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**RESOLUTION NO.**

**BE IT RESOLVED,**

**that the American College of Radiology adopt the ACR–ASNR–ASSR–SIR–SNIS Practice Parameter for the Performance of Vertebral Augmentation**

**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 2012 (Resolution 6)\*

**ACR–ASNR–ASSR–SIR–SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF VERTEBRAL AUGMENTATION**

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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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the practice parameters when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to

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<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.

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always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these practice parameters will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these practice parameters is to assist practitioners in achieving this objective.

### I. INTRODUCTION

This practice parameter was revised 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).

This document addresses vertebral augmentation, which includes all percutaneous techniques used to achieve internal vertebral body stabilization. Vertebral augmentation encompasses a variety of procedures for treating pathologically weakened vertebral bodies. The more common ones are vertebroplasty and acrylic vertebroplasty, which involve injecting surgical bone cement; balloon kyphoplasty (also called balloon-assisted vertebroplasty), which involves inflation of a balloon in the weakened vertebral body to attempt fracture reduction before cement is injected; and radiofrequency ablation (RFA) and coblation techniques [1]. Other less common procedures include mechanical void creation (also called mechanical cavitation) with an osteotome, injection of bone graft material or bone substitutes, and insertion of materials **and/or implants** in an attempt to restore ~~the patient's~~ **vertebral height or attempt to decrease the possibility of extravasation [2,3]**. The field is evolving rapidly and this document also applies to any new methods for achieving the same end: vertebral augmentation.

A thorough 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.

Introduced by Galibert and Deramond et al in France in 1987 [4], vertebroplasty entails injection of material into the weakened vertebra. Radiologic imaging has been a critical part of vertebroplasty from its inception. Most procedures are performed using fluoroscopic guidance for needle placement and material injection or placement. The use of computed tomography (CT) has also been described for these purposes [5,6].

Vertebral augmentation is an established and safe procedure [4,5,7-24]. **The New England Journal of Medicine published 2** blinded, randomized controlled trials **that** failed to demonstrate an advantage in their study populations for vertebroplasty over a control intervention for either pain reduction or disability improvement [25,26]. However, larger non-blinded, ~~prospective~~ **systematic reviews and meta-analyses of the randomized controlled trials** have shown its efficacy [27-46]. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians.

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

Use of other technologies to treat patients for the same indications should yield similar or better success rates and complication profiles.

44 **II. DEFINITIONS**

45  
46 Vertebral augmentation includes all percutaneous techniques used to achieve internal vertebral body stabilization.

47  
48 Vertebroplasty is a minimally invasive surgical or interventional **image-guided** procedure, performed by  
49 percutaneously injecting radiopaque bone cement, **osteoinductive substance, or other therapeutic material** into  
50 a painful osteoporotic or neoplastic compression fracture or a painful vertebral body weakened by any other  
51 etiology.

52  
53 Kyphoplasty is an image-guided procedure in which a device such as a balloon or osteotome is employed to  
54 create a cavity within the vertebra, which is then filled with material. Balloon inflation may sometimes be  
55 employed to attempt vertebral height restoration.

56  
57 Other similar vertebral augmentation techniques involving the adjunctive implantation of devices in conjunction  
58 with bone filling materials have been described as well. These techniques may possibly effect vertebral height  
59 restoration and/or potentially decrease extravasation of the filler material.

60  
61 Kyphoplasty is an image-guided percutaneous procedure that creates a cavity within the bone that is then filled  
62 with material.

63  
64 Failure of medical therapy is defined as:

- 65
- 66 1. A patient rendered nonambulatory because of pain from a weakened or fractured vertebral body; pain  
67 persisting at a level that prevents ambulation despite 24 hours of analgesic therapy
  - 68 or
  - 69 2. A patient with sufficient pain from a weakened or fractured vertebral body that physical therapy is  
70 intolerable; pain persisting at that level despite 24 hours of analgesic therapy
  - 71 or
  - 72 3. Any patient with a weakened or fractured vertebral body and unacceptable side effects such as excessive  
73 sedation, confusion, or constipation due to the analgesic therapy necessary to reduce pain to a tolerable  
74 level
- 75

76 **III. OVERVIEW**

77  
78 Vertebral compression fractures are a common and often debilitating complication of osteoporosis [47-51].  
79 Although most fractures heal within a few weeks or months, a minority of patients continue to suffer pain that  
80 does not respond to conservative therapy [52-54]. Vertebral compression fractures are a leading cause of nursing  
81 home admission. Open surgical fixation is rarely used to treat these fractures **unless there is neurological**  
82 **compromise**. The poor quality of bone at the adjacent unfractured levels does not provide a good anchor for  
83 surgical hardware, and the advanced age of most affected patients increases the morbidity and mortality risks of  
84 major surgery.

85  
86 Initial success with vertebroplasty for treating aggressive hemangiomas [4,15] and osteolytic neoplasms [13,24]  
87 led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy  
88 [5,7-12,14,16-22]. Vertebral augmentation is currently being used to treat a wide variety of osteolytic metastases  
89 and multiple myelomas [39,55-58].

90  
91 Perioperative imaging that identifies the painful vertebral body in concordance with the clinical examination is  
92 considered essential for the safe and effective performance of vertebral augmentation.

94 **IV. INDICATIONS AND CONTRAINDICATIONS**

95  
96 The major indication for vertebral augmentation is the treatment of symptomatic osteoporotic vertebral body  
97 fracture(s) refractory to medical therapy or vertebral bodies weakened because of neoplasia. Currently, there is ~~no~~  
98 ~~indication for a lack of conclusive evidence to support~~ the use of **prophylactic** vertebral augmentation ~~for~~  
99 ~~prophylaxis against future to prevent future osteoporotic~~ fracture. The indications and contraindications for  
100 vertebral augmentation may change in the future as more research and information become available.

101  
102 A. Indication Threshold—95%

- 103 1. Painful osteoporotic vertebral fracture(s) refractory to medical therapy  
104 2. Vertebral bodies weakened by neoplasm  
105 3. Symptomatic vertebral body microfracture (as documented by magnetic resonance imaging [MRI] or  
106 nuclear imaging, and/or lytic lesion seen on computed tomography [CT]) without obvious loss of  
107 vertebral body height

108  
109 When fewer than 95% of vertebral augmentations in an institution are performed for the above indications, it  
110 should prompt a review of practices related to selection of patients for this procedure.

111  
112 B. Absolute Contraindications

- 113 1. Septicemia  
114 2. Active osteomyelitis of the target vertebra  
115 3. Uncorrectable coagulopathy  
116 4. Allergy to bone cement or opacification agent

117  
118 C. Relative Contraindications

- 119 1. Radiculopathy in excess of local vertebral pain, caused by a compressive syndrome unrelated to vertebral  
120 collapse. Occasionally preoperative vertebroplasty can be performed before a spinal decompressive  
121 procedure.  
122 2. Retropulsion of a fracture fragment causing severe spinal canal compromise  
123 3. Epidural tumor extension with significant encroachment on the spinal canal  
124 4. Ongoing systemic infection  
125 5. Patient improving on medical therapy  
126 6. Prophylaxis in osteoporotic patients (unless being performed as part of a research protocol)  
127 7. Myelopathy **or cauda equina syndrome** originating at the fracture level

128  
129 **V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

130  
131 A. Physician

132  
133 In general, the requirements for physicians performing vertebral augmentation may be met by adhering to the  
134 recommendations listed below:

- 135  
136 1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American  
137 Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège  
138 des Médecins du Québec, and **has performed (with supervision) a sufficient number of vertebral**  
139 **augmentation procedures to demonstrate competency as attested by the supervising physician(s).**  
140 ~~must include performance of successful vertebral augmentation procedures in at least 5 patients as the~~  
141 ~~primary operator, under the supervision of a qualified physician, and without major complications.~~  
142 or  
143 2. Completion of an approved residency or fellowship program by the Accreditation Council for Graduate  
144 Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPS), the  
145 Collège des Médecins du Québec, or an American Osteopathic Association (AOA) approved residency

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146 program and has performed (with supervision) a sufficient number of vertebral augmentation  
147 procedures to demonstrate competency as attested by the supervising physician(s). ~~that included 6~~  
148 ~~months of training in cross-sectional imaging, including CT and MR imaging, and 4 months of training in~~  
149 ~~image-guided interventional radiological techniques, including vertebral augmentation, biopsy and~~  
150 ~~drainage procedures, and vascular embolization. This must include performance of successful vertebral~~  
151 ~~augmentations in at least 5 patients as the primary operator, under the supervision of a qualified~~  
152 ~~physician, and without major complications.~~

153 or

- 154 3. A physician who did not successfully complete an ACGME approved radiology residency or fellowship  
155 program that included the above may still be considered qualified to perform vertebral augmentation  
156 provided the following can be demonstrated: the physician must have at least 1 year of experience in  
157 performing percutaneous image-guided spine procedures, during which the physician was supervised by a  
158 physician with active privileges in these spine procedures. During this year he or she must have  
159 performed a minimum of 5 vertebral augmentations as primary operator with outcomes within the quality  
160 improvement thresholds of this practice parameter.

161 and

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

175  
176  
177 The written substantiation should come from the chief of interventional radiology, the chief of  
178 neuroradiology, the chief of interventional neuroradiology, or the chair of the department of the institution  
179 in which the physician will be providing these services<sup>2</sup>. Substantiation could also come from a prior  
180 institution in which the physician provided the services, but only at the discretion of the current  
181 interventional, neurointerventional, or neuroradiology chief, or the chair who solicits the additional input.

182 and

- 183 5. Physicians must possess certain fundamental knowledge and skills that are required for the appropriate  
184 application and safe performance of vertebral augmentation:
- 185 a. In addition to a basic understanding of spinal anatomy, physiology, and pathophysiology, the  
186 physician must have sufficient knowledge of the clinical and imaging evaluation of patients with  
187 spinal disorders to determine those for whom vertebral augmentation is indicated.
  - 188 b. The physician must fully appreciate the benefits and risks of vertebral augmentation and the  
189 alternatives to the procedure.
  - 190 c. The physician is required to be competent in the use of fluoroscopy, CT, and MRI or interpretation of  
191 images in the modalities used to evaluate potential patients and guide the vertebral augmentation  
192 procedure.
  - 193 d. The physician should be able to recognize, interpret, and act immediately on image findings.

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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 [43].

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- 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 vertebral augmentation, including administration of basic life support, treatment of pneumothorax, 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 have 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.

Some methods of vertebral augmentation may require specialized training and experience, and such needs should be assessed before a physician contemplates using any method.

Maintenance of Competence

Physicians should perform a sufficient number of vertebral augmentation 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 vertebral augmentation is necessary.

Continuing Medical Education

The physician’s continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [59].

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team but not as primary operator. These nonphysician practitioners can function as independent members of the team but not as primary operator. See the [ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management](#) [60].

C. 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) [59]

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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.)

**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)

**E. 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 vertebral augmentation procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. 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 vertebral augmentation procedure and be certified by the American Registry of Radiologic Technologists (ARRT) and/or have an unrestricted state license.

**F. 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 vertebral augmentation procedure.

**VI. SPECIFICATIONS OF THE PROCEDURE**

**A. Technical Requirements**

Vertebral augmentation may be performed with either fluoroscopy or CT imaging guidance. The choice is a matter of operator preference and patient characteristics. In either case, there are several technical requirements to ensure safe and successful vertebral augmentations. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum requirements for any institution in which vertebral augmentation is to be performed:

1. A procedural suite large enough to allow safe and **easy 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.
2. 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

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281 orthogonal planes and with capabilities for permanent image recording, is strongly recommended. The  
282 fluoroscope should be compliant with IEC 601-2-43 [61]. Imaging findings are acquired and stored either  
283 on conventional film or digitally on computerized storage media. Imaging and image recording must be  
284 consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.

- 285 3. **Immediate Prompt** access to CT and ~~rapid (within 30 or 45 minutes) access to~~ MRI is necessary to  
286 evaluate potential complications. This may be particularly important if vertebral augmentation is planned  
287 in patients with osteolytic vertebral metastasis and/or with significant pre-existing spinal canal  
288 compromise.
- 289 4. The facility must provide adequate resources for observing patients during and after vertebral  
290 augmentation. Physiologic monitoring devices appropriate to the patient's needs—including blood  
291 pressure monitoring, pulse oximetry, and electrocardiography—and equipment for cardiopulmonary  
292 resuscitation must be available in the procedural suite.

### 294 B. Surgical and Emergency Support

295  
296 Although serious complications of vertebral augmentation are infrequent, there should be prompt access to  
297 surgical, interventional, and medical management of complications.

### 299 C. Patient Care

#### 301 1. Preprocedural care

- 302 a. The clinical history and findings, including the indications for the procedure, must be reviewed and  
303 recorded in the patient's medical record by the physician performing the procedure. Specific inquiry  
304 should be made with respect to relevant medications, prior allergic reactions, and bleeding/ clotting  
305 status.
- 306 b. The vital signs and the results of physical and neurological examinations must be obtained and  
307 recorded.
- 308 c. The indication(s) for the procedure, including (if applicable) documentation of failed medical therapy,  
309 must be recorded.
- 310 d. The indication(s) for treatment of the fracture should have documentation of imaging correlation and  
311 confirmation.

#### 313 2. Procedural care

- 314 a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong  
315 Procedure, Wrong Person Surgery™ is required for procedures in non–operating room settings,  
316 including bedside procedures.  
317 The organization should have processes and systems in place for reconciling differences in staff  
318 responses during the “time-out.”
- 319 b. Vital signs should be obtained at regular intervals during the course of the procedure, and a record of  
320 these measurements should be maintained.
- 321 c. Patients undergoing vertebral augmentation must have intravenous access in place for the  
322 administration of fluids and medications as needed.
- 323 d. If the patient receives sedation, pulse oximetry must be used. Administration of sedation for vertebral  
324 augmentation should be in accordance with the [ACR–SIR Practice Parameter for Sedation/Analgesia](#)  
325 [62]. A registered nurse or other appropriately trained personnel should be present and have primary  
326 responsibility for monitoring the patient. A record of medication doses and times of administration  
327 should be maintained.

#### 329 3. Postprocedural care

- 330 a. A procedural note should be written in the patient's medical record summarizing the course of the  
331 procedure and what was accomplished, any immediate complications, and the patient's status at the  
332 conclusion of the procedure (see section VIII.A.2 below). This note may be brief if the formal report

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333 will be available within a few hours. This information should be communicated to the referring  
334 physician in a timely manner. A more detailed summary of the procedure should be written in the  
335 medical record if the formal ~~typed~~ **transcribed** report will not be on the medical record within the  
336 same day.

- 337 b. All patients should be at bed rest and observed during the initial postprocedural period. The length of  
338 this period will depend on the patient's medical condition.
- 339 c. During the immediate postprocedural period, skilled nurses or other appropriately trained personnel  
340 should monitor the patient's vital signs, urinary output, sensorium, and motor strength. Neurological  
341 status should be assessed frequently at regular intervals. Initial ambulation of the patient must be  
342 carefully supervised.
- 343 d. The operating physician or a qualified designee (another physician or a nurse) should evaluate the  
344 patient after the initial postprocedural period, and these findings should be summarized in a progress  
345 note on the patient's medical record. The physician or designee must be available for continuing  
346 **postprocedural** care ~~during hospitalization at the facility~~ and after discharge.

### 348 VII. EQUIPMENT QUALITY CONTROL

349 Each facility should have documented policies and procedures for monitoring and evaluating the effective  
350 management, safety, and proper performance of imaging and interventional equipment. The quality control  
351 program should be designed to maximize the quality of the diagnostic information. This may be accomplished as  
352 part of a routine preventive maintenance program.  
353

### 354 VIII. QUALITY IMPROVEMENT AND DOCUMENTATION

#### 355 A. Documentation

356 Results of vertebral augmentation procedures should be monitored on a continuous basis. Records should be kept  
357 of both immediate and long-term results and complications. The number of complications should be documented.  
358 Any biopsies performed in conjunction with vertebral augmentation should be followed up to detect and record  
359 any false negative and false positive results.  
360

361 A permanent record of vertebral augmentation procedures should be maintained in a retrievable image storage  
362 format.  
363

- 364 1. Imaging labeling should include permanent identification containing:
  - 365 a. Facility name and location
  - 366 b. Examination date
  - 367 c. Patient's first and last names
  - 368 d. Patient's identification number and/or date of birth.
- 369 2. The initial progress note and final report should include:
  - 370 a. Procedure undertaken and its purpose
  - 371 b. Type of anesthesia used (local, moderate, deep, or general)
  - 372 c. Listing of level(s) treated and amount of cement injected at each level
  - 373 d. Evaluation of injection site and focused neurologic examination
  - 374 e. Immediate complications, if any, including treatment and outcome
  - 375 f. Radiation dose estimate (or fluoroscopy time and the number of images obtained on equipment that  
376 does not provide direct dosimetry information) [63-65]

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### 3. Follow-up documentation:

- a. Postprocedure evaluation to assess patient response (pain relief, mobility improvement). Standardized assessment tools such as the SF 36 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. Pathology (biopsy) results, if any
- e. Record of communications with patient and referring physician
- f. Patient disposition

Reporting should be in accordance with the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [66].

### B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must comply with the [ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures](#) [67]. Risks cited ~~should~~ **may** include, **but are not limited to**, infection, bleeding, allergic reaction, rib or vertebral fracture, vessel injury, pneumothorax (for appropriate levels), ~~and~~ implanted material displacement, ~~into the adjacent epidural or paravertebral veins resulting in~~ worsening pain or paralysis, spinal cord or nerve injury, ~~or~~ pulmonary complication, **or death**. The potential need for immediate surgical intervention should be discussed. The possibility that the patient may not experience significant pain relief should also be discussed.

### C. Success and Complication Rates and Thresholds [4,5,7-24]

Although practicing physicians should strive to achieve perfect outcomes (ie, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, for example, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of fracture of rib or other bone is one measure of the quality of vertebral augmentation, values in excess of the defined threshold (in this case <1%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication.

Thresholds may vary from those listed herein; for example, 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 improvement 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). The complication rates and thresholds described herein refer to major complications.

Routine periodic review of all cases having less than perfect outcomes is strongly encouraged. Serious complications of vertebral augmentation are infrequent. A review is therefore recommended for all instances of death, infection, or symptomatic pulmonary embolus.

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**Success Rates**

When vertebral augmentation 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 1 of the relevant and validated measurement tools, such as the 10-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).** ~~for osteoporosis, procedure outcomes can be defined using the criteria by Hodler et al [68] with patients categorized as worse, same, better, or pain/disability gone. For the purpose of this document pain/disability gone is defined as improved. Therefore patients should be categorized as either improved, the same, or worse. This categorization should be determined with the use of a validated measurement tool.~~

~~When vertebral augmentation is performed for neoplastic involvement, success is defined as achievement of significant pain relief and/or improved mobility as measured by validated measurement tools.~~

**Table 1: Vertebral Augmentation Success Rates [69-76]**

	<u>Published Success Rates</u>	<u>Threshold for Review</u>
Neoplastic, all causes	70% to 92%	<60%
Osteoporosis, all causes	80% to 95%	<70%

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**Complications**

Major complications occur in less than 1% of patients treated for compression fractures secondary to osteoporosis and in less than 5% of treated patients with neoplastic involvement. Published complication rates and suggested thresholds are given below.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, for example, early in a quality improvement program. In this situation, the suggested threshold is more appropriate for use in a quality improvement program than is the published rate.

**Table 2: Specific Complications for Vertebral Augmentation [70,71,77-82]**

<u>Specific Complication</u>	<u>Published Rates</u>	<u>Thresholds for Review</u>
Transient neurological deficit (within 30 days of the procedure)		
Osteoporosis	1%	>2%
Neoplasm	10%	>10%
Permanent neurological deficit (within 30 days of the procedure or requiring surgery)		
Osteoporosis	<1%	>1%
Neoplasm	2%	>5%
Fracture of rib, sternum, or vertebra	1%	>2%
Allergic or idiosyncratic reaction	<1%	>1%
Infection	<1%	>0%
Symptomatic pulmonary material embolus	<1%	>0%
Significant hemorrhage or vascular injury	<1%	>0%

**Table 2: Specific Complications for Vertebral Augmentation [70,71,77-82]**

<u>Specific Complication</u>	<u>Published Rates</u>	<u>Thresholds for Review</u>
Symptomatic hemothorax or pneumothorax	<1%	>0%
Death	<1%	>0%

The overall procedure threshold for all complications resulting from vertebral augmentation performed for osteoporosis is 2%, and when performed for neoplastic indications it is 10%.

**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](#)<sup>®</sup>, 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<sup>®</sup> for children ([www.imagegently.org](http://www.imagegently.org)) and Image Wisely<sup>®</sup> 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 (<http://www.acr.org/guidelines>).

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533 of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine  
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### Appendix A

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

#### MINOR COMPLICATIONS

- 752 A. No therapy, no consequence  
753 B. Nominal therapy, no consequence; includes overnight admission for observation only  
754

#### MAJOR COMPLICATIONS

- 755  
756  
757 A. Require therapy, minor hospitalization (<48 hours)  
758 B. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)  
759 C. Have permanent adverse sequelae  
760 D. Result in death  
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\*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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