACP, Co-Chair
- Alexandru C. Bageac, MD, MBA
- Twyla B. Bartel, DO, MBA
- Murray D. Becker, MD, PhD, FACP
- Erica J. Cohen, DO, MPH
- Joanna R. Fair, MD
- Erin C. Grady, MD
- Edward D. Green, MD
- Jeffrey S. Kempf, MD, FACP
- Jennifer J. Kwak, MD
- Charito Love, MD
- Syam P. Reddy, MD
- Levi Sokol, MD
- Rathen M. Subramaniam, MD, PhD, MPH
- Stephanie P. Yen, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

- Beverley Newman, MB, BCh, BSc, FACP, Chair
- Timothy J. Carmody, MD, FACP
- Tara M. Catanzano, MB, BCh
- Lee K. Collins, MD
- Kassa Darge, MD, PhD
- Monica S. Epelman, MD
- Dorothy L. Gilbertson-Dahdal, MD
- Safwan S. Halabi, MD
- Kerri A. Highmore, MD
- Sue C. Kaste, DO
- Terry L. Levin, MD, FACP
- Matthew P. Lungren, MD, MPH
- Helen R. Nadel, MD
- Sumit Pruthi, MBBS
- Pallavi Sagar, MD
- Richard B. Towbin, MD, FACP
- Richard A. Barth, MD, FACP, Chair, Commission on Pediatric Radiology
- Jacqueline Anne Bello, MD, FACP, Chair, Commission on Quality and Safety

Comments Reconciliation Committee
- Gregory N. Nicola, MD, FACP, Chair
- Sachin Kumbhar, MD

PRACTICE PARAMETER Parathyroid Scintigraphy
2019 Resolution No. 38
PRACGRRTISE PARAMETER

NOT FOR PUBLICATION, QUOTATION, OR CITATION

Comments Reconciliation Committee
Catherine J. Everett, MD, MBA, FACR, Co-Chair
Shane B. Anderson, MD
Kevin P. Banks, MD
Twyla B. Bartel, DO
Richard A. Barth, MD, FACR
Jacqueline A. Bello, MD, FACR
Richard K. J. Brown, MD, FACR
Richard Duszak, Jr., MD, FACR
Bennett S. Greenspan, MD, MS, FACR
Nadia F. Mahmood, MD
Helen R. Nadel, MD, FRCPC
Mary S. Newell, MD, FACR
Beverley Newman, MB, BCh, BSc, FACR
Marguerite T. Parisi, MD, MS
Matthew S. Pollack, MD, FACR
Timothy L. Swan, MD, FACR
Don C. Yoo, MD, FACR

REFERENCES


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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
1995 (Resolution 31)
Revised 1999 (Resolution 14)
Revised 2004 (Resolution 31d)
Amended 2006 (Resolution 35)
Revised 2009 (Resolution 16)
Revised 2014 (Resolution 32)
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 39

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Radium-223

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 THE PERFORMANCE OF THERAPY WITH RADIUM-223

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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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 unsealed radiopharmaceutical sources. Such therapy requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient and those who administer radiopharmaceutical therapy and manage the attendant side effects. Adherence to this parameter should help to maximize the efficacious use of radium-223, maintain safe conditions, and ensure compliance with applicable regulations.

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

The goal of therapy with unsealed radiopharmaceutical sources is to provide either cure or significant prolongation of disease specific survival, and effective reduction and/or prevention of adverse disease-related symptoms or untoward events while minimizing treatment-associated side effects and complications.

II. DEFINITION

Therapy with unsealed sources involves administration of radiopharmaceuticals for the treatment of medical conditions.

Radium-223 dichloride (radium-223) is an alpha particle–emitting isotope used for targeted bone therapy. It is used for the treatment of metastatic cancer to bone.

III. INDICATIONS

Radium-223 is indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic metastatic to bone, and without known visceral metastatic disease. Selected patients with CRPC metastatic to bone, but with minimal visceral disease, may be appropriate candidates for treatment with radium-223.

As no widely accepted criteria to define CRPC exist outside of a clinical trial, the decision requires the clinical judgment of the treating physician. In practice, patients who have evidence of disease progression despite adequate (serum testosterone <50 ng/dL) androgen-deprivation therapy [2,3] are considered castration resistant.
Evidence of disease progression includes:

- New metastasis while on androgen-deprivation therapy.
- Progression of existing metastases while on androgen-deprivation therapy.
- A rise in serum prostate-specific antigen (PSA) while on androgen-deprivation therapy, particularly in patients without metastases, confirmed by a second PSA at least 1 week apart.

Bone metastases may be considered symptomatic for the purposes of qualification for radium-223 therapy at the discretion of the treating physician. Symptomatic bone metastases are defined as two or more metastases to the skeleton resulting in clinical signs or symptoms, including pain, decreased mobility, impaired function, or fracture. Bone metastases requiring intervention with surgery or external-beam radiation therapy are also considered to be symptomatic.

Visceral metastatic disease includes involvement of liver and other solid intra-abdominal organs, peritoneum, lung, and brain. Other soft-tissue sites of disease (eg, prostate bed or bladder wall) and lymph nodes are not considered as visceral.

Radium-223 dichloride is not currently FDA approved for use in the treatment of malignancies other than CRPC though it is anticipated that radium-223 may be of benefit in patients with other cancer types demonstrating osteoblastic metastases. Additional uses of radium-223 may occur as part of a clinical trial.

IV. 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–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [1,4]. In addition, training and experience must be in compliance with the applicable laws and regulations.

V. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

The written or electronic request for a radiopharmaceutical 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 - revised in 2016, Resolution 12-b)

General Procedures

1. Clinical evaluation

Clinical Evaluation: Radium-223 dichloride is a radiopharmaceutical delivered intravenously (monthly for six injections). It is FDA approved for the treatment of patients with symptomatic CRPC with bone-predominant metastatic disease. At least two bone metastases should be identified on imaging studies, and there should be no evidence of visceral metastases (malignant adenopathy ≤3 cm in the short axis is allowed). Before the treatment is administered, each patient should have a consultation with a radiation oncologist, nuclear medicine physician, or nuclear radiologist that includes a complete history and physical
examination and a review of prior radiotherapy and systemic therapy for prostate cancer. The patient’s life expectancy should be >6 months with a preferable ECOG Performance Status of 0 to 2. Pain assessment and patient-reported symptoms should be documented to evaluate the quality of life of patients before, during, and after the treatment. Laboratory studies including a complete blood count (CBC) with an absolute neutrophil count (ANC), should be obtained within 30 days prior to first injection. PSA and alkaline phosphatase (ALP) may be obtained prior to first injection. During radium-223 therapy, however, changes in ALP have been shown to correlate more with response compared with changes in PSA alone. A bone scan or NaF-PET-CT should be obtained to assess for active osteoblastic metastases prior to first therapy. A CT scan of the chest, abdomen, and pelvis should be performed to assess for visceral metastasis. Because myelosuppression is a side effect of radium-223, a CBC with differential should be performed before each subsequent injection. Special consideration of the benefits and risks of radium-223 should be given for patients with the following situations: Exclusion criteria include cytotoxic chemotherapy within 4 weeks prior to administration of radium-223, external-beam hemibody radiation treatment, and systemic radionuclides within 24 weeks of therapy, and imminent spinal cord compression. Epidural tumor or spinal cord compression should be treated with external-beam radiation therapy prior to radium-223 therapy. Currently, it is not recommended to use radium-223 in combination with abiraterone plus prednisone/prednisolone outside a clinical trial (see below: 7j). For initial treatment with radium-223, the following hematologic parameters are recommended: ANC > 1.5 × 10^9/L, platelets ≥ 100 × 10^9/L; hemoglobin (Hgb) ≥ 10.0 g/dL. For subsequent treatments: ANC > 1.0 × 10^9/L, platelets > 50 × 10^9/L, and with no set parameters for Hgb. For patients who experience a decrease in Hgb while on radium-223 therapy, a transfusion of red blood cells may be considered at the discretion of the referring and treating physicians.

2. Quality Management

In order to use radiopharmaceuticals as unsealed sources for therapy, a “quality management” program must be in place as required by the U.S. Nuclear Regulatory Commission (NRC) or by Agreement State regulations. (An Agreement State is any state with which the NRC or the U.S. 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.) All radium-223 injections should be preceded by a written directive from the authorized user specifying radiopharmaceutical, indication, prescribed dose, and route of administration. As with any radionuclide therapy, the treating physician is responsible for confirming the patient identity using a minimum of two forms of identification (ie, name, date of birth) prior to radium-223 injection.

The radiopharmaceutical is ordered 1 week prior to therapy. The activity should be measured and documented before injection in order to confirm that the activity is within acceptable NRC or state regulatory specifications. After the patient receives the injection, the residual activity of the postinjection needle and line will be determined. The ordered and measured pre- and postinjection activities should be recorded, and the actual administered radium-223 activity with the radiopharmaceutical lot number should be made part of the permanent hospital/clinic record. Under ideal conditions, the consulting physician should be the medical professional administering the radium-223. If this is not possible because of scheduling issues, a covering physician with experience in unsealed radiopharmaceutical therapy should assume responsibility for patient identification and for safe and effective injection. Reliable intravenous access must be ensured prior to dose delivery. A procedure using a superficial upper-extremity or antecubital vein butterfly needle, three-way stopcock, and 10-ml saline flush works best and allows for safe, maximum effective delivery of the prescribed radiopharmaceutical. All intravenous lines and connections used in the delivery of radium-223 should be secure. The treatment should be administered, using an appropriate syringe shield and disposable gloves, into an intravenous port or an arm resting on a bedside
3. Informed consent

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

4. Treatment

The procedure and follow-up should be performed per an established system of procedural steps in a facility that is appropriately licensed for and by staff who comply with local, state, and national rules for the administration of radiopharmaceuticals.

Radium-223 is usually administered once every 4 weeks for six injections.

The standard administered activity of radium-223 is 55 kBq (1.49 μCi) per kilogram of body weight, given by slow intravenous injection over 1 minute. The intravenous access line should be well-established and flushed with isotonic saline before injection of radium-223 to ensure patency and avoid extravasation. The intravenous access line should also be flushed with isotonic saline after injection of radium-223.

Administration of radium-223 may be delayed up to 6 to 8 weeks after the last administration of radium-223 for recovery of treatment-related cytopenias. If blood counts do not recover within 6 to 8 weeks after the last radium-223 administration despite supportive care, further treatment with radium-223 should be discontinued.

5. Radiation precautions

With each treatment in the six-part therapy, patients should receive instructions regarding limited radiation precautions for the home, largely relating to blood, stool, and body fluid precautions in the initial week following therapy. Patients should be advised to sit when urinating, to use disposable gloves to manage catheters conveying urine or other bodily fluids, and to clean spilled urine or other soiled surfaces or garments. Heavily contaminated or soiled garments should be washed separately. Fluid intake and bathroom usage should be encouraged. Sharing of food or drink and sexual contact should be discouraged along with prolonged close contact with children or pregnant women for a period of 2 weeks after injection.

6. Complications

The 3-year safety profile of radium-223 dichloride in patients with CRPC and symptomatic bone metastases, in Alpharadin Symptomatic Prostate Cancer trial (ALSYMPCA), has been recently published [6]. During treatment to 12 weeks following the last injection, 564/600 (94%) radium-223 and 292/301 (97%) placebo patients had treatment-emergent adverse events (TEAEs). Myelosuppression incidence was low. Grade 3/4 hematologic TEAEs in radium-223 and placebo groups were anemia (13% versus 13%), neutropenia (2% versus 1%), and thrombocytopenia (7% versus 2%). Ninety-eight of 600 (16%) radium-223 and 68/301 (23%) placebo patients experienced grade 5 TEAEs. Long-term follow-up showed no acute myelogenous leukemia, myelodysplastic syndrome, or new primary bone cancer. Secondary non-
treatment-related malignancies occurred in four radium-223 and three placebo patients. One radium-223 patient had aplastic anemia 16 months after the last injection. The most common adverse reactions in patients receiving radium-223 include nausea, diarrhea, vomiting, and peripheral edema. Transient increase in bone pain or “flare” has also been reported.

7. Published data, background, and trials

Radium-223 dichloride has primarily been investigated for the treatment of CRPC with symptomatic skeletal metastases [6-8].

a. A multinational phase III randomized (2:1) double-blind controlled trial (ALSYMPCA) of 922 men with CRPC and symptomatic bone metastases was performed to test radium-223 (given intravenously at 50 kBq/kg) versus placebo for up to six cycles at 4-week intervals.

b. Overall survival was the primary endpoint.

c. The study was stopped early following a planned interim analysis when data showed a median overall survival advantage in favor of radium-223 (14.0 versus 11.2 months, \( p = .019 \); hazard ratio (HR) 0.695).

d. Fewer skeletal-related events (SREs) were seen in the radium-223 arm. In particular, radium-223 resulted in a significant reduction in epidural spinal cord compression events (3% versus 6%, \( p = .016 \)).

Also, the time to first SRE was extended for subjects in the radium-223 arm (13.6 versus 8.4 months, \( p = .0005 \)).

e. There were no differences in adverse events or serious adverse events between the arms.

f. Radium-223 was associated with modest effects on Grade 3/4 neutropenia (1.8% versus 0.8%) and thrombocytopenia (4% versus 2%) [8].

g. Both safety and efficacy of radium-223 versus placebo were favorable even in subjects with prior docetaxel treatment [7].

h. Cytotoxic chemotherapy can be safely delivered to patients following radium-223 treatment [9].

i. Treatment with radium-223 resulted in an improvement in key quality of life measures versus placebo [10].

j. Although an early phase trial suggested concomitant use of radium-223 with abiraterone, enzalutamide or denosumab were safe and resulted in an improved median overall survival compared with radium-223 alone [11], a subsequent phase III trial (ERA223) exploring radium-223 plus abiraterone in patients with asymptomatic or mildly symptomatic chemotherapy-naïve metastatic CRPC was unblinded early after more fractures and deaths were observed in patients receiving both radium-223 and abiraterone acetate compared with patients receiving abiraterone alone. The package insert for radium-223 was updated to state that its use in combination with abiraterone plus prednisone/prednisolone is not recommended outside a clinical trial.

k. Retreatment with radium-223 following disease progression after a first course was both safe and effective in a phase I/II study, with a median overall survival of 24.4 months in retreated patients [12].

Clinical trials for radium-223 for patients with cancers of the prostate, breast, thyroid, bladder, kidney, osteosarcoma, and multiple myeloma are ongoing.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR-ASTRO Practice Parameter for Communication: Radiation Oncology [13].

The report should include the radiopharmaceutical used, the dose and route of administration, as well as any other pharmaceuticals administered, also with dose and route of administration.
VII. ACR 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 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 therapies using unsealed radioisotopes. 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 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 therapy with specific unsealed radiopharmaceuticals under the supervision of an AU for the specific therapeutic radiopharmaceutical. Although they may not issue written directives for those specific radiopharmaceuticals, they may administer such a dosage as designated by an AU.

- Physicians who are board-certified in DR, NR, NM, or RO and hold AU status based on that certification and site-specific credentialing.

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 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
IX. 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [14].

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 — Nuclear Medicine and Molecular Imaging of the ACR Commissions on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters — Radiation Oncology of the ACR Commission on Radiation Oncology, in collaboration with the ACNM, the ASTRO, and the SNMMI.

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

ACR
Mark Hurwitz, MD, Co-Chair
Eric M. Rohren, MD, PhD, Co-Chair
Rathan M. Subramaniam, MD, PhD, MPH
Ying Xiao, PhD

ACNM
Alan K. Klitzke, MD
Dominick Lamonica, MD
Yang Lu, MD

ASTRO
Tod W. Speer, MD
Michael B. Tomblyn, MD
William W. Wong, MD

SNMMI
John R. Buscombe, MD
Heather A. Jacene, MD
Daniel A. Pryma, MD
Holly M. Thompson, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Richard K. J. Brown, MD, FACR, Co-Chair
Alexandru C. Bageac, MD, MBA
Twyla B. Bartel, DO, MBA
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH

Edward D. Green, MD
Jeffrey S. Kempf, MD, FACP
Jennifer J. Kwak, MD
Charito Love, MD
Syam P. Reddy, MD
Levi Sokol, MD
Committee on Practice Parameters – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Joanna R. Fair, MD
Erin C. Grady, MD
Rathan M. Subramaniam, MD, PhD, MPH
Stephanie P. Yen, MD

Committee on Practice Parameters – Radiation Oncology
(ACR Committee responsible for sponsoring the draft through the process)

Alan C. Hartford, MD, PhD, FACR, Chair
Naomi R. Schechter, MD, Vice Chair
Nathan H. J. Bittner, MD
Samuel T. Chao, MD
Chee-Wai Cheng, PhD, FAAPM
Neil B. Desai, MD
Nancy A. Ellerbroek, MD, FACR
Mark Hurwitz, MD
Lesley A. Jarvis, MD, PhD
Join Y. Luh, MD
Matthew Poggi, MD
Helen A. Shih, MD
Nikhil Thaker, MD
Paul E. Wallner, DO, FACR
Kristina L. Woodhouse, MD
Ying Xiao, PhD
Sue S. Yom, MD, PhD
Bassem I. Zaki, MD

Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Seth A. Rosenthal, MD, FACR, Chair, Commission on Radiation Oncology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Darlene F. Metter, MD, FACR, Chair
William Small, Jr., MD, FACR, Co-Chair
Gad Abikhzer, MD
Helena Balon, MD
Kevin P. Banks, MD
Jacqueline A. Bello, MD, FACR
Richard K. J. Brown, MD, FACR
John R. Buscombe, MD
Richard Duszak, Jr., MD, FACR
Saeed Elojeimy, MD, PhD
Alan C. Hartford, MD, PhD, FACR
Mark Hurwitz, MD
Heather A. Jacene, MD
Alan K. Klitzke, MD
Dominick Lamonica, MD
Yang Lu, MD
Mary S. Newell, MD, FACR
Matthew S. Pollack, MD, FACR
Daniel A. Pryma, MD
Eric M. Rohren, MD, PhD
Seth A. Rosenthal, MD, FACR
Naomi R. Schechter, MD
Tod W. Speer, MD
Rathan M. Subramaniam, MD, PhD, MPH
Timothy L. Swan, MD, FACR
Holly M. Thompson, MD
Michael B. Tomblyn, MD
Daniel J. Wale, DO
William W. Wong, MD
Ying Xiao, PhD
Don C. Yoo, MD, FACR

REFERENCES


PRACTICE PARAMETER
Radium-223
2019 Resolution No. 39


*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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RESOLUTION NO. 40

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–SNMMI–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease

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 33)*

ACR–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF SCINTIGRAPHY AND UPTAKE MEASUREMENTS FOR BENIGN AND MALIGNANT THYROID DISEASE

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, ___ N.W.2d ___ (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

Thyroid Scintigraphy

2019 Resolution No. 40
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 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 and interpreting thyroid scintigraphy, thyroid radioiodine uptake (RAIU) measurements, and whole-body radioiodine scintigraphy. Properly performed imaging and uptake examinations provide critical information on a variety of conditions that relate to the thyroid gland. Although results can suggest specific medical conditions or diseases, the examination should be correlated with clinical information, including thyroid function tests, thyroid physical examination, and recent medications or iodine ingestion. Findings should be correlated with other available imaging examinations, such as computed tomography (CT), magnetic resonance imaging (MRI), positron emission/computed tomography (PET/CT), radiography, ultrasonography, and/or prior thyroid scintigraphy. Adherence to this practice parameter should optimize detection and characterization of abnormal thyroid morphology and function.

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

Thyroid scintigraphy facilitates the detection of focal and/or diffuse abnormalities of thyroid morphology, correlation of morphology with function, and detection of aberrant or metastatic functioning thyroid tissue, or residual native tissue after therapy.

Thyroid uptake allows measurement of global function of the thyroid gland as reflected by the quantitative evaluation of radioiodine accumulation and kinetics.

II. INDICATIONS AND CONTRAINDICATIONS

A. Thyroid scintigraphy is useful in, but not limited to, the evaluation of the following:

1. Size and location of thyroid tissue
2. The cause of overt and subclinical thyrotoxicosis hyperthyroidism
3. Suspected focal masses or diffuse thyroid disease
4. Clinical laboratory tests suggestive of abnormal thyroid function
5. Function of thyroid nodules detected on clinical examination or other imaging examinations
6. Congenital thyroid abnormalities, including ectopia
7. Differentiating hyperthyroidism from other forms of thyrotoxicosis (eg, subacute or chronic thyroiditis and thyrotoxicosis factitia)
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B. Thyroid uptake is useful for the following:

1. Differentiating hyperthyroidism from other forms of thyrotoxicosis (eg, subacute or chronic thyroiditis and thyrotoxicosis factitia)

2. Calculating iodine-131 sodium iodide administered activity for patients to be treated for hyperthyroidism or ablative therapy (see the ACR Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources) [2]

C. Whole-body imaging for thyroid carcinoma is useful for determination of presence and location of the following:

1. Residual functioning thyroid tissue or cancer after surgery for thyroid cancer or after ablative therapy with radioiodine

2. Metastases from iodine-iodine-avid forms of thyroid cancer

D. Contraindications

Administration of iodine-131 sodium iodide to pregnant or lactating patients (whether currently breastfeeding or not) is contraindicated. Complete cessation of breastfeeding 6 weeks prior to administration of iodine-131 sodium iodide is recommended to decrease the radiation absorbed dose to the maternal breast tissue and prevent the ingestion of radioactive breast milk by the nursing child [3-5].

The ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [6].

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 thyroid scintigraphy and uptake measurements 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

PRACTICE PARAMETER

Thyroid Scintigraphy

2019 Resolution No. 40
A. Thyroid Scintigraphy

1. Radiopharmaceutical

The preferred radiopharmaceutical for thyroid scintigraphy is iodine-123 sodium iodide administered orally in a capsule or as a liquid. In adults, the administered activity is 0.2 to 0.4 mCi (7.4-14.8 MBq). For children, the administered activity should be 0.006 0.0075 mCi/kg (0.28 MBq/kg) with a minimum administered activity of 0.025 0.027 mCi (0.925 1 MBq) and a maximum administered activity of 0.4 0.3 mCi (14.8 11 MBq) [7]. Use of iodine-131 sodium iodide is strongly discouraged for routine scintigraphy use because of its much greater radiation dose to the thyroid.

An alternative radiopharmaceutical is technetium-99m sodium pertechnetate administered intravenously. In adults, the administered activity is 2 to 10 mCi (74-370 MBq). For children, the administered activity is 0.003 0.03 mCi/kg (0.1-1.1 MBq/kg) with a minimum administered activity of 0.2 19 mCi (7.4 7 MBq) and maximum administered activity of 2.5 mCi (74 92.5 MBq) [7]. Technetium-99m sodium pertechnetate is the preferred agent for evaluating congenital hypothyroidism in neonates due to its ability to provide information about morphology and also excessive trapping as seen in organification defects.

The choice between iodine-123 sodium iodide and technetium-99m sodium pertechnetate for thyroid scintigraphy depends on local practice and physician preference. The longer physical half-life (13.2 hours) and intrathyroidal organification of iodine-123 sodium iodide allows for improved target-to-background ratio, functional thyroid gland imaging, and radioiodine uptake RAIU assessment. Technetium-99m has a higher photon flux, which results in shorter imaging times. It results in a lower radiation exposure to the thyroid, although the total body exposure is slightly higher. Technetium-99m is readily available from a molybdenum-99/technetium-99m generator and is less expensive than iodine-123 sodium iodide. Technetium-99m does not undergo thyroidal organification, and rapid thyroid washout of technetium-99m limits its use for quantitative assessment of thyroid uptake. Rarely, findings on radioiodine and technetium images may be discordant in nodular disease because pertechnetate is not handled by the same physiologic mechanism as iodine.

2. Pharmacologic considerations

Many medications interfere with the accumulation of radiopharmaceuticals in the thyroid gland.

### Compounds That May Decrease Thyroid Iodine Uptake

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>TIME*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methimazole</td>
<td>3-5 days</td>
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<tr>
<td>Propylthiouracil</td>
<td>3-5 days</td>
</tr>
<tr>
<td>Bromides</td>
<td>1 week</td>
</tr>
<tr>
<td>Mercurials</td>
<td>1 week</td>
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<tr>
<td>Nitrates</td>
<td>1 week</td>
</tr>
<tr>
<td>Perchlorate</td>
<td>1 week</td>
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<tr>
<td>Salicylates (large doses)</td>
<td>1 week</td>
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<tr>
<td>Sulfonamides</td>
<td>1 week</td>
</tr>
<tr>
<td>Thiocyanate</td>
<td>1 week</td>
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<tr>
<td>Iodine-containing cough medicines and vitamins</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Iodine solution (Lugol’s or SSKI**)</td>
<td>2-3 weeks</td>
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<tr>
<td>Iodine-containing topical agents</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Kelp</td>
<td>2-3 weeks</td>
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<tr>
<td>Tri-iodothyronine (T3)</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Levothyroxine (T4)</td>
<td><strong>4-6 weeks</strong></td>
</tr>
<tr>
<td>Thyroid extracts (desiccated thyroid extracts)</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>
Intravenous iodinated contrast materials 4-6 to 8 weeks
Oil-based iodinated contrast materials 3-6 months
Amiodarone 3-6 months

*Time that patients should wait after medication is discontinued in order to obtain accurate uptake

**Saturated solution of potassium iodide

A thorough medical history should be obtained prior to administering the radiopharmaceutical and, if necessary, the examination should be delayed appropriately.

3. Patient

The patient should be placed in a supine position, with the neck comfortably extended. It may be helpful to gently immobilize the head. When indicated, the physician should palpate the thyroid gland while the patient is in the imaging position as well as when the patient is upright.

4. Imaging

With iodine-123 sodium iodide, imaging can commence as early as 3 to 4 hours or as late as 24 hours after administration. For technetium-99m pertechnetate, imaging should commence 5 to 30 minutes after injection. Radioactive sources or lead markers may be used to identify anatomic landmarks, such as the sternal notch and thyroid cartilage. The location of palpable nodules should be confirmed with a marker for anatomic correlation.

B. Thyroid Uptake

1. Radiopharmaceutical

   If thyroid radioiodine uptake RAIU is performed in conjunction with thyroid scintigraphy, the activity administered for the scan will suffice. If the uptake is performed separately or in conjunction with a technetium-99m pertechnetate scan, as little as 0.1 mCi (3.7 MBq) of iodine-123 sodium iodide or 0.004 to 0.005 mCi (0.15-0.185 MBq) of iodine-131 sodium iodide may be used. If only a thyroid uptake with iodine-131 sodium iodide is obtained, the administered activity should not exceed 0.01 mCi (0.37 MBq).

2. Pharmacologic considerations: See section IV.A.2

3. Procedure

   The usual time of measurement is approximately 24 hours after radiopharmaceutical administration. An additional uptake measurement may be performed at 4 to 6 hours, particularly in cases of suspected rapid iodine turnover. The percent uptake should be compared to normal values measured at the same time after radiopharmaceutical administration, if available. The patient should sit or lie with neck extended; an open-faced collimated detector probe should be directed at the neck, with the crystal usually no more than 20 to 30 cm away.

   There are several acceptable measurement and calculation techniques; the following is one example. Counts are acquired for 1 minute over the thyroid gland. Counts are then acquired over the patient’s mid-thigh for 1 minute and at the same distance (eg, 20-30 cm), taking care to exclude the urinary bladder from the detector field. A standard (source of the same radiopharmaceutical of identical activity to that administered to the patient) or the radioiodine capsule being administered to the patient is placed in a standardized Lucite scattering neck phantom and counts are acquired for 1 minute using the same geometry. The room background counts also are acquired for 1 minute.
The radioiodine uptake (RAIU) is calculated using the following formula:

\[
\text{RAIU} = \frac{\text{Neck Counts} - \text{Thigh Counts}}{\text{Phantom Counts} - \text{Background}} \times 100\%
\]

C. Imaging for Thyroid Carcinoma

1. Radiopharmaceutical

Whole-body radioiodine imaging for thyroid cancer can be performed either as a diagnostic examination (after administration of activity of radioiodine in the diagnostic range) or after administration of a therapeutic administered activity of iodine-131 sodium iodide. Diagnostic whole-body imaging can be performed with either iodine-123 sodium iodide or iodine-131 sodium iodide. Image quality is better with iodine-123 sodium iodide, but its use may be limited by commercial availability or cost [8,9]. Occasionally, other radiopharmaceuticals, including fluorine-18 fluorodeoxyglucose, technetium-99m sestamibi, technetium-99m tetrofosmin, or thallium-201 thallous chloride are used to evaluate and image thyroid cancer.

a. Preparation

Thyroid hormone replacement should be withheld for a time sufficient to render the patient hypothyroid (serum thyroid-stimulating hormone [TSH] level greater than 30 mU/L), or recombinant human thyroid-stimulating hormone (rhTSH; thyrotropin alpha, such as Thyrogen®) stimulation should be used according to an established protocol.

The use of a low-iodine diet may increase the sensitivity of the imaging examination and the efficacy of iodine-131 sodium iodide ablation by decreasing serum iodine levels, which can increase RAIU [10-12]. Subsequently, use of a low-iodine diet may also increase the sensitivity of the imaging examination. Typically, the low-iodine diet is started 1 to 2 weeks prior to radioiodine administration [10], and continued for several days during imaging and/or radioiodine therapy [4].

b. Procedures

i. Diagnostic Whole-Body Radioiodine Scintigraphy

Administered activity of 1.0 to 5.0 mCi (37-185 MBq) of iodine-131 sodium iodide is given orally, and imaging of the neck and the whole body is performed 24 to 72 hours later using a high-energy collimator designed for iodine-131 sodium iodide. Iodine-123 sodium iodide is considered an alternative radiopharmaceutical because of the “stunning” phenomenon that may be encountered when administering iodine-131 sodium iodide for pretherapy diagnostic scintigraphy [13]. Typically administered activity for iodine-123 sodium iodide is 1.5 to 5 mCi (55.5-185 MBq).

In addition to whole-body anterior and posterior parallel-hole collimator images, spot views of the thyroid bed and neck obtained with a pinhole collimator [14], Pinhole images of the thyroid bed and anterior, posterior, and right and left lateral parallel-hole images of the head and neck, chest, and, as needed, anterior and posterior images of the chest and abdomen obtained with a parallel-hole collimator may improve lesion detection. Single photon emission computed tomography (SPECT) imaging may be performed as needed. SPECT/CT imaging may replace or complement planar and pinhole imaging by improving anatomical localization, lesion detection, and diagnostic accuracy [15,16].
Administered activity for children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality. Consensus practice parameters are currently in progress but not yet finalized. Currently, consensus practice parameters for body weight–based administered activity of iodine-131 and iodine-123 for whole-body scintigraphy for children are not available. However, administered activity of 1.5 to 5 mCi, similar to adults, can be used. Activity range of 3 to 5 mCi of iodine-123 for whole-body scintigraphy has been used for children [17].

ii. Posttherapy Whole-Body Radioiodine Scintigraphy

Iodine-131 sodium iodide whole-body imaging may be performed 2 to 14 days (typically at 5–7 days) after thyroid ablative therapy to detect residual thyroid tissue in the neck and/or iodine-avid metastases that may not have been detected on pretherapy imaging examinations, if performed [18]. Uptake values may also be calculated for the residual thyroid tissue in the thyroid bed using the technique described in section IV.B.3.

c. Alternative protocols

Whole-body F-18-fluorodeoxyglucose-PET/CT (FDG-PET/CT) may be used to evaluate patients who have a history of well-differentiated thyroid cancer that is not iodine-avid and have elevated thyroglobulin levels [10]. FDG-PET/CT can detect metastatic disease and change patient management in suspected thyroid cancer recurrence [19]. Studies have demonstrated that stimulated TSH levels with thyroid hormone withdrawal or rhTSH may increase the sensitivity of FDG PET/CT for the detection of metastatic thyroid cancer [20,21]. Studies have shown that FDG-PET and PET/CT detect metastatic disease in approximately 70 percent of these patients. Most of the studies have been performed while patients are on thyroid hormone, but there is emerging evidence that the sensitivity of the examination may increase in patients with stimulated TSH levels [8].

V. EQUIPMENT SPECIFICATIONS

A. Thyroid Imaging

Typically, a gamma camera equipped with a pinhole collimator is used. Images are acquired in the anterior, and often both anterior oblique, projections for a minimum of 100,000 counts or 8 minutes, whichever occurs first. The distance between the collimator aperture and the neck should be such that the thyroid occupies most of the field of view. With pinhole collimators, significant geometric distortion occurs. Additional views with a parallel-hole collimator may be useful when searching for ectopic tissue or estimating thyroid size. Collimator choice should be appropriate to the radiopharmaceutical used.

B. Thyroid Uptake

A thyroid probe is typically used. A gamma camera with a parallel-hole collimator may be used instead of a probe, but the use of a standardized neck phantom remains necessary.

C. Imaging for Thyroid Carcinoma

For iodine-131 sodium iodide imaging, a high-energy collimator should be used with an appropriately shielded detector head. Pinhole collimator imaging of the thyroid bed may also be useful.

Whole-body imaging examinations are acquired with a low-energy collimator for iodine-123 sodium iodide and a high-energy collimator for iodine-131 sodium iodide. For imaging with iodine-123 sodium iodide, using a medium-energy collimator rather than a low-energy collimator may improve image quality due to down
scatter from a small amount of high-energy photons with photon energies greater than 300 keV [22,23]. If a low-energy collimator is used, down scatter correction should be applied [24,25]. For iodine-123 sodium iodide, the whole-body scan for iodine-123 sodium iodide may be performed 18 to 24 hours post administration of 2 mCi of iodine-123 sodium iodide at a scan speed of 8 cm per minute, matrix of 256 × 1,024. Typically for iodine-131 sodium iodide, whole-body imaging is performed in anterior and posterior images as a whole-body sweep (typically 4 cm per minute for approximately 30 minutes, from head to knees). Another protocol is 8 cm per minute with a 256 × 256 × 16 matrix for anterior and posterior images. In some patients, such as young children, it may be easier to acquire multiple planar images. If static planar images will be used, all images should be acquired for the same period of time to facilitate image comparison. Typically for iodine-131 sodium iodide, images of the torso are planned to acquire 300,000 to 500,000 counts. In some situations it may be helpful to image the thyroid bed with a pinhole collimator or to calculate thyroid bed radioiodine uptake RAIU as part of pretherapy imaging [14].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [26].

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

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

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

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

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [27].

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 SNMMI, and the SPR.

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

ACR
Jennifer J. Kwak, MD, Chair
Erin C. Grady, MD
Helen R. Nadel, MD

SNMMI
Anca M. Avram, MD, FACNM
Neeta D. Pandit-Taskar, MD

SPR
Sabah Servaes, MD
S. Ted Treves, MD
Jennifer L. Williams, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Richard K. J. Brown, MD, FACR, Co-Chair
Alexandru C. Bageac, MD, MBA
Twyla B. Bartel, DO, MBA
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH
Joanna R. Fair, MD
Erin C. Grady, MD

Edward D. Green, MD
Jeffrey S. Kempf, MD, FACR
Jennifer J. Kwak, MD
Charito Love, MD
Syam P. Reddy, MD
Levi Sokol, MD
Rathan M. Subramaniam, MD, PhD, MPH
Stephanie P. Yen, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverley Newman, MB, BCh, BSc, FACR, Chair
Timothy J. Carmody, MD, FACR
Tara M. Catanzano, MB, BCh

Kerri A. Highmore, MD
Sue C. Kaste, DO
Terry L. Levin, MD, FACR
Committee on Practice Parameters – Pediatric Radiology
Lee K. Collins, MD
Kassa Darge, MD, PhD
Monica S. Epelman, MD
Dorothy L. Gilbertson-Dahdal, MD
Safwan S. Halabi, MD
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Sumit Pruthi, MBBS
Pallavi Sagar, MD
Richard B. Towbin, MD, FACP

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Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Timothy A. Crummy, MD, FACR, Chair
Darlene F. Metter, MD, FACR, Co-Chair
Anca M. Avram, MD, FACNM
Kevin P. Banks, MD
Richard A. Barth, MD, FACR
Jacqueline A. Bello, MD, FACR
Richard K.J. Brown, MD, FACR
Richard Duszak, Jr., MD, FACR
Erin C. Grady, MD
Arnold Jacobson, MD
Jennifer J. Kwak, MD
Helen R. Nadel, MD
Beverley Newman, MB, BCh, BSc, FACR
Neeta D. Pandit-Taskar, MD
J. Anthony Parker, MD
Matthew S. Pollack, MD, FACR
Sabah Servaes, MD
Timothy L. Swan, MD, FACR
S. Ted Treves, MD
Mark Tulchinsky, MD
Jennifer L. Williams, MD
Don C. Yoo, MD, FACR

REFERENCES


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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year
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Amended 2006 (Resolution 35)
Revised 2009 (Resolution 17)
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NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 41

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources

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 49)*

ACR–ACNM–ASTRO–SNMMI PRACTICE PARAMETER FOR THE PERFORMANCE OF THERAPY WITH UNSEALED RADIOPHARMACEUTICAL SOURCES

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, ___ N.W.2d ___ (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 Unsealed Radiopharmaceutical Sources

2019 Resolution No. 41
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 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 who performing therapy procedures with unsealed radiopharmaceutical sources. Such therapy requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient and those who determine the appropriateness and timing, administer radiopharmaceutical therapy, manage the attendant safety and side effects. Adherence to this parameter should help to maximize the efficacious use of these procedures; maintain safe conditions for patients, medical personnel, and others possibly exposed; 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], as that standard also relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public. There must also be compliance with applicable state and federal laws and regulations.

Therapy with unsealed radiopharmaceutical sources entails the use of ionizing radiation, delivered internally via oral, parenteral, intra-articular or intracavitary methods to effectively treat cancer and other diseases. Such therapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education along with close cooperation and communication between the physicians who are responsible for the clinical management of the patient. Because the practice occurs in a variety of clinical environments, the judgment of a qualified authorized user (AU) should be used to apply these practice parameters to individual practices.

This practice parameter addresses the overall role of the applicable AU (generally a nuclear radiologist, nuclear medicine physician, or radiation oncologist), the Qualified Medical Physicist, and other specialized personnel involved in the delivery of radiopharmaceutical therapy. It includes detailed discussion of several therapeutic agents that hold a long-standing, well-defined role in cancer treatment (strontium-89, samarium-153 lexidronam, yttrium-90 ibritumomab tiuxetan), whereas separate practice parameters and standards define the appropriate use of novel radiopharmaceuticals or radiopharmaceuticals whose appropriate use are evolving.

AUs are specifically trained to weigh the benefits with the risks associated with exposure to ionizing radiation and should always follow the guiding principle of limiting radiation exposure to the patient while accomplishing the therapeutic goal.

The goal of therapy with unsealed radiopharmaceutical sources is to provide either cure or effective palliation of disease while minimizing untoward side effects and complications.
II. DEFINITION

Therapy with unsealed sources **may involve the oral, parenteral, intra-articular, or intracavitary** administration of radiopharmaceuticals for the treatment of **malignant and benign** medical conditions.

III. INDICATIONS

Examples of therapy with unsealed radiopharmaceutical sources include, but are not limited to, the following:

A. Alpha emitters: Alpha emitters emit a helium nucleus upon decay (two protons/two neutrons) at very high velocity. The combination of heavy particles and high speed make for highly energetic particles capable of substantial tissue damage. Alpha particles have short tissue penetration, usually in the range of 40 to 90 µm [2]. The limited penetration of alphas mitigates the risk of adverse side effects. The linear energy transfer (LET) of alpha particles is approximately 80 to 100 keV/µm, 100- to 1,000-fold higher than that of beta particles, translating into high rates of biologic damage [3]. Tissue damage is predominantly in the form of DNA strand breaks, with a propensity for the alpha-induced breaks to be double stranded and lethal. In general, double strand breaks are difficult to repair via normal DNA repair mechanisms [4]. Additionally, there is a potential role for immunologic factors to augment radiation-induced cell death [5].

- Radium-223 (more detailed information can be found in the ACR–ACNM–ASTRO–SNMMI Practice Parameter of Therapy with Radium-223).

B. Beta emitters: Beta particles are negatively charged electrons emitted from the nucleus of decaying radioactive atoms with the conversion of a neutron to a proton. They have various energies and thus a distribution of ranges from approximately 1 µm to 10 mm. The LET of these energetic and negatively charged particles is very low, approximately 0.2 keV/µm, making them sparsely ionizing [6]. Consequently, a very high radionuclide concentration is required in the targeted tissue, but the long range of beta particles leads to the production of cross-fire of the bystander effect, potentially destroying additional cells within the range of the decaying atoms that were not directly targeted by the radiopharmaceutical.

1. Iodine-131 (more detailed information can be found in the ACR–ACNM–ASTRO–SNMMI–SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with Iodine 131)
2. Iodine-131 MIBG (FDA approved July 2018, practice parameter in development)
3. Strontium-89 (strontium chloride) for adjuvant and palliative treatment of painful skeletal metastases
4. Samarium-153 lexidronam ethylene diamine tetra methylene phosphonic acid (EDTMPA), and radium-223 (radium dichloride) for adjuvant and palliative treatment of painful skeletal metastases.
5. Lutetium-177 DOTATATE (FDA approved January 2018, practice parameter in development)
6. Yttrium-90 ibritumomab tiuxetan (murine monoclonal antibody targeting the CD20 antigen) for treatment of patients with CD20-positive follicular B-cell non-Hodgkin lymphoma (NHL), with or without transformation, including but not limited to disease that is refractory to rituximab and has relapsed following chemotherapy. On September 3, 2009, the FDA granted expanded approval for the use of yttrium-90 ibritumomab tiuxetan in patients with previously untreated follicular non-Hodgkin’s lymphoma who
have demonstrated partial or complete response to first-line chemotherapy (consolidation after chemotherapy) [2,3].

7. Yttrium-90 microsphere (for further information see the ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignances) [7].

Additional unsealed radiopharmaceuticals for therapy include phosphorus-32 (sodium phosphate) for treatment of myeloproliferative disorders, phosphorus-32 (colloidal chromic phosphate) for treatment of malignant ascites/effusions, and iodine-131 radio immunotherapy for NHL. These radiopharmaceuticals are not currently available and will not be discussed further.

For more information on radioembolization, see the ACR–SIR Practice Parameter for Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignancies.

1. Iodine-131 (sodium iodide)
   a. Treatment of hyperthyroidism
   b. Ablation of postoperative thyroid remnant and therapy of iodine-avid thyroid cancer.

2. Phosphorus-32 (sodium phosphate)
   Treatment of myeloproliferative disorders such as polycythemia vera and thrombocytosis

3. Phosphorus-32 (colloidal chromic phosphate)
   Intracavitary therapy of malignant ascites, malignant pleural effusions, malignant pericardial effusions, and malignant brain cysts

IV. 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 [1] and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [8]. In addition, training and experience must be in compliance with the applicable laws and regulations, including 10 CFR 35.390 [9].

V. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

The written or electronic request for a radiopharmaceutical 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’s scope of practice requirements. (ACR Resolution 35, adopted in 2006 - revised in 2016, Resolution 12-b)

A. General Procedures

1. Clinical evaluation – In concordance with the ACR–ASTRO Practice Parameter for Radiation Oncology and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [8,10]. The treating physician’s initial evaluation of the patient must include review of the patient’s history, physical examination, and pertinent diagnostic studies and reports, including a complete history of all previous radiotherapy and radiopharmaceutical therapy. These findings should be communicated to the referring
2. Quality management – In order to use therapeutic unsealed radiopharmaceuticals, as unsealed sources for therapy a “quality management” program must be in place as required by the US Nuclear Regulatory Commission (NRC) or by Agreement State regulations. (An Agreement State is any state with which the 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 specified procedures for shipment acceptance, handling, and storage; duplicative procedures for patient identification; patient care registries; careful record-keeping to ensure prescribed administered activity; procedures to minimize the possibility of infiltration for radiopharmaceuticals that are administered intravenously; 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.

3. Informed consent – Informed consent must be obtained and documented. Given the unique nature of therapy with unsealed sources, the informed consent should ideally address known potential near and long-term radiation risks to patient. It is also encouraged that the consent and instructions include a statement regarding risk of exposing caregivers and family members to unnecessary radiation if radiation precautions are not appropriately followed. See the ACR Practice Parameter on Informed Consent – Radiation Oncology [11].

4. Treatment – The procedure and follow-up should be performed according to an established system of procedural steps predetermined facility policies and procedures that may be unique for each type of application.

5. Regardless of whether the radiopharmaceutical route is oral, intravenous, or intraperitoneal, a patient should not be pregnant, breastfeeding, or lactating at the time of radiopharmaceutical administration. The decision to provide therapy in a pregnant, breastfeeding, or lactating patient should only be made with full understanding and provided with careful patient and provider dialogue. Pregnancy should be excluded prior to radiopharmaceutical administration by one of the following: negative human chorionic gonadotropin test, documented hysterectomy, postmenopausal state (absence of menstrual bleeding for 2 years), or by premenarche (child patient age 10 years or younger).

6. Radiation precautions – Radiation precautions and patient release criteria may be regulated federally by the NRC in many states or by the Agreement 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 should follow provide information on the applicable federal or state regulations. Details on the federal regulations can be obtained at the NRC website, www.nrc.gov. Under the guidelines of federal code 10 CFR 35.75 [12,13] and key sections of NUREG 1556 [14], the patient may be released 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). And, 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 maintain doses to others by utilizing the “as low as reasonably achievable” (ALARA) [15] principle. Agreement 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 & Measurements (NCRP) differ somewhat from the NRC regulations [16]. 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 connection to the patient and for whom there is 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 survey meters measure exposure rates in milliroentgens/hour (mR/h). For purposes of radiation protection and for low LET radiation (including beta particles and most x-rays and gamma rays), the authors of the organizations that developed this consensus 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.

All routine blood work and laboratory specimens should be obtained prior to treatment with the radiopharmaceutical. If confinement in a health care facility is needed, it is not usually necessary to store body effluents, such as urine, stool, or vomitus. For effluent disposal, where acceptable under state or federal regulations, the toilet should be flushed two or three times after each use to ensure sufficient dilution and disposal of radioactivity. Food trays and linens should be stored in the patient’s room until monitored and cleared by radiation safety staff. The patient must stay remain in the room except in a medical or nonmedical (eg, fire) emergency, and access by personnel and visitors must be limited. All trash and residual nondisposable items must 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 be contained in safe storage for 10 half-lives or when 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 the survey is performed [16]. Room and contents release survey must be documented in the patient and facility records.

If the admitting physician responsible for the patient’s care during their confinement (eg, hospital admission) is different from the physician who is responsible for and administers the radiopharmaceutical, there must be a mechanism to prevent premature discharge or release of the patient from confinement.

The lactating breast concentrates significant iodine/radioiodine. Thus, radioiodine therapy during lactation will cause a high radiation exposure to the breast and to a nursing infant. If radioiodine therapy is to be administered, breastfeeding must be stopped completely for that infant but may be resumed during a subsequent pregnancy. A 3-month delay in radioiodine therapy is recommended after discontinuing breastfeeding [8]. It is recommended that pregnancy be delayed at least 6 months after radioiodine therapy [8].

B. Specific Procedures Beta Emitters for Palliation of Bone Metastases

1. Strontium-89
   a. Background

   Strontium-89 has was one of the first bone-seeking radiopharmaceuticals approved for the treatment of painful bone metastases. It has a physical half-life of 50.6 days and emits a beta particle with a maximum energy of 1.46 meV and an average soft-tissue range of 2.4 mm. It emits beta radiation. As a calcium analog, strontium-89 and is taken up in the skeletal system in proportion to osteoblastic activity, with metastatic osteoblastic metastatic bone lesions with approximately accumulating the radiopharmaceutical up to 10- times fold greater efficiency than is observed with normal bone [17]. The radiopharmaceutical can remain in these lesions for as long as 100 days an extensive period, with 20% of injected activity present in the skeleton after 90 days [18]. Strontium emits a comparatively small fraction of gamma photons (0.01%) and hence poses reduced minimal
radiation risk to those in contact with the patient while also precluding imaging or dosimetry studies. Given that the radiopharmaceutical is excreted by the kidneys, precautions should be directed toward excreted urine or urinary obstruction.

b. Summary of selected data

Strontium-89 has primarily been investigated primarily in the context of osseous metastasis in prostate cancer. The use of this radiopharmaceutical in other malignancies, including breast and lung cancer, has also been investigated.

i. A phase III placebo-controlled randomized controlled trial evaluated conventional palliative radiotherapy ± strontium-89 as a single injection of 10.8 mCi or placebo in 126 patients with metastatic castration-resistant prostate cancer (CRPC) [19].
   1. Complete pain relief at 3 months was achieved in a greater number of patients treated with strontium-89 compared with placebo (40% versus 23%).
   2. There was a significant reduction in the need for subsequent and continued analgesic use in the strontium-89 group (P < .05).
   3. Significantly fewer patients in the strontium-89 group experienced new sites of pain compared with placebo (P < .002), which translated into a longer disease-free interval and subsequent retreatment with radiotherapy (35 weeks versus 20 weeks).
   4. Quality-of-life analysis demonstrated superiority of strontium-89 with alleviation of pain and improvement in physical activity being statistically significant (P < .05).

ii. A study including of 284 patients with symptomatic bone metastases from prostate cancer who were randomly allocated for assigned to either conventional palliative radiotherapy or 5.4 mCi of strontium-89 treatment found [20] that:
   1. The analgesic effect was similar in both treatment groups, but fewer patients developed new sites of pain in the strontium-89 group (P < .05).
   2. Significantly fewer patients required local radiotherapy to new sites following strontium-89 treatment compared with the local radiotherapy group (P < .01).
   3. Platelet and leukocyte counts fell by approximately 35% after strontium-89 treatment, but functional sequelae were rare.
   4. Notably, There was no significant difference in overall survival between groups (P = .10).

c. Clinical results

Approximately 57% to 92% of patients respond to therapy. Pain relief onset typically begins in 2 to 4 weeks after administration, and its effect is maintained for 4 to 15 months with an average 6-month duration [21,22]. A small percentage of patients may experience a transient flare phenomenon 2 to 3 days after injection. This flare is usually mild, controlled well with analgesics, and heralds a good response [23].

d. General treatment recommendations

For strontium-89, the current standard administered activity is 1.48 to 2.22 MBq (40-60 μCi per kilogram of body weight, approximately 4 mCi [148 MBq]) for standard weight) given by intravenous infusion over several minutes.

2. Samarium-153 lexidronam

a. Background

Samarium-153 is a third-generation radiopharmaceutical indicated for metastatic bone pain palliation. The isotope is bound to ethylenediamine tetramethylene (EDTMP) with the phosphonate groups present in the EDTMP providing its biologic properties, accumulating in skeletal tissue in association with hydroxypatite in an identical manner to technetium-99–methyl diposphonate-MDP [23]. Bone metastases accumulate five times more samarium-153 than healthy bone tissue, to produce the bone-seeking therapeutic complex. Compared with strontium-89, samarium-153 has a short physical half-life of only 46.3 hours. Samarium-153 emits both beta particles and gamma radiation. The beta particles have a maximum energy of 0.81 meV and an average soft-tissue range of 0.8 mm. Gamma radiation can The beta decay is accompanied by 28%
emission of gamma rays of 103.2 keV, which can be detected using gamma camera for a low-resolution bone scan and dosimetry, be detected using gamma camera for a low-resolution bone scan.

b. Summary of selected data

Samarium-153 has primarily been investigated in the context of osseous metastatic prostate cancer.

A phase III randomized controlled trial of 152 patients with CRPC randomized patients to radioactive samarium-153 at 1 mCi/kg versus nonradioactive samarium-152 [24].

i. There was a significant improvement in pain descriptor scale scores by week one and in pain intensity visual analogue scale scores by week two for patients treated with samarium-153.

ii. There was significant reduction in opioid consumption by week 3 with samarium-153 use.

iii. Grade 3 thrombocytopenia and leukopenia developed in 3% and 5% of patients, respectively, in the samarium-153 treatment arm. Counts returned to baseline after approximately 8 weeks. No grade 4 hematologic toxicity was noted in either platelets or white bloods cells.

iv. Notably, There was no significant difference in overall survival between groups.

c. Clinical results

Approximately 62% to 84% of patients respond to therapy [22]. Pain relief usually commences within 1 week of administration and as early as 2 days in some individuals. The palliative effect endured anywhere from 4 to 35 weeks, with an average of 8 weeks [25].

d. General treatment recommendations

The recommended samarium-153 lexidronam activity is 37.0 MBq (1.0 mCi) per kilogram of body weight, given intravenously over several minutes. When samarium-153 lexidronam is used, whole-body gamma camera If desired, imaging may be performed between 2 and 24 hours postinjection.

3. General recommendations for all radiopharmaceuticals used to treat skeletal metastases (since hematologic toxicity is less with radium-223, clinical judgment should be exercised for less strict criteria)

a. Patient

Patients with multiple osseous metastases that show increased tracer uptake on bone imaging, who are obtaining diminishing relief from other methods of pain management (eg, analgesics, bisphosphonates, external-beam irradiation), and whose bone marrow is competent, are candidates for radiopharmaceutical therapy. Complete blood cell count with platelets should be obtained within 7 to 10 days prior to therapy. Platelet count should be greater than 60,000 to 100,000/µL, leukocyte count greater than 2,400 to 5,000/µL, and absolute granulocyte count greater than 2,000/µL. Patients with disseminated intravascular coagulation (DIC) must be excluded from therapy. Other patients may be treated after a case-specific by case evaluation, as adjuvant therapy to delay symptomatic skeletal metastases. Urinary incontinence is not a contraindication to treatment, although the patient or caregiver should be instructed on how to minimize radiation contamination from spilled urine. For samarium-153 lexidronam and strontium-89, bladder catheterization should be considered for patients incontinent of urine, to minimize the risk of radioactive contamination. This is less of an issue with radium-223 dichloride as it is primarily excreted through the intestine.

b. Complications

A “flare” phenomenon occurs in some patients, patients with transient worsening of pain within several days after treatment. This flare is a self-limited process, although it can occasionally be severe. Patients should be counseled concerning the possibility of a flare phenomenon. The pain associated with the flare phenomenon can usually be managed with analgesics or corticosteroids, at medication. In the event of intravenous administration, extravasation of the radiopharmaceutical should be avoided by secure It is imperative to have excellent intravenous access that is confirmed prior to injection isotope administration. Although local skin damage is unusual rare, some experts clinicians believe it is prudent to follow a vesicant protocol for radiotherapy infusion [26]. For both samarium-153 and strontium-89, bone marrow depression may occur transiently, with a nadir at about 3 to 6 weeks, and with recovery in about 3 to 6 additional weeks. Complete blood and platelet counts should be followed routinely for 8 to 12 weeks.
c. Interactions with other forms of treatment
   i. Hormone administration need not be discontinued before the administration of radiopharmaceutical therapy because it does not interfere with the mechanism of action and does not potentiate any side effects.
   ii. External-beam radiation therapy may be used in-concert synchronously with radiopharmaceutical therapy for local treatment of selected sites, especially those in which pathologic fracture or cord compression might occur. Careful evaluation of complete blood and platelet counts is required when these potentially myelosuppressive therapies are combined.
   iii. Caution should be exercised when delivering concomitant myelosuppressive chemotherapy to these patients. There are multiple trials that have been and are ongoing to determine the clinical efficacy and safety, primarily with taxane-based chemotherapy.

4. Radiation precautions
   There are none. No special precautions are required for strontium-89 as long as the patient is continent of urine and feces. For Because samarium-153 lexidronam has a gamma-ray emission, the patient may be released if the total effective dose equivalent to any other individual who is exposed to the patient is not likely to exceed 5 mSv (0.5 rem) per year. When in doubt, check Applicable state and or NRC/federal facility regulations and facilities policies must be as they should be followed.

5. Retreatment
   Retreatment may be administered if initial treatment fails or if symptoms recur. Special attention consideration should be paid given to recovery of bone marrow and blood counts. Retreatment may be given after adequate bone marrow recovery, occurs, which is typically in 2 to 3 months. Data are currently limited on retreatment with radium-223 chloride, so caution should be exercised.

6. As with all other forms of therapy with unsealed sources, patient Management should be coordinated with clinical services and with other involved parties health care providers involved in management of the patient, especially radiation oncology, if external beam irradiation has been used or is being considered.

C. Specific Procedures Yttrium-90 Ibritumomab Tiuxetan for Radioimmunotherapy of Non-Hodgkin’s Lymphoma

1. Radiopharmaceuticals
   The marker CD20 is expressed in the pro-B-cell stage as the B-cell evolves from the stem cell precursor and throughout the life of the mature B-cell, but is neither present in the stem cells nor in plasma cells derived from B-cells. CD20 is also expressed on many of the B-cell lymphomas: follicular lymphoma and diffuse large B-cell lymphoma. Thus, CD20 is an attractive target, potentially sparing stem cells and allowing regeneration of normal B-cells.

   Yttrium-90 ibritumomab tiuxetan consists of ibritumomab, the murine IgG1 kappa monoclonal antibody from which rituximab was developed, and tiuxetan, which stably chelates yttrium-90 for therapy. Iodine-131 tositumomab is a murine IgG2a lambda monoclonal antibody covalently linked to iodine-131. Both antibodies are directed against the CD20 antigen.

2. Patients
   a. Patients with CD20-positive follicular B-cell NHL, including patients who are refractory to rituximab, are candidates for radioimmunotherapy. The radiopharmaceutical is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell NHL [27] as well as the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy [28].
   b. Summary of selected data
i. **A One** study evaluated ibritumomab tiuxetan in the treatment of rituximab-refractory follicular NHL [27].
   - Fifty-seven patients were treated. The median age was 54 years, 74% had tumors that were ≥5 cm. and **All had been** were extensively pretreated.
   - The overall response rate for the 57 patients with follicular NHL was 74% (15% complete response [CR] and 59% partial response [PR]).
   - The Kaplan-Meier–estimated **TTP time-to-progression** was 6.8 months for all patients and 8.7 months for responders.
   - Adverse events were primarily hematologic; the incidence of grade 4 neutropenia, thrombocytopenia, and anemia was 35%, 9%, and 4%, respectively.
   - An international, randomized, phase III trial evaluated the efficacy and safety of consolidation with yttrium-90 ibritumomab tiuxetan in patients with advanced-stage follicular lymphoma in first remission [28].
     - A total of 414 patients (consolidation, n = 208; control, n = 206) were enrolled at 77 centers.
     - Yttrium-90 ibritumomab tiuxetan consolidation significantly prolonged median progression-free survival (PFS) regardless of whether patients achieved PR, CR, or unconfirmed CR.
     - The most common toxicity was hematologic; and grade 3 or 4 infections occurred in 8% of patients.
   - **c. The principal toxicity of anti-CD20 radioimmunotherapy is hematologic. A careful hematologic evaluation** needs to **must** be performed prior to therapy. **Since Because** lymphomatous involvement of in the bone marrow will increase the **radiation** dose to the marrow, a recent bone marrow biopsy within 6 to 12 **weeks of anticipated isotope therapy** must be evaluated by an experienced hematopathologist to document less than 25% bone marrow involvement by tumor. A recent **CBC complete blood count obtained 7 to 10 days prior to anticipated isotope therapy** should be reviewed, to confirm absolute neutrophil count (ANC) greater than 1,500 and platelet **count** greater than 100,000.

3. Dosimetry and assessment of biodistribution
   a. **When clinical circumstances warrant and the isotopic emission creates the opportunity, individual patient dosimetry and/or biodistribution can be considered by appropriate imaging or other techniques. Altered biodistribution is uncommon, and hence pre-therapy biodistribution imaging is no longer required.**

4. Administered activity
   a. According to manufacturer’s instructions, the therapeutic dose of yttrium-90 ibritumomab tiuxetan is administered on days 7 to 9, with day 1 being the day of the administration of the cold antibody (see below).
   b. Biodistribution of radiolabeled antibody is improved by concurrent administration of unlabeled radiopharmaceuticals in order to saturate readily accessible CD20-positive sites, including circulating B-cells and cells in the spleen. Biodistribution of radiolabeled ibritumomab tiuxetan is improved with the prior administration of rituximab (cold antibody).
   c. The therapeutic dosage of yttrium-90 ibritumomab tiuxetan, after an infusion of rituximab, is 14.8 MBq/kg (0.4 mCi/kg) for patients with a platelet count greater than 150,000 cells/μL and 11.1 MBq/kg (0.3 mCi/kg) for patients with platelet count of 100,000 to 149,000 cells/μL. The maximum allowable dosage of yttrium-90 ibritumomab tiuxetan is 1.184 GBq (32.0 mCi).
   d. Because yttrium-90 is a pure beta emitter, on-site administered-dose measurement can be very difficult. A standard **operating procedure for evaluation, administration, and follow-up** precise technique with careful attention to detail should be established with the help of a radiopharmacist and **Qualified Medical Physicist.**

5. Complications
   a. Hypersensitivity reactions **may occur** and may be severe. Patients who have **previously** received murine proteins previously should be screened for human anti-mouse antibodies (HAMA). Patients
who are positive are likely to be at increased risk of anaphylaxis and serious hypersensitivity and may show altered biodistribution of the antibody. Known hypersensitivity to rituximab or murine proteins is considered a contraindication to administration of yttrium-90 ibritumomab tiuxetan. Premedication with acetaminophen and diphenhydramine is recommended and should be considered prior to infusion, but patients should be carefully monitored. Reactions to the infusion of unlabeled rituximab are common. Although reactions to subsequently infused ibritumomab tiuxetan are uncommon, a physician must be present during the infusion. Medications for the treatment of hypersensitivity reactions (eg, epinephrine, antihistamines, and corticosteroids) and equipment for resuscitation should be immediately available.

b. The most common serious adverse reactions associated with yttrium-90 ibritumomab tiuxetan are severe or life-threatening cytopenias. Retrospective studies showed grade 3 or 4 thrombocytopenia in 57% of patients. The percent decline in platelets was 79% (±17%). The ANC nadir for yttrium-90 ibritumomab tiuxetan was ±36 days [29]. Precautions include net delay or avoidance of treatment of patients who have more than 25% of bone marrow involved, or who have poor bone marrow reserve (including but not limited to prior stem-cell or bone marrow transplant, ANC less than 1,500 cells/μL, or previous failure of stem-cell collection). The radiation dose is modified according to the pretreatment platelet counts. Blood counts are should be monitored weekly for at least 10 to 12 weeks, or more frequently as needed until recovery occurs. Stem-cell support and/or transfusions are provided as necessary, and cases of febrile neutropenia or infection are treated as appropriate.

6. Interactions with other forms of treatment
   a. A time interval sufficient to allow for bone marrow recovery after cytotoxic chemotherapy is recommended. Concomitant use of chemotherapy with yttrium-90 ibritumomab tiuxetan has not been fully evaluated and should be considered with caution when not performed in conjunction with a defined research protocol.
   b. Prior to radiopharmaceutical therapy, external beam radiation therapy may be necessary for local treatment of selected sites, especially when with life-threatening or function-threatening presentations (such as fracture or spinal cord compression), involvement such as fracture or spinal cord compression exists or is likely to occur without such treatment. Careful consideration must be given to the amount of bone marrow treated, as treatment of a large percentage of the patient’s bone marrow is likely to significantly affect the ability to tolerate radioimmunotherapy.
   c. The concern that patients treated with yttrium-90 ibritumomab tiuxetan will may have severe marrow impairment rendering them ineligible for further therapy is not substantiated by the results of several studies comparing retreatment with chemotherapy, stem-cell mobilization, and successful autotransplantation of treated patients to otherwise matched control groups [30].
   d. Adding ibritumomab tiuxetan to marrow-ablative CT regimens is also being tested in poor risk NHL and diffuse large B-cell lymphoma (DLBCL) as well in patients ≥60 years. Data from phase II trials are encouraging, with acceptable toxicity (http://dx.doi.org/10.1016/j.critrevonc.2016.07.008).

7. Radiation precautions
   a. No special precautions are necessary for yttrium-90 ibritumomab tiuxetan there are no special precautions beyond the usual care taken to minimize radiation exposure to patients and to medical personnel, consistent with institutional radiation safety practices, and patient management procedures, and applicable regulations. Yttrium-90 is a pure beta emitter, and safety precautions for medical professionals are include universal precautions, with the addition of acrylic shielding for the yttrium-90 ibritumomab tiuxetan. Patients may be released immediately after administration of yttrium-90 ibritumomab tiuxetan, with basic instructions. after administration of yttrium-90 ibritumomab tiuxetan
   b. If Applicable federal or state or facility regulations and facility policies are more restrictive, they should must be followed.
8. As with all other forms of therapy with unsealed sources, patient management should be coordinated with clinical services and other involved health care providers, parties especially medical and radiation oncology.

D. Posttherapy Follow-Up After Treatment

Physicians using unsealed radiopharmaceutical sources for therapy should participate with the patient’s primary physician in the follow-up and management of all patients treated with curative, adjuvant, or palliative intent and should document the outcome of therapy, including results of treatment (tumor control, survival, degree of palliation, time to retreatment) and significant sequelae [31]. Because the effect of radionuclide therapy may require time to be evident, patients should be seen in follow-up within intervals appropriate for the specific agent and therapeutic intent.

B. Iodine-131 (sodium iodide)

1. Therapy for Hyperthyroidism

a. Background

Iodine-131 has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation that allows imaging, though imaging of the dose administered for treatment of hyperthyroidism is not performed in practice.

b. Summary of selected data

i. 50% to 90% of hyperthyroid patients reach a euthyroid or hypothyroid state within 1 year of treatment with iodine-131 [13].

ii. In a study of 1,278 patients seen over an approximate 20-year time period, hyperthyroid patients were rendered euthyroid or hypothyroid after a single dose of 600 MBq (16.2 mCi), 370 MBq (10 mCi), or 185 MBq (5 mCi) in 84.1%, 74.9%, and 63% of cases, respectively [14].

iii. Failure rates for iodine-131 treatment for Graves disease as a cause for hyperthyroidism are higher in patients with large thyroid volumes, high iodine uptake, and high iodine turnover [15].

e. Treatment recommendations

Patient preparation — A recent radioiodine thyroid uptake should be available (See the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [16]). The size of the thyroid gland should be noted. Optimally, the patient’s system should be free of iodide-containing medications, iodinated contrast radiopharmaceuticals, exogenous thyroid hormone, and antithyroid medications. The patient should avoid foods containing very large amounts of iodine for the week prior to therapy; however, a strict low-iodine diet is usually unnecessary. Ideally, patients should not receive thioamide medications (e.g., propylthiouracil or methimazole) for at least 2 to 7 days prior to therapy [17-19].

Administered activities

i. Diffuse hyperfunctioning thyroid/Graves Disease

Initial activity of 1.85 to 7.4 MBq (50 to 200 μCi) per gram of thyroid (after adjusting for current 24-hour radioiodine uptake) may be administered. Rarely, it may be necessary to administer an activity greater than 1.22 GBq (33 mCi). Alternatively, an empiric adult administered activity of 185 to 555 MBq (5 to 15 mCi) may be given. The measurement of radioiodine uptake before therapy is necessary to establish the cause of the patient’s hyperthyroid state, to avoid the inappropriate administration of radioiodine in the setting of subacute thyroiditis or factitious hyperthyroidism, and to provide information on the radiation emanating from the patient for purposes of counseling the patient on radiation safety matters.

ii. Toxic nodular goiter and solitary toxic nodule

These conditions tend to be more resistant to radioiodine therapy. Activity of up of 1.22 GBq (33 mCi) or more may be administered.

Administered activity for pediatric patients can be empiric, weight-based, or based on dosimetry [20].

e. Side effects/complications

Side effects are usually minor. Patients may occasionally experience neck tenderness and/or odynophagia from radiation thyroiditis. Serious complications are rare. However, on occasion patients with severe hyperthyroidism may experience exacerbation of symptoms within the first 2 weeks following iodine-131
therapy. These symptoms usually respond to short-term beta-blocker therapy, but rarely may progress to frank thyroid storm. Patients should be instructed to contact their referring physician or seek immediate medical care should such symptoms occur.

Hypothyroidism is often considered to be a likely or even desired outcome of successful therapy of Graves disease or toxic nodular goiter and can occur within the first few months following therapy or even decades later, with a small, ongoing annual incidence. If a solitary toxic nodule has fully suppressed the function of the remaining thyroid, the risk of resulting hypothyroidism is decreased, but hypothyroidism may still occur.

Hypothyroidism is treated with carefully monitored hormone replacement therapy. Based on previous multicenter trials, there is no evidence of increased risk of thyroid carcinoma or other malignancy, infertility, or increased incidence of birth defects following iodine-131 therapy for hyperthyroidism.

f. Treatment failures and subsequent therapies

In 5% to 10% of patients, the initial therapeutic dosage of iodine-131 fails to sufficiently control hyperthyroidism. In patients who have not adequately responded to prior iodine-131 therapy, subsequent radiiodine treatments may be given. An equal or higher treatment dosage is generally used for retreatment. To achieve the maximal therapeutic effect, repeat therapies are usually not recommended until at least 6 months after the most recent radiiodine therapy. In the setting of diffuse hyperthyroidism, the likelihood of residual hyperthyroidism is greater for lower initial radiiodine administered activities.

2. Therapy for Thyroid Remnant Ablation, Residual Thyroid Cancer, or Metastases from Thyroid Cancer

Background

Iodine-avid thyroid cancers frequently take up radiiodine in the absence of significant amounts of residual normal thyroid tissue. In order to optimize ablative radiiodine therapy for residual or metastatic disease, or to facilitate the follow-up of patients, the thyroid remnant should be eliminated by surgery and/or radiiodine treatment. In planning therapy for a suspected thyroid remnant or metastasis, a total-body radiiodine scan may be of assistance in assessing extent of disease. Details regarding risk stratification of patients with thyroid cancer, appropriateness of radiiodine therapy in various clinical situations, and overall management of patients with thyroid cancer are covered extensively elsewhere [21-22].

Summary of selected data

i. A study evaluating thyroid cancer over a 40-year period reported that for patients with cancers greater than or equal to 1.5 cm in diameter post-thyroidectomy and without distant metastases, the addition of iodine-131 therapy alone for remnant thyroid ablation reduced the rate of recurrence and cancer death by at least one half and reduced the risk of recurrence by more than two-thirds [23].

ii. In a phase III trial comparing results of iodine-131 therapy in patients with low-risk thyroid cancer post-thyroidectomy using thyroid hormone withdrawal versus use of recombinant human thyrotropin, the ablation rate was found to be equivalent between iodine-131 doses of 30 mCi and 100 mCi. There was also no difference in the ablation rate between patients withdrawn from thyroid hormone versus those who received recombinant human thyrotropin[24].

iii. In one study assessing the effectiveness of radiiodine therapy for pulmonary metastases in differentiated thyroid cancer, a better outcome was seen in patients with lower pre-ablation stimulated TG and iodine-131 positive but anatomically negative disease [25].

Treatment recommendations

Iodine-131 has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation, which is suitable for imaging. Because of increased sensitivity afforded by the therapeutic dosage of iodine-131, post-therapy imaging (usually performed 2 to 10 days after treatment) is useful to identify sites of disease not detected on pretherapy radiiodine imaging.

Patient preparation

The serum TSH must be elevated, usually to a level in excess of 30 µIU/mL, either by withholding oral thyroid hormone to induce endogenous TSH secretion or by injecting recombinant human TSH (rhTSH) to raise the patient’s blood level of this hormone before therapy [26]. If a remnant is suspected, scintigraphy may be performed to determine how avidly the thyroid remnant is accumulating radiiodine. If a large thyroid remnant is present, performing a completion thyroidectomy before the iodine-131 therapy should also be considered. Documentation of an elevated TSH level as well as adherence to a low-iodine diet for 1 to 2 weeks prior to treatment is recommended. Optimally, the patient’s system should be free of iodide-containing medications,
iodinated contrast radiopharmaceuticals, and exogenous thyroid hormone (for withdrawal therapy). The patient should be fasting and should abstain from eating 2 to 4 hours before and 1 to 2 hours after therapy.

Administered activities

Iodine-131 may be administered to all ages in the management of thyroid cancer, but pediatric dosages should be weight-adjusted. The patient may need to be placed on radiation precautions.

i. Ablation of thyroid remnant

Activities of 1.11 to 3.7 GBq (30 to 100 mCi) of iodine-131 (sodium iodide) administered orally are most often used. Higher dosages may be used for more extensive disease.

ii. Known or suspected residual thyroid cancer

For residual tumor in the thyroid bed or in the setting of local lymph node metastases in the neck without evidence of distant metastasis, activities of 3.7 to 5.55 GBq (100 to 150 mCi) are usually administered.

iii. Known or suspected distant metastases will usually require administered radioiodine activities equal to or greater than 5.55 GBq (150 mCi).

Side effects/complications

The most commonly reported side effect is salivary gland dysfunction due to acute sialadenitis. Some investigations suggest that these effects are dose related [27,28], however, studies addressing this complication report varied results. Following radioiodine therapy, copious hydration is recommended, however the use of sialagogues is debatable. Acute sialadenitis is often transient. Permanent xerostomia is rare and reported in 2 to 4% of affected patients [27,29,30] and is generally associated with a history of single or multiple high administered activities of radioiodine.

Reports of pulmonary fibrosis and/or pneumonitis have been described. A whole-body retention threshold of 2.96 GBq (80 mCi) at 48 hours has been used for intense iodine-avid diffuse pulmonary metastases to avoid lung injury. This administered activity is approximately 7.4 GBq (200 mCi), ie, the upper limit of the administered activity should be 200 mCi. Pulmonary function studies should be considered prior to treatment if there are idespread pulmonary metastases [22,31,32]. Discussion of fertility should be considered, particularly in young patients who may need multiple treatments.

However, a recent study of 2,673 pregnancies in differentiated thyroid cancer patients who had been treated with radioiodine showed no effect on outcome of subsequent pregnancies [33]. Most experts recommend that pregnancy should be delayed by at least 6 months after radioiodine therapy [34] to complete follow-up evaluation of therapeutic effectiveness and completion of therapy.

The potential for the development of secondary primary malignancies (SPM) following high administered activities of therapeutic radioiodine is controversial. A large European study of 6,871 patients reported an increase in solid tumors and leukemia after radioiodine therapy [35]. A recent literature review, however, reassessed the data and reported a nonlinear dose effect [36]. Review of the Surveillance, Epidemiology, and End Results (SEER) program with a database of 18,882 patients, with a mean follow-up of 61.8 months, concluded that radioiodine therapy did not increase the risk of SPM [37]. However, a significantly greater risk of leukemia or other SPM was reported for patients treated with cumulative activities of 22 GBq (600 mCi) of radioiodine, particularly if combined with external beam radiotherapy [38]. Almost all cases of SPM have occurred in patients who received cumulative administered activities in excess of 29.6 GBq (800 mCi) [34]. Significant bone marrow depression is likely when cumulative administered activities exceed 29.6 GBq (800 mCi).

Radiation fibrosis may develop in patients with diffuse lung metastases who have received repeated administered activities of over 5.55 GBq (150 mCi) of radioiodine at short intervals, especially if within 6 months [39]. This risk increases if the cumulative administered activity exceeds 22 GBq (600 mCi) [34].

a. Residual or recurrent disease

After successful remnant ablation, a measurable serum thyroglobulin level suggests functioning thyroid tissue and the possibility of recurrent disease and may be an indication for additional treatment. However, both high and low thyroglobulin levels are unreliable in the presence of antithyroglobulin antibodies. In particular, falsely low thyroglobulin levels may occur in antibody-positive patients; therefore, antibody assays should accompany all thyroglobulin measurements. Even when a diagnostic whole-body scan is negative, if the stimulated...
thyroglobulin level is greater than 10 ng/mL, or there is other evidence of disease in a patient with a high risk of recurrence, empiric therapy with 3.7 to 5.5 MBq (100 to 150 mCi) can be considered [21,40].

In the setting of a negative whole-body scan and suspected metastatic disease, an FDG-PET/CT scan may be helpful to identify and localize non-iodine-avid disease (See the ACR SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [16]).

Interactions with other forms of treatment

i. Patients with a high risk of local/regional recurrent disease may be treated with both iodine-131 and external beam irradiation. The use of external beam irradiation prior to or alternating with radiiodine treatment has not been shown to be associated with a subsequent reduction in tumor uptake of radiiodine. Therefore, external beam irradiation, if indicated, need not be delayed. The toxicity, acute and late, is likely to be additive within the field of irradiation. Dosimetry calculations should be considered if iodine-131 therapy and external beam radiotherapy are both being considered or have previously been performed in patients with spinal lesions, to avoid potential radiation-induced spinal cord damage.

ii. Distant metastatic lesions that are painful or are a threat to life or function may be treated with external beam irradiation or surgery in addition to iodine-131.

4. Radium-223 dichloride

a. Background

Radium-223 is a bone-seeking calcium analogue that is unique in that, rather than emitting beta energy, it emits high-energy alpha particles. Radium-223 has a half-life of 11.4 days. Alpha particles have high biologic effectiveness and linear energy transfer to cause double-strand DNA breaks. Alpha particles travel the width of approximately 4–10 cells, thus limiting toxicity on the adjacent underlying bone marrow. In addition, radium-223 has primarily intestinal clearance.

Radium-223 chloride has been approved for the treatment of symptomatic bone metastases from CRPC [44]. Radium-223 joins samarium-153 and strontium-89 as approved radiopharmaceuticals for treating painful skeletal sites of disease. All 3 have demonstrated significant improvements in pain scores and symptomatic relief; however, radium-223 is the first to demonstrate an overall survival benefit in a large prospective randomized phase III trial. For this reason, radium-223 is now often utilized prior to strontium-89 and samarium-153 as first-line therapy, however all 3 radionuclides are therapeutic options.

b. Summary of selected data

Radium-223 is FDA approved for the treatment of CRPC and is actively being investigated in earlier stages of metastatic prostate cancer and other cancers, such as breast cancer [44].

i. A multinational phase III, double-blinded, randomized controlled trial of 922 men with symptomatic CRPC to 6 injections of radium-223 (50 kBq/kg intravenous (i.v.)) over 4 weeks versus placebo. Unique to this study was that the primary endpoint was overall survival.

ii. The trial was stopped early at a planned interim analysis after an overall survival benefit was already reached. The benefit in median overall survival with radium-223 treatment was 2.8 months (14.0 versus 11.2 months; \(P = 0.0019\); hazard ratio 0.695 [95% CI 0.552–0.875]).

iii. Lower incidence of skeletal-related events in the radium-223 group, including reduction in development of spinal-cord compression (3% versus 6%; \(P = 0.016\)),

iv. Reduction in time to first skeletal-related event was significantly delayed with radium-223 (13.6 versus 8.4 months; \(P = 0.0005\)).

v. Treatment with radium-223 was well tolerated with low incidence of grade 3 or 4 neutropenia (1.8% versus 0.8%) and thrombocytopenia (4% versus 2%).

vi. There were no significant differences between radium-223 and placebo in terms of adverse events.

c. General treatment recommendations

The recommended radium-223 dosing schedule is 6 injections of radium-223 (50 kBq/kg intravenous (i.v.)) with one injection occurring each month for 6 months.

C. Phosphorus-32 (sodium phosphate) for Polycythemia Rubra Vera Associated With Thrombocytosis

a. Background
Phosphorus-32 (sodium phosphate) may be used for treatment of thrombocytosis associated with polycythemia vera unresponsive to other therapies such as phlebotomy. Given its association with increased risk of the development of leukemia, Phosphorus-32 treatment is generally not used as a first-line agent [46] and is generally reserved for patients who fail chemotherapy and in the elderly (greater than 65–70 years old) [47]. However, the relationship between phosphorus-32 and development of leukemia and other effects as well as its side-effect profile relative to other agents, radiopharmaceuticals used to treat polycythemia vera are complex [48].

b. Summary of selected data
   i. In the Polycythemia Vera Study Group, which included 400 patients, median survival was 11.8 years for the individuals randomly assigned to the phosphorus-32 treatment arm, versus 13.9 years for the phlebotomy group and 8.9 years for the chlorambucil group [49].
   ii. In the French Polycythemia Group study (461 patients over the age of 65 years), the administration of low-dose maintenance treatment with hydroxyurea (HU) after phosphorus-32 significantly prolonged the duration of phosphorus-32-induced remissions but was also associated with a significant increase in carcinomas and in the leukemia rate when therapy went beyond 8 years. The study concluded that the use of HU as maintenance therapy was only appropriate when a patient had rapid recurrence (less than 2 years) following phosphorus-32 therapy [48].
   iii. Favorable response to phosphorus-32 has been reported in patients with extramedullary hematopoiesis with a painful spleen, hypersplenism, abdominal pain, splenic infarcts, pruritus, or uncontrolled hyperuricemia.

D. Phosphorus-32 (colloidal chromic phosphate) for Malignant Ascites, Pleural Effusion or as an Adjunct to Treatment of Borderline Ovarian Neoplasms

a. Background
   Phosphorus-32 (colloidal chromic phosphate) may be used in the treatment of malignant ascites or pleural effusion. This is a palliative therapy and can be administered again to treat recurring effusion/ascites [51].

b. Summary of selected data
   The therapy has not been shown to prevent relapse or affect mortality in the largest study to date [52].

c. Treatment recommendations
   The usual activity for intracavitary therapy is 222 to 555 MBq (6 to 15 mCi) in the pleural cavity and 370 to 740 MBq (10 to 20 mCi) in the peritoneum, although the largest study to date used a fixed dose of 555 MBq (15 mCi) injected into the intraperitoneal cavity. The ability of the radiopharmaceutical to spread uniformly throughout the cavity should be documented using technetium-99m sulfur colloid (See the ACR–SNM–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy [53].) as an intraperitoneal or intrapleural injection followed by appropriate imaging. The patient should be turned to distribute the radiopharmaceutical. After documented dispersal, ie, no evidence of loculation or penetration into the bowel, the patient may be treated. The combination of intraperitoneal phosphorus-32 colloidal chromic phosphate and external irradiation to the pelvis has been reported to be associated with a high incidence of morbidity, particularly bowel obstruction; accordingly, caution must be observed when this combination of therapies is used.

d. Treatment and Palliation of Neuroendocrine Tumors

1. Peptide receptor radionuclide therapy (PRRT) for metastatic or inoperable neuroendocrine tumors
   a. Background
      The high prevalence of somatostatin receptors in neuroendocrine tumors allows for the rational design of a series of agonists and antagonists labeled with therapeutic nuclides in metastatic or inoperable patients with primary neuroendocrine tumors. Ongoing and completed trials primarily in Europe and recently in the United States have demonstrated the efficacy of these therapies in patients with adequate expression of the targeted somatostatin receptor type [58,59]. In the future, these therapies are likely to be carried out in phase III trials in the United States. Patient selection and endpoints will determine the speed of the approval process.
   e. Treatment recommendations
      The administered activity may be based on body surface area (85 MBq [2.3 mCi] per square meter intravenously) but may also be standardized to a dose of 111 to 185 MBq [3.0 to 5 mCi] intravenously but
should not exceed 185 MBq (5.0 mCi). Relapse or failure to respond within 12 weeks may require retreatment with dosages up to 259 MBq (7.0 mCi). Phosphorus-32 should not be given if the platelet count is less than 100,000/μL or the leukocyte count is less than 3,000/μL. Duration of response ranges from months to years with the potential for retreatment at the time of disease progression.

Iodine-131 tositumomab was discontinued by the manufacturer in February 2014 and is currently not available.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [10].

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

VII. ACR STATEMENT ON THERAPEUTIC USE OF UNSEALED RADIOPHARMACEUTICAL SOURCES

On the basis of their education, training pathway(s), experience, initial board certification(s), subsequent fellowship training, and maintenance of certification(s), NRC AU status, and clinical work experience, diagnostic radiologists (DRs), interventional radiologists (IRs), nuclear medicine physicians (NMs), and radiation oncologists (ROs) may have the necessary qualifications to supervise and perform therapies using unsealed radioisotopes. 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 board-eligible or board-certified in DR, NR, NM, IR/DR, or RO but do not hold AU status: These physicians may participate in the practice of therapy with specific unsealed radiopharmaceuticals under the supervision of an AU for the specific therapeutic radiopharmaceutical. Although they may not issue written directives for those specific radiopharmaceuticals, they may administer such a dosage as designated by an AU.

- Physicians who are board-certified in DR, NR, NM, IR/DR or RO and hold AU status based on that certification and site-specific credentialing: These physicians may practice radioisotope therapy consisting of oral radioiodine at all dosage levels under their own AU and facility license qualifications.

- Physicians who are board-certified in DR, NR, NM, or RO and hold the appropriate AU statuses and site-specific credentialing: These physicians may practice parenteral radioisotope therapy(ies) as permitted by their own specific training leading to such AU statuses.

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 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).
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.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).

A. Whenever possible, removal of bodily fluids and/or tissue should be avoided following therapeutic instillation of unsealed radioactive sources into any body area until such time as permitted by the facility radiation safety officer or responsible provider.

B. Patient instructions should specify a time interval for safe removal of body fluids and/or tissues based on the therapeutic isotope employed in the procedure.

C. For in-patient facilities, patient orders should specify procedures for handling of removed bodily fluids and/or tissues as well as notification of the responsible radiation safety officer or provider.

D. In the unlikely event of a patient death following instillation of unsealed therapeutic radionuclides, the responsible radiation safety officer or provider should be notified immediately of the death and handling of the body should be directed by that individual.

IX. 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 Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [32].
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 – Nuclear Medicine and Molecular Imaging of the ACR Commissions on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Radiation Oncology of the ACR Commission on Radiation Oncology, in collaboration with the ACNM, the ASTRO, and the SNMMI.

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

**ACR**
- Kevin P. Banks, MD, Co-Chair
- Bassem I. Zaki, MD, Co-Chair
- Paul E. Wallner, DO, FACR

**ACNM**
- Bital Savir-Baruch, MD

**ASTRO**
- Adam P. Dicker, MD, PhD
- Zoubir Ouhib, MS, FACR
- James S. Welsh, MD

**SNMMI**
- Hossein Jadvar, MD, PhD, MPH, MBA
- Erik Mittra, MD, PhD
- Rathan M. Subramaniam, MD, PhD, MPH

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

- Kevin P. Banks, MD, Co-Chair
- Richard K. J. Brown, MD, FACR, Co-Chair
- Alexandru C. Bageac, MD, MBA
- Twyla B. Bartel, DO, MBA
- Murray D. Becker, MD, PhD, FACR
- Erica J. Cohen, DO, MPH
- Joanna R. Fair, MD
- Erin C. Grady, MD
- Edward D. Green, MD
- Jeffrey S. Kempf, MD, FACR
- Jennifer J. Kwak, MD
- Charito Love, MD
- Syam P. Reddy, MD
- Levi Sokol, MD
- Rathan M. Subramaniam, MD, PhD, MPH
- Stephanie P. Yen, MD

Committee on Practice Parameters – Radiation Oncology
(ACR Committee responsible for sponsoring the draft through the process)

- Alan C. Hartford, MD, PhD, FACR, Chair
- Naomi R. Schechter, MD, Vice Chair
- Nathan H. J. Bittner, MD
- Samuel T. Chao, MD
- Chee-Wai Cheng, PhD, FAAPM
- Neil B. Desai, MD
- Nancy A. Ellerbroek, MD, FACR
- Beth A. Erickson, MD, FACR
- Mark Hurwitz, MD
- Lesley A. Jarvis, MD, PhD
- Join Y. Luh, MD
- Matthew Poggi, MD
- Helen A. Shih, MD
- Nikhil Thaker, MD
- Paul E. Wallner, DO, FACR
- Kristina L. Woodhouse, MD
- Paul E. Wallner, DO, FACR
- Ying Xiao, PhD
- Sue S. Yom, MD, PhD
- Bassem I. Zaki, MD

Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Seth A. Rosenthal, MD, FACR, Chair, Commission on Radiation Oncology
Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards
Mary S. Newell, MD, FACR, Vice Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee
Darlene F. Metter, MD, FACR, Chair
Ralph P. Lieto, MS, FACR, Co-Chair
Kevin P. Banks, MD
Jacqueline A. Bello, MD, FACR
Richard K. J. Brown, MD, FACR
Adam P. Dicker, MD, PhD
Richard Duszak, Jr., MD, FACR
Michael L. Goris, MD
Paul A. Larson, MD, FACR
Erik Mittra, MD, PhD
Mary S. Newell, MD, FACR

Zoubir Ouhib, MS, FACR
Seth A. Rosenthal, MD, FACR
Bital Savir-Baruch, MD
Naomi R. Schechter, MD
Timothy L. Swan, MD, FACR
Ryan Wallner, DO, FACR
Don C. Yoo, MD, FACR
Bassem I. Zaki, MD

REFERENCES


PRACTICE PARAMETER

Unsealed Radiopharmaceutical Sources

2019 Resolution No. 41


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 11)
Revised 2000 (Resolution 27)
Revised 2005 (Resolution 21)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 26)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 49)
RESOLUTION NO. 42

Independent Medical Judgement

WHEREAS,
a physician's paramount responsibility is to his or her patients; and

WHEREAS,
a core purpose of the ACR is to support and promote patient centered care; and

WHEREAS,
the ACR continues to provide training for and promote that radiologists are best equipped
to supervise and deliver the full gamut of medical imaging services; and

WHEREAS,
radiologists, especially in employed practice settings, may encounter situations where
patient care may be in conflict with employer interests; and

WHEREAS,
the AMA has established similar policy; therefore,

BE IT RESOLVED,
that radiologists should be free to exercise their personal and professional judgment
in voting, speaking, and advocating on any matter regarding patient care interests,
the profession, health care in the community, and the independent exercise of
medical judgment; and

BE IT FURTHER RESOLVED,
that radiologists should always make treatment and referral decisions based on the
best interests of their patients.

Sponsored by:  Board of Chancellors
             Council Steering Committee
Independent Medical Judgement

To support the resolution Independent Medical Judgement, the ACR would incur the following estimated costs:

Costs:

- De minimis (<$10,000)
RESOLUTION NO. 43

Burnout

WHEREAS, radiologist, radiation oncologist, interventional radiologist, nuclear medicine and physicist burnout has been identified as a significant problem for our profession; and

WHEREAS, measurement tools to identify and interventions to reduce burnout have recently become available; and

WHEREAS, the ACR Board of Chancellors has deployed a measurement tool as a member benefit to help members understand their personal risk of burnout; therefore,

BE IT RESOLVED, that the ACR Commission on Human Resources develop a definition of burnout; and

BE IT FURTHER RESOLVED, that the ACR Board of Chancellors and Council Steering Committee provide a list of resources or interventions that can be used by members to address identified burnout issues; and

BE IT FURTHER RESOLVED, that the ACR Board of Chancellors and the Council Steering Committee encourage radiology, radiation oncology, interventional radiology, nuclear medicine, and physics specialty societies to promote the use of interventions to reduce identified burnout among their membership; and

BE IT FURTHER RESOLVED, that the ACR Board of Chancellors perform a second measurement approximately 18 months after the initial assessment to determine whether these interventions have reduced member burnout.

Sponsored by: Board of Chancellors
Council Steering Committee
To support the resolution **Burnout**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
RESOLUTION 44

SUMMARY: The ACR bestows the title of ACR Fellowship on Members and Associate Members who maintain at least 10 consecutive years of membership and meet rigorous criteria set forth in the ACR bylaws, reviewed by the ACR Committee on Fellowship Credentials and approved by the ACR Board of Chancellors. Criteria for consecutive years of membership may place a significant burden on individuals who may have a gap in ACR/chapter membership for a variety of reasons including transitioning to a new job, maternal or paternal leave, attending to an infirm parent, or other personal or professional circumstances. Few members reach the title of ACR Fellow in the minimum amount of years and are more likely to meet the criteria at the 20-year level. ACR would like to foster its members to reach this esteemed membership title and it is believed that by changing the requirement to a minimum of 10 years of membership will encourage those who otherwise would not meet the criteria due to a gap in membership to be nominated.

ARTICLE II – Membership

Section 1

Classes of Membership

a. An individual in the Member class shall not be eligible for nomination to fellowship until he/she has completed ten (10) consecutive years as a Member of the College and one of its local chapters.

b. An individual in the Associate Member class shall not be eligible for nomination to fellowship until he/she has completed twenty (20) consecutive years, without interruption, as a member of the College, and one of its local chapters.

Sponsored by: Board of Chancellors
Council Steering Committee