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2019 (Resolution 14)

## **ACR–ASNR–ASSR–SIR–SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF IMAGE-GUIDED EPIDURAL STEROID INJECTION**

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### **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<sup>1</sup>. 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 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.

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

## I. INTRODUCTION

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

Interventional spine procedures comprise a broad spectrum of treatment techniques (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, 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 craniocervical junction to the second sacral segment [6], with some anatomic compartmentalization by dorsal median connective tissue [7]. It is filled with compressible fat and

venous structures [8]. The epidural space can be accessed using different approaches (eg, caudal, interlaminar, and transforaminal). Once the needle is in the epidural space, the medication is injected and epidurography with contrast media is usually performed to verify the proper needle position, and subsequently navigates cranially and caudally within the epidural space. ESIs are performed in the cervical and lumbar spine and less often in the thoracic spine.

#### Interlaminar ESI:

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

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

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

#### Transforaminal ESI:

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

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

The infraneural/retrodiscal approach is an alternative TFESI trajectory using Kambin's triangle, which is defined as a right triangle over the dorsolateral disc [36]. In addition to avoiding epidural bleeding and scarring, the advantage of this approach is the decreased risk of intravascular penetration. Murthy et al. reported that the artery of Adamkiewicz (or artery) runs through the “safe triangle,” and this may result in injection of medications within the artery or directly damage a feeding vessel [37]. By spinal angiography, the radiculomedullary artery is located in

the superior half of the intervertebral foramen in 97% of cases and is never seen in the inferior one-fifth of the intervertebral foramen [37]. The authors concluded that the safest needle placement for a TFESI, particularly at L3 and above, may be in an inferior and slightly posterior position within the foramen and relative to the nerve. Although there is decreased risk of injuring a radiculomedullary artery, this approach still carries 6.6% risk of vascular injections [38]. Although some authors have found the risk of inadvertent vascular injection during lumbosacral transforaminal 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 transforaminal 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 transforaminal 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 transforaminal 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 ( $\leq 2$  weeks) follow-up and risk of surgery at short-term ( $> 2$  weeks to  $\leq 3$  months) follow-up [60]. However, there were no differences between ESIs and placebo interventions in likelihood of experiencing a successful pain, function, or composite outcome or likelihood of undergoing surgery in the long term [60]. There were no clear differential effects of the epidural approach used, different corticosteroids, different doses, use of imaging correlation, restriction to patients with herniated disc, duration of symptoms, or exclusion of patients with prior surgery. For spinal stenosis or nonradicular back pain treated with ESIs versus placebo interventions, the limited evidence showed no differences in outcomes related to pain or function [60]. Of note, the trials assessed used placebo interventions—such as epidural local anesthetic injection, epidural saline injection, soft-tissue injections, and no injection—and it is possible that these interventions may have had some therapeutic effects [61]. In addition, using different data points in different papers makes the literature less generalizable to the wider patient population. Other studies report that TFESIs and ILESIs are clinically effective for short-term and long-term relief of radicular pain and radiculopathy [51,62-64], although the paucity of high-quality randomized trials literature continues to confound the evidence.

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

However, some studies have shown that epidural injections with or without steroids are efficacious in various spinal degenerative pathologies [5,71], suggesting that the mechanism of action of ESIs may not be the anti-inflammatory effect of the steroid as it is traditionally thought. Many corticosteroids activate not only the target glucocorticoid receptor (GR) but also the mineralocorticoid receptor, which may have proinflammatory effects countering the effects of GR activation [72]. A recent multicenter randomized controlled trial on ESI (interlaminar or 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- $\gamma$ , among other proinflammatory agents, are not nearly as active in the nonacute setting. Anesthetics can mitigate neurotransmitter release at the sites of injury and inhibit the physiological cause of pain. Short-acting anesthetics are known to have a neuromodulating effect, possibly delaying or preventing the transition of acute pain

into the chronic pain syndromes. The individual biology and psychological effects of pain clearly adds to the different patient outcomes [85]. The role of local anesthetic in the postoperative patient has been studied as well and supports the concept of preventing acute migration into a chronic pain syndrome [86]. Rehabilitation after injections can also play an additive positive role. Such is the reason that multidisciplinary teams are necessary for the best outcomes, and most of the literature supports this integrative medicine.

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

#### **IV. INDICATIONS AND CONTRAINDICATIONS**

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

1. Radiculopathy: complex of symptoms that can arise from nerve root pathology, including paresthesia, hypoesthesia, anesthesia, motor loss, and pain [90]; specific observable physical examination and electrophysiologic findings. Radiculopathy may be confined to a single nerve root distribution (mono-), or more than one (poly-).
2. Radicular pain: single symptom of pain that can arise from one or more cervical, thoracic, or lumbar spinal nerve roots [90], which are inflamed and irritated [91]; diagnosed by a combination of physical examinations (eg, straight leg test) and controlled selective nerve blocks. Radicular pain and radiculopathy that are due to nerve root compression from local malignancy may also be amendable by palliative treatment with ESIs.
3. Spinal stenosis: mechanical pressure on the spinal cord, dura, or nerve roots that is due to a multitude of degenerative causes; pain, numbness, or upper- or lower-extremity weakness have a gradual onset and improve with forward flexion, “shopping cart sign” [92]
4. Axial pain: symptoms exacerbated by forward flexion [92]; sources of axial LBP include the facet joint, sacroiliac joint, intervertebral disc, vertebral end plates, paraspinal muscles, and fascia. These various targets are beyond the scope of this document.
5. Postsurgery syndrome or failed back surgery syndrome (FBSS): residual or recurrent back pain and disability after surgical intervention, which reportedly accounts for up to 40% of patients with chronic LBP. It may be possible to manage some etiologies with interventional techniques, including epidural fibrosis, sacroiliac joint pain, disc herniation, discogenic pain, spinal stenosis, recurrent synovial cysts, seromas, other collections, and facet joint pain [93-100]. Caudal ESIs have been reported to be effective in managing FBSS [101,102], with long-term pain relief achieved by adding hyaluronidase [102].
6. Persistent/incomplete pain relief following vertebral augmentation (kyphoplasty, vertebroplasty).

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

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

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

## V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

### A. Physician

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

1. Certification in Radiology, Diagnostic Radiology, or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of ESI procedures to demonstrate competency as attested by the supervising physician(s).
- or
2. Completion of an approved residency or fellowship program by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or an American Osteopathic Association (AOA)–approved residency program and has performed (with supervision) a sufficient number of ESI procedures to demonstrate competency as attested by the supervising physician(s).
- or
3. A physician who did not successfully complete an ACGME-approved radiology residency or fellowship program that included the above may still be considered qualified to perform ESI provided the following can be demonstrated: the physician must have at least 1 year of experience in performing percutaneous image-guided spine procedures, during which the physician was supervised by a physician with active privileges in these spine procedures. During this year, he or she must have performed (with supervision) a sufficient number of image-guided spine interventional procedures, particularly ESIs as primary operator with outcomes within the quality improvement thresholds of this practice parameter.

and

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must have written substantiation that they are familiar with all of the following:
  - a. Indications and contraindications for ESIs.
  - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient, and particularly the recognition and initial management of procedural complications.
  - c. Appropriate use and operation of fluoroscopic and radiographic equipment, digital subtraction systems, and other electronic imaging systems.
  - d. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements, as well as principles of ALARA, as they apply to both patients and personnel.
  - e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
  - f. Pharmacology of contrast agents and implanted materials and recognition and treatment of potential adverse reactions to these substances.
  - g. Technical aspects of performing this procedure. These include proper sterile techniques.

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the chief of musculoskeletal radiology, the chief of interventional neuroradiology, or the chair of the department of the institution in which the physician will be providing these services<sup>2</sup>. 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.
  - g. 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.

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<sup>2</sup>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.



## 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, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#). [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). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

### C. Non-Physician Radiology Provider (NPRP)

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

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

### 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 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 [106,111,112]. Both C-arm and bi-plane fluoroscopy provide multiplanar imaging of the target anatomy, which can help reduce procedural time [113] 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 [114-116]. Additionally, modification of planning CT can reduce the radiation exposure in CTF lumbar spine injections [117]. 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 [118]. 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 [119]. 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 [120] 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 injections of contrast material [121-124]. To confirm needle placement in the epidural

space, a dose of contrast agent is injected (1 to 5 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 [125]. 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 [126] 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 [127]. 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 [128-130].

In patients that have had a severe or anaphylactic reaction to contrast media, CO<sub>2</sub> 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 [131].

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

- a. A procedural suite large enough to allow safe and straightforward transfer of the patient from bed to procedural table with sufficient space for appropriate positioning of patient monitoring equipment, anesthesia equipment, respirators, etc. There should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other staff within the room without contaminating the sterile conditions.
- b. The majority of these procedures are performed under fluoroscopic guidance. A high-resolution image intensifier or flat-panel detector and video system with adequate shielding, capable of rapid imaging in orthogonal planes and with capabilities for permanent image recording is strongly recommended. The fluoroscope should be compliant with IEC 601-2-43 [132]. 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 [133]. Particulate steroids have a delayed but sustained anti-inflammatory effect [134]. In contrast, nonparticulate steroids dissolve immediately and are taken up rapidly by cells [134]. Dexamethasone sodium phosphate, a non-particulate steroid with a typical particle size of 0.5 µm [56,75,133], 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 [56,75,133].

The propensity of different corticosteroid particles to aggregate into larger particles depends on the chemical ingredient (esters have larger particulate size), on the varying concentrations, on the drug vehicle, or on the drug mixtures with local anesthetics and/or contrast media prepared in situ for pain treatment [75]. These aggregates, particularly the larger particle sizes, have the potential to embolize with risk for occlusion of small vessels and subsequent neural ischemic injury [135]. 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 [56,135]. 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 [136].

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 [137].

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 [138] with relative strength approximately 5 times that of hydrocortisone. Bethamethasone combines a short- and long-acting form and has approximately 30 times the strength of hydrocortisone. A minimal effective dose of corticosteroid is recommended to expose the patient to the least adverse effects. For example, a study comparing 40 and 80 mg of methylprednisolone found comparable results, with a less adverse profile with the 40-mg dosage [139]. 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 [140].

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% [141].

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 [142]. 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 [143,144] that is in part due to a fast and permanent increase in intracellular calcium levels [145]. 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 [146]. 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 [147].
- 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 [148,149]. Age and body weight affect the amount of posterior epidural fat [150,151], 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 [152], 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 [153]. 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 [154]. 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 [155]. 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 [156].

## 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 [157].
- 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](#) [158]. 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 [159]. 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) [160-162]
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](#) [163].

## 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](#) [164].

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%) [125] 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); for further information, see the [Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee](#) [165]. 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 [134,203,204], have also been questioned as potential cause of arachnoiditis, but direct causation has never been proven.

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

#### Bleeding

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

#### Infection

Even with the use of proper sterile technique, infection can occur with spine interventions. Goodman et al noted an infection rate of 1% to 2%, with severe infections noted in 0.01% of all spinal injections, varying among meningitis, epidural abscess, osteomyelitis, and discitis [125].

#### 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. Intra-neural hematoma may occur from puncture of the nerve root with the needle. Intra-neural 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. 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]. Maillefert et al found decreased serum cortisol, Adrenocorticotropic hormone (ACTH), and urinary cortisol after the single epidural injection of 15 mg of dexamethasone acetate [243]. The levels returned to normal at day 21. This effect may be dose dependent. Hsu et al found that a single epidural injection of 40 mg of triamcinolone markedly decreased plasma cortisol for only 24 hours, whereas 80 mg resulted in a decrease for up to 14 days posttreatment; HPA axis function returned to normal within 35 days in both groups [244]. A recent article demonstrated fewer systemic effects (ie, suppression of the pituitary axis for up to 3 weeks) with dexamethasone compared with particulate steroids [137].

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 of protection and application

of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578\\_web-57265295.pdf](http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf).

Nationally developed guidelines, such as the ACR's [Appropriateness Criteria®](#), should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

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

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children ([www.imagegently.org](http://www.imagegently.org)) and Image Wisely® for adults ([www.imagewisely.org](http://www.imagewisely.org)) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

## **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.

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

#### ACR

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

#### ASNR

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

#### ASSR

John D. Barr, MD, FACR  
Daniel T.D. Nguyen, MD

#### SNIS

Kristine A. Blackham, MD  
Allan L. Brook, MD, FACR

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

Jeffrey A. Stone, MD, FACR

Joshua A. Hirsch, MD, FACR

Committee on Practice Parameters – Neuroradiology

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

Raymond K. Tu, MD, FACR, Chair

Kristine A. Blackham, MD

Brian A. Conley, MD

Kavita K. Erickson, MD

Adam E. Flanders, MD

H. Simms Hardin, IV, MD

Steven W. Hetts, MD

John E. Jordan, MD, MPP, FACR

Jacqueline C. Junn, MD

Robert J. McDonald, MD

Alexander M. McKinney, IV, MD

David M. Mirsky, MD

Robin J. Mitnick, MD, FACR

Lubdha M. Shah, MD

Max Wintermark, MD

Alexander M. Norbash, MD, FACR, Chair, Commission on Neuroradiology

Jacqueline Anne Bello, MD, FACR, Chair, Commission on Quality and Safety

Matthew S Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

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

Comments Reconciliation Committee

Catherine J. Everett, MD, MBA, FACR, Chair

Daniel Ortiz, MD, Co-Chair

John D. Barr, MD, FACR

Jacqueline A. Bello, MD, FACR

Kristine A. Blackham, MD

Allan L. Brook, MD, FACR

Harry R. Cramer, Jr., MD

Richard Duszak, Jr., MD, FACR

Joseph J. Gemmete, MD, FACR

Wende N. Gibbs, MD

Bassem A. Georgy, MD

Manraj K.S. Heran, MD

Steven W. Hetts, MD

Joshua A. Hirsch, MD, FACR

John E. Jordan, MD, MPP, FACR

Paul A. Larson, MD, FACR

Mary S. Newell, MD, FACR

Alexander M. Norbash, MD, FACR

Daniel T.D. Nguyen, MD

A. Orlando Ortiz, MD, MBA, FACR

Matthew S. Pollack, MD, FACR

Martin G. Radvany, MD

Kent B. Remley, MD

Lubdha M. Shah, MD

John D. Statler, MD

Jeffrey A. Stone, MD, FACR

Timothy L. Swan, MD, FACR

Venu Vadlamudi, MD

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

Development Chronology for this Practice Parameter

2019 (Resolution 14)

Amended 2020 (Resolution 8)

Amended 2022 (Resolution 41f)