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**REFERENCE COMMITTEE II**

**ACR STAFF:**

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<tr>
<th>Role</th>
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<tr>
<td>Director</td>
<td>Dina Hernandez</td>
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<td>Moderator</td>
<td>Deeanna Hafer</td>
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<td>Recorder</td>
<td>Dee Salem</td>
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<td>Assistant</td>
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<td>Attorney</td>
<td>Gloria Romanelli</td>
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<td>Observer</td>
<td>Pam Platt</td>
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REFERENCE COMMITTEE II

Reference Committee II met on Monday, May 20, 2019 in the Washington Marriott Wardman Park Hotel in Washington, D.C. The members of this committee were Christoph Wald, MD, PhD, FACR, Chair, Amanda S. Corey, MD, FACR, Daniel G. Gridley, MD, David S. Kirsch, MD, Ashley E. Rubinstein, PhD, Aradhana M. Venkatesan, MD.

The session was attended by approximately 650 members.

The Reference Committee recognizes the following reports as informational and I recommend that they be filed.

COMMISSIONS, COMMITTEES & TASK FORCES:

Commission on Economics
Commission on Government Relations
Commission on Human Resources
Commission on Interventional & Cardiovascular
Commission on Neuroradiology
Journal of the American College of Radiology
Commission on Leadership & Practice Development
Commission on Medical Physics

The Committee was assigned the following resolutions for consideration:

Resolution | Sponsor
---|---
13. Ten Year Extension of Policies: | CSC
  (a) Public Health and Radiation Protection
  10. Pneumoconiosis
  (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
  17. State Licensure of Medical Radiological Physicians
  (d) Third Party Carriers and Compensation
  2. ACR Carrier Advisory Committee Networks
15. ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology Clinical Practice and Management | CSC
16. ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Spectroscopy of the Central Nervous System | CSC
17. ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Brain | CSC
18. ACR–ASNR Practice Parameter for the Performance of Non-Breast Magnetic Resonance Imaging (MRI)-Guided Procedures | CSC
19. ACR–ASNR–SPR Practice Parameter for the Performance of Myelography and Cisternography | CSC
20. ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures | CSC
21. 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 | CSC
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45. Firearm Injury Prevention Consensus Statements

THE REFERENCE COMMITTEE RECOMMENDS THE FOLLOWING CONSENT CALENDAR FOR
ACCEPTANCE:

RECOMMENDED FOR ADOPTION:

Resolution No. 13  Ten Year Extension of Policies
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).

(c) 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).

Resolution No. 17 ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Brain

Resolution No. 18 ACR–ASNR Practice Parameter for the Performance of Non-Breast Magnetic Resonance Imaging (MRI)-Guided Procedures

Resolution No. 19 ACR–ASNR–SPR Practice Parameter for the Performance of Myelography and Cisternography

Resolution No. 23 Imaging Guided Procedures Core Privileges

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.

Resolution No. 45  Firearm Injury Prevention Consensus Statements

Proceedings from inaugural Medical Summit on Firearm Injury Prevention

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”

RECOMMENDED FOR ADOPTION AS AMENDED:

(Lines 262, 268, 469)

The ASNR, ASSR, SIR and SNIS representatives affirm that in their best judgement the proposed changes would be acceptable to ASNR, ASSR, SIR and SNIS; subject to ratification by ASNR, ASSR, SIR and SNIS.

Resolution No. 15  ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology Clinical Practice and Management
(Lines 303-305)

The SIR, SNIS and SPR representatives affirm that in their best judgement the proposed changes would be acceptable to SIR, SNIS and SPR; subject to ratification by SIR, SNIS and SPR.

Resolution No. 16  ACR–ASNR–SPR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Spectroscopy of the Central Nervous System
(Lines 235-236)

The ASNR and SPR representatives affirm that in their best judgement the proposed changes would be acceptable to ASNR and SPR; subject to ratification by ASNR and SPR.

Resolution No. 20  ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures
(Lines 71, 106-109)

The SIR and SPR representatives affirm that in their best judgement the proposed changes would be acceptable to SIR and SPR; subject to ratification by SIR and SPR.

Resolution No. 21  ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization with Microsphere Device Brachytherapy Device (RMBD) for Treatment of Liver Malignancies
The ABS, ACNM, ASTRO, SIR and SNMMI representatives affirm that in their best judgement the proposed changes would be acceptable to ABS, ACNM, ASTRO, SIR and SNMMI; subject to ratification by ABS, ACNM, ASTRO, SIR and SNMMI.

Resolution No. 22  ACR–AAPM–SIIM Practice Parameter for Electronic Medical Information Privacy and Security
(Lines 389-394, 764-765)

The AAPM and SIIM representatives affirm that in their best judgement the proposed changes would be acceptable to AAPM and SIIM; subject to ratification by AAPM and SIIM.

Reference Committee II wishes to thank the Councilors and visitors for their valuable input in these deliberations.

Respectfully Submitted:

________________________________
Christoph Wald, MD, PhD, FACR, Chair
Amanda S. Corey, MD, FACR
Daniel G. Gridley, MD
David S. Kirsch, MD
Ashley E. Rubinstein, PhD
Aradhana M. Venkatesan, MD
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


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

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 (eg, 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 transforaminal 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, etc.
and (4) appropriate patient follow-up. The outcome measures or indicators for these processes are indications, success rates, and complication rates.

II. DEFINITIONS

The epidural space is essentially continuous from the craniovertebral 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 (e.g., 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 Bastrup disease, the paramidline approach may be preferred. Blunt-tip needles have been advocated for overall safety (e.g., 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 non-target 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 (i.e., 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 lumbar-sacral transfornaminal 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 transfornaminal 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 transfornaminal 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 transfornaminal 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 nuclear 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 transforaminal) 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 transduction, 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-γ, 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 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.
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
7. Infection at the skin puncture site

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 intra-procedural 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.

\(^2\)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)
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 paraspinal 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 0.25 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 have had a 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 fluoroscopy 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 with 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 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. Betamethasone 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].
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.
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 (eg, 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 ILEISIs [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].

I 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 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 transforaminal 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]. Maillefer 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 (ie, 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 does 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 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 Appropriate 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).

ACKNOWLEDGEMENTS

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

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REFERENCES

Epidural Steroid Injection

PRACTICE PARAMETER

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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

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 18)*

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

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.

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

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

I. INTRODUCTION

This practice parameter has been developed, 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, and interventional neuroradiology are clinical subspecialties of radiology 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 neuradiologists 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.
- 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
patients. Nurse coordinators are particularly helpful in assisting in screening or triaging referrals or assisting with research protocols.

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

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
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 the 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
The interventional radiology practice is often the best place to address periprocedure inpatient service. The 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, is the responsibility of the interventional radiologist. IR physician Examples include the following:

- Painful procedures that will require prolonged analgesia (eg, uterine artery embolization)
- Procedures requiring prolonged monitoring (eg, carotid stent)
- Procedures known to have greater than minimal risk (eg, neuroendovascular procedures, new biliary tube, percutaneous nephrostomy, cancer therapy)
- Significant unexpected procedural complications
- Other considerations (eg, 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 practitioners APP, and any other ancillary staff that the interventional radiologist or interventional neuroradiologist 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 Interventional 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 procedures may be acceptable to schedule some invasive diagnostic radiology procedures, such as a superficial biopsy or arthrography, based on a direct request from a physician’s office, many 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
Biplane imaging and 3-D angiography are strongly recommended for the interventional neuroradiology practice. Cone-beam CT capability may also be 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 the patient for 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 and/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, and LPNs/MAs. Intensive care patients or sedated pediatric patients require one-to-one nurse staffing. Facilities with high volumes of intensive care or pediatric patient populations may require a higher nurse-to-bed ratio in the recovery room setting.

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 intraprocedural 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 forums. This type of targeted, personal, and repeated attention will not only bring new business but will also build long-term relationships. Other groups such as emergency physicians, nurses, and field crews also have an interest in the treatment and outcomes of their patients who are ultimately cared for by interventional radiologists.

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 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.

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 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].

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 Cardiovascular and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the SIR, the SNIS, and the SPR.

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PRACTICE PARAMETER Interventional Clinical Practice Resolution No. 15
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REFERENCES

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

Development Chronology for this Practice Parameter
2004 (Resolution 24)
Amended 2006 (Resolution 34)
Revised 2009 (Resolution 24)
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

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 7)*

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. 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 such as MI and the Glx complexes, is obtained.
2. Intermediate echo (eg, 280-288 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].

For those physicians interpreting MRS in neonates and young infants, the physician should be familiar with MRS in normal neonates and young infants this age group. 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 (1H) MRS, other nuclei for MRS that can be used include helium-3 (3He), lithium-7 (7Li), carbon-13 (13C), oxygen-17 (17O), fluorine-19 (19F), sodium-23 (23Na), phosphorus-31 (31P), and xenon-129 (129Xe). 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 1H.
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.

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)

MRS 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 these field strengths 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 RF power deposition (specific absorption rate), and maximum acoustic noise levels.
VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website [38].

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.

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REFERENCES


Cerebral metabolism, magnetic resonance spectroscopy


*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)
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.
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, including contrast type and volume
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
c. Teaching

d. Informing patients and families

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. **Patient Name**
   ii. Medical record number (MRN)
   iii. Date of birth (DOB)
   iv. **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

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 (KAP).
   • 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 1 such an image in unsubtracted or images 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 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.
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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.*
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

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.

PRACTICE PARAMETER

Radioembolization

2019 Resolution No. 21
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 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.
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 the 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 RMBD radioembolization should be tailored to the individual patient, whether it is palliative curative or a bridge to surgical resection or liver transplantation. Transplant should be defined and communicated to the patient and treatment team. The goal of RMBD is to achieve intrahepatic tumor control. Appropriately selected patients with no or minimal extrahepatic metastases may have improved outcomes following treatment with RMBD. RMBD can induce a partial tumor response, allowing for subsequent surgical excision or liver transplantation. RMBD 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 RMBD 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. i.e., 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 Portal vein thrombosis
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 macroaggregated albumin (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.

7. Monitoring the patient during the periprocedural period to provide support and clinical management and radiation safety information.

8. Monitoring radiation safety and spill periprocedural events.

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 who are the experts on locoregional therapy with microsphere embolization 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).

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).

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 Interventional radiologists 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 As well as having training and expertise in the overall management and specific radiation treatment of a wide range of human malignancies, radiation oncologists are experts on liver tolerance to radiation therapy and radiation complications in normal tissues. He or she, The radiation oncologist may be the AU at the treating facility, and also 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. The involved radiation oncologist should have must meet all of the following qualifications and certification criteria:

1. Demonstrate satisfactory training and certification
   a. 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

2. Demonstrate continuing education in addition to certification, in accordance with the ACR Practice Parameter for Continuing Medical Education (CME), [9], and other credentials

3. If acting as AU, 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. Demonstrate 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.

5. Have a thorough understanding of each procedure with which he or she is involved, ensuring appropriate utilizations 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. Participate in 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.

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.

   or

   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).

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

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 (e.g., 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. Interventionsal 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 RMBD is to achieve intrahepatic tumor control optimal tumor response. 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 intervention radiologist appropriate health care provider 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 intervention 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, RMBD 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 delicate 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. Redistribute the flow of blood away from 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

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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 unilobar 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 administered activity should can 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 (e.g., 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. RMBD 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 administered activity, date and time and/or activity ordered, in gigabequyles [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 administered activity 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 method is based on the MIRD model and involves implanting the highest possible activity to the tumor while maintaining acceptable 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 technitum-99 MAA SPECT or SPECT-CT study.

   ii. 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>
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<tr>
<th>Estimated Tumor Involvement of Liver</th>
<th>Recommended Activity for Treatment</th>
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<tr>
<td>&gt;50%</td>
<td>3 GBq</td>
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<tr>
<td>25% to 50%</td>
<td>2.5 GBq</td>
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<tr>
<td>≤25%</td>
<td>2 GBq</td>
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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 multiheaded 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 = (GM lung/GM liver + GM lung) × 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 interpretation 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.

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

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3 The 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.
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 Appropriate 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).

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 technitium-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.

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 and Cardiovascular Radiology of the ACR Commission on Interventional and Cardiovascular, 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 – Radiation Oncology of the ACR Commission on Radiation Oncology in collaboration with the ABS, the ACNM, the ASTRO, the SIR, and the SNMMI.

Collaborative Committee – members represent their societies in the initial and final revision of this technical standard

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<th>ACR</th>
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<tr>
<td>Kelvin Kai-Wen Hong, MD, Chair</td>
<td>Phillip M. Devlin, MD, FACP</td>
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<tr>
<td>Don C. Yoo, MD, FACP</td>
<td>Catheryn M. Yashar, MD, FACP</td>
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<td>Murthy RK Chamarthy, MD</td>
<td>Andrew S. Kennedy, MD</td>
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<td>Olaguoke Akinwande, MD</td>
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<td>Riad Salem, MD</td>
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PRACTICE PARAMETER
Radioembolization
2019 Resolution No. 21
REFERENCES


PRACTICE PARAMETER

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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]. 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]. Radioembolization RMBD 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. Radioablation Radioembolization for chemorefractory liver metastases: Radioembolization RMBD 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 radioablation 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 RMBD 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. 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.

Resin microspheres have also been evaluated in the treatment of metastatic colorectal cancer. 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. RMBD Radioembolization ith 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 42.8 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 last 2–4 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>
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<td>63.9</td>
<td>84</td>
<td>nr</td>
<td>34.4</td>
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</table>

**Author**  
**Year**  
**Total Patients**  
**Embolotherapy**  
**Study Design**  
**Median Activity/ Treatment**  
**CR + PR**  
**Symptom Response%**  
**Tumor Marker Response%**  
**Median Survival (months)**  
**5-year Survival (months)**
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)
Revised 2014 (Resolution 17)
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.

Revised 2014 (Resolution 37)*

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 now 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 and 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

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 the staff in the organization department
2. Security issues for ePHI and personally identifiable information (PII) electronic personal health information
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 manufacturers 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.

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. Initiate 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 in health care systems are outlined in 21CFR11, Subpart B and C. Details 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. These 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 three 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\(^3\).

Satisfactory image and report deidentification features may or may not be included in the operational clinical infrastructure (eg, 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 in 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 2 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-The_RSNA-Clinical_Trial_Processor) 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 (ie, 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.

\(^3\) For further information see the Health Information Privacy – Research 45 CFR 164.501, 164.508, 164.512(ii) (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 [1]. 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. Hardware-based two-factor authentication (2FA) should be considered. Other methods of 2FA such as text/SMS are vulnerable to SIM swaps where the telephone’s text could be forwarded to another number. App based software tokens may be more secure for 2FA than text/SMS. However, with a SIM swap attack on one’s mobile device, the capture of the token could allow an attacker unlimited access to all two-factor codes. A hardware device has no moving parts, is easy to use and generally can be carried into secure working environments such as military bases. [14]

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, and what hours they can use. 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, and physical controls. 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 someone besides the valid user from using the session. As above, this should generally be 30 minutes, but exceptions can be made depending on use case and sensitivity of data.

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 viral 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 offsite 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 system 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 survive the 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\(^4\) 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).

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\(^4\) Code of Federal Regulations (found in the Federal Register).
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

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 – Medical Physics of the ACR Commission on Medical Physics in collaboration with the AAPM and the SIIM.

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**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
2. Applications
   a. Downtime
      i. Risk: moderate
      ii. Cost: low
   b. Unauthorized access
      i. Risk: moderate
      ii. Cost: low (if data anonymized)
   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 (invalidates research)

2. Applications
   a. Downtime
      i. Risk: moderate
      ii. Cost: low
   b. Unauthorized access
      i. Risk: moderate
      ii. Cost: low (if data anonymized)
   c. Tampering
      i. Risk: moderate
      ii. Cost: high (invalidates 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
      i. Risk: moderate (most FDA products have basic controls)
      ii. Cost: high (patient care, medicolegal)

2. Applications
   a. Downtime
      i. Risk: variable (depends on application availability tools used)
      ii. Cost: high (patient care, revenue loss)
   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 21 CFR 11 are required including report controls and digital signing
   b. Practice: high uptime, case 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 21CF11 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
   f. Encrypted data transmission beyond the firewall
   g. Digital signing to verify identity of remote senders

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 (eg, 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)