

## Research Reporting Standards for Percutaneous Vertebral Augmentation



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SINCE the first description of vertebroplasty in 1987 for the treatment of aggressive hemangiomas (1), vertebroplasty has become established as a safe and effective, minimally invasive procedure that offers a therapeutic option for patients with back pain from osteoporotic or tumor-related fractures. This initial success has spawned additional techniques for percutaneous vertebral augmentation, in which imaging guidance is used to inject radiopaque bone cement into a painful osteoporotic or neoplastic lesion in the spine. The typical treatment for a vertebral compression fracture involves the injection of bone cement into the vertebral body to fixate the fracture. Two of the most common methods involve either injection of a low-viscosity cement directly into the vertebral body (ie, vertebroplasty) or the use of a balloon to create a void in the cancellous bone and injection of the bone cement into this created void (ie, balloon kyphop-

lasty). There are new vertebral augmentation systems that allow an injection of ultra-high-viscosity bone cement. The title of this document intentionally includes the phrase "Percutaneous Vertebral Augmentation" to be applicable to all vertebral techniques that are used to stabilize compression fractures by percutaneous cement injection.

Initial therapy for patients who present with painful vertebral body fractures is usually limited to conservative management including bed rest and pain medications. Some investigators have advocated use of vertebral augmentation as first-line therapy. However, most patients undergo a 4–6-week period of conservative therapy while diagnostic evaluation is obtained and medical therapy with analgesics, bracing, and calcium supplementation is initiated.

The mechanism for pain relief is not completely understood, but likely in-

volves mechanical stabilization of vertebral body microfractures via direct structural reinforcement by the cement. In addition, tumor necrosis and damage to small peripheral nerve endings that mediate pain sensation may be induced by the exothermic reaction to the cement polymerization that transiently reaches as high as 70°C (2).

In September 2007, the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurologic Surgeons/Congress of Neurologic Surgeons, and American Society of Spine Radiology published a position statement on percutaneous vertebral augmentation (3). The societies stated that "vertebral augmentation with vertebroplasty or kyphoplasty is established therapy and should be reimbursed by payers as a safe and effective treatment for painful compression fractures." However, from the standpoint of evidence-based medicine, there is only a single study with level 1 evidence confirming the effectiveness of vertebral augmentation (4). The purpose of this document is to improve the quality and relevance of research reporting of vertebral augmentation.

### PRETREATMENT EVALUATION

#### Population Description

Accurate description of the patient population is essential for several reasons: (i) it enables a reader to determine whether a study is relevant to his or her patient population; (ii) it helps to delin-

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eat which patient subsets are likely to benefit from the intervention being described; and (iii) it facilitates meaningful comparison with other studies describing patient cohorts who were treated with the same or different medical, surgical, or interventional therapies. The main indications for vertebral augmentation include osteoporotic compression fractures (5), hematologic malignancies such as multiple myeloma and lymphoma, metastatic disease (6,7), and symptomatic benign tumors of the spine, particularly hemangiomas (8).

### Osteoporotic Compression Fractures

Postmenopausal women represent the principal group at risk of osteoporotic compression fractures. It is estimated that as many as 50% of postmenopausal women will experience an osteoporosis-related fracture in their lifetime (9). Vertebral compression fracture is the most frequent fracture, occurring in 25% of the osteoporotic population. Additional well defined risk factors include age, cigarette smoking, ethnicity, and early menopause. Other groups at risk include patients receiving chronic steroid therapy, patients with renal failure, and individuals with prolonged immobilization (10).

Painful compression fractures may result in a marked decrease in physical activity and/or bed rest, which can lead to various complications including physical deconditioning, lung atelectasis and pneumonia, deep vein thrombosis, and pulmonary embolism. Vertebral compression fractures represent one of the leading causes of admission to nursing homes (11). Medications used for pain control in patients with osteoporotic compression fractures include narcotics and nonsteroidal antiinflammatory drugs. Although commonly prescribed, these medications are not without complications. Ulcers can be documented by endoscopy in as many as 40% of chronic nonsteroidal antiinflammatory drug users (12). Serious nonsteroidal antiinflammatory drug-induced gastrointestinal complications, such as hemorrhage, perforation, and death, occur collectively in as many as 1.5% of patients per year (13). In a review of patients receiving opioid agents for noncancer pain, approximately 80% of patients experienced at least one adverse event, with constipation (41%),

nausea (32%), and somnolence (29%) being most common (14).

In cases in which there is significant spinal cord compression or neurologic deficit associated with a compression fracture, patients should receive surgical treatment with anterior decompression and fusion followed by posterior segmental instrumentation and fusion. However, osteopenic adjacent vertebrae provide a poor anchor for surgical hardware (15). These procedures represent significant interventions for fragile patients, who are often poor surgical candidates with appreciably increased peri- and postoperative morbidity and mortality.

Long-term medical management and prevention of osteoporosis relies on adequate dietary calcium intake, calcium and vitamin D supplementation, weight-bearing exercise and estrogen replacement therapy. Bisphosphonates and calcitonin are effective in bone augmentation when prolonged therapy is used, although they do not provide pain relief. Prolonged therapy is required, and some medications may be difficult to tolerate because of side effects.

### Malignancies

In North America, vertebral augmentation has not been as widely applied to the treatment of patients with nonosteoporotic vertebral lesions. However, this patient population may benefit considerably, with rapid and durable reduction in vertebral pain after vertebral augmentation. Metastatic lesions are the most common tumors of the spine, but hematologic malignancies such as multiple myeloma and lymphoma may also frequently involve multiple vertebral levels. Patients usually present with severe pain secondary to osseous involvement, with or without vertebral collapse. Pain can also be a result of spinal cord and/or nerve root compression.

Conventional therapy for malignant disease consists of bed rest, bracing, antiinflammatory or narcotic medication, and radiation therapy. These conservative options, not dissimilar from the management of osteoporotic compression fractures, may be associated with the same type of complications, ie, atelectasis and pneumonia, deep vein thrombosis, and pulmonary embolism. Surgical options consist of interventions such as corpectomy or cage placement,

with significant postprocedural recovery periods and high morbidity and mortality rates in patients who often have limited life expectancies. In addition, multifocal vertebral lesions are common and may contraindicate surgery. Therefore, for many patients, vertebral augmentation may be the treatment of choice.

Vertebral augmentation is best indicated in patients who present with a severe, focal, and mechanical back pain related to a vertebral collapse without epidural involvement. In the absence of spinal cord compression or epidural involvement, partial osteolysis of the posterior wall of the vertebral body is not a contraindication (7). Preventive treatment of osteolytic lesions at high risk of vertebral collapse in asymptomatic patients may be appropriate. Vertebral augmentation is rarely indicated at the cervical and cervicothoracic junction but may be of value when surgery is contraindicated. The second and third cervical vertebrae can be approached transorally; the other cervical vertebra can be treated from the anterolateral approach. Prophylactic vertebral augmentation in asymptomatic patients has been described anecdotally but is not widely accepted.

### Hemangioma

Vertebral hemangiomas are benign lesions usually incidentally discovered on magnetic resonance (MR) imaging studies of the spine performed for back pain. They are generally confined to the vertebral body and characterized by a bright T1- and T2-weighted signal. Painful, destructive vertebral body hemangiomas are relatively rare. However, they may cause pain related to fracture, mass effect with thecal sac compression, or neural foraminal compromise. Vertebral hemangiomas are amenable to vertebroplasty; the first report of vertebroplasty ever performed was for a hemangioma (1).

### Baseline Clinical Evaluation

The pretreatment clinical status of spinal disease in the study group should be characterized. Levels of pain and functional ability/disability should be accurately described so that the results of any intervention can be evaluated. The visual analog scale is a well established method of documenting patient

pain levels (16), and should be used to document pain levels both before and following interventions. The Oswestry Disability Index (17,18) and Roland Morris Disability Questionnaire (19) are well established condition-specific outcome measures used in the management of low back pain. The Short Form-36 (Medical Outcomes Trust, Boston, Massachusetts) is a form comprising 36 questions that yields an eight-scale profile of scores as well as physical and mental health summary measures. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group (20). Accordingly, the Short Form-36 has been useful in comparing general and specific populations, comparing the relative burden of diseases, differentiating the health benefits produced by a wide range of different treatments, and screening individual patients (21).

On physical examination, percussion of the spine typically elicits pain within one to two vertebral levels of the compression fracture. The amount of compression of a vertebral body frequently bears little relation to degree of pain or the suitability for vertebroplasty. In patients with multiple vertebral compression fractures, localization of the symptomatic level may be difficult. In such cases, bone scan or MR imaging may be helpful.

Diagnostic studies usually include anteroposterior and lateral plain radiographs of the spine and/or MR imaging, which has the advantage of documenting additional spine conditions and vertebral levels that may contribute to the pain syndrome, in particular spinal degenerative disease. MR imaging provides a better evaluation of the degree of spinal canal compromise and/or spinal cord involvement, and may suggest underlying malignant disease based on the presence of soft tissue or epidural extension. Some patients may have contraindications to MR imaging such as a pacemaker or spinal instrumentation that compromises image quality. In these patients, nuclear medicine bone scans can help localize symptomatic levels amenable to treatment (22). Painful vertebral bodies may not demonstrate edema on short  $\tau$  inversion recovery MR imaging, but the edema state should be reported. MR imaging protocols should be described in detail.

## Recommendations

The number of patients and the number of treatments per patient must be reported. A basic demographic description must be provided, including age, sex, and ethnicity. Number of participating institutions and the number per institution should be reported. Symptom duration before vertebral augmentation must be reported. Previous and concomitant medical/other treatments must be described. Comorbid conditions and risk factors should be documented, as this may yield important insights into patient populations that may benefit, or may have increased morbidity, as a result of interventions intended to improve quality of life. A baseline assessment of pain and disability with validated measurement tools must be reported. The same measurement tools should be used for follow-up so that change over time can be identified and reported. Because there are different disease processes that predispose patients to vertebral compression fractures, it is important that these distinct patient populations are recognized. The etiology of compression fracture (eg, osteoporosis, hemangioma, malignancy) should be documented, as these different patient populations have different characteristics. The purpose of treatment (eg, pain relief, prophylaxis) should be documented. The study inclusion and exclusion criteria must be stated, and the method of treatment assignment must be reported.

Imaging modalities used for evaluation must be documented. The grade of compression fracture, as determined by imaging, should be documented. Fracture characteristics may yield information as to fractures more prone to complication and thus a uniform terminology for grading of compression fractures should be used. The system developed by Genant et al (23) has been used as a grading system in several studies, such as that of Klazen et al (24). According to this semiquantitative approach, each vertebra is assigned a grade of 0–3, whereby a grade of 0 (ie, normal) indicates no reduction in vertebral body height, grade 1 (ie, mild) indicates a reduction in vertebral body height of 20%–25%, grade 2 (ie, moderate) indicates a reduction of 25%–40%, and grade 3 (severe) indicates a reduction of more than 40%. For patients with osteolytic metastasis the presence of pathologic fractures as well

as the degree of osteolytic involvement of the vertebral body should be described. Trumm et al (25) have devised a grading system that quantifies osteolytic destruction of the vertebral body, posterior cortical wall and spinal canal, and the outer cortical wall in increments of 25%.

## TREATMENT DESCRIPTION

Radiologic imaging has been a critical part of vertebral augmentation from its inception. Most procedures are performed with use of single-plane or biplane fluoroscopic guidance for needle placement and to monitor bone cement injection. The use of computed tomography (CT) has been described (25,26) as well as cone-beam C-arm CT (27).

### Description of Technique

Polymethylmethacrylate is currently the most commonly used cement for vertebral augmentation. Most complications are related to extravasations of cement into the spinal canal and venous system. Various polymethylmethacrylate formulations have different properties of setting time, polymerization temperature, and strength. The cement properties affect cement distribution and handling, as well as the means by which the cement is injected through the needle and even the size of needle through which the cement can be injected. Current polymethylmethacrylate formulations have largely overcome many of these limitations; however, polymethylmethacrylate is neither biodegradable nor osteoconductive and thus becomes a permanent implant that may interfere in the natural remodeling process of bone (28). Cements containing calcium phosphate, calcium sulfate hydroxyapatite, as well as composite resins are being developed to address these issues (29).

Because of the systemic nature of osteoporosis and possible altered mechanics of the spine after vertebral augmentation, patients are at risk for the development of fractures at adjacent levels (30,31). Different cement compositions may also reduce the risk of fractures at adjacent levels by more closely approximating the biomechanical properties of bone.

Vertebral augmentation is frequently performed via a transpedicular route/approach, although other approaches

**Table 1**  
**SIR Standards of Practice Committee Classification of Complications by Outcome**

**Minor Complications**

- A. No therapy, no consequence.
- B. Nominal therapy, no consequence; includes overnight admission (up to 23 hours) for observation only.

**Major Complications**

- C. Require therapy, minor hospitalization ( $\geq 24$  h, but  $< 48$  h).
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization ( $> 48$  h).
- E. Permanent adverse sequelae.
- F. Death.

can be used, particularly in the cervical region. The choice of needle size may be influenced by the planned approach to the vertebral body. The size of the needle may also impact extravasation along the needle tract, as well as associated complications with needle placement. The number of levels treated also appears to be associated with development of complications (32). There are reports of successful vertebral augmentation of more than three to five levels in one sitting (33,34).

Vertebroplasty and kyphoplasty are the two most common techniques for vertebral augmentation at this time. Both techniques have been shown to stabilize vertebral compression fracture, but there is controversy as to which technique is superior. It is important to note that they are not mutually exclusive procedures, and one procedure may be preferable to the other depending on the location of the vertebral body to be treated and the nature of the abnormality. The use of vertebroplasty or kyphoplasty has been reported for osteoporotic vertebral compression fractures (35,36), as well as vertebral compression fractures associated with malignancy (37). Vertebroplasty is a somewhat simpler procedure, with fewer steps; after needle placement, cement is injected through the needle. Kyphoplasty requires several steps before the injection of cement. These additional steps include drilling a path into the vertebral body for the balloon, inflating a balloon to compact the bone and create a potential space, followed by injection of the bone cement. The larger size of the needle used in kyphoplasty may limit its application. All procedural steps, rationale for their choice, and procedural endpoints must be described.

The most significant difference between the procedures is the restoration

of lost vertebral body height, thus reducing kyphosis at the treated level; and the associated potential long-term complications (38–40). Another potential benefit to kyphoplasty is the lower reported rate of cement extrusion (41). It has been shown that kyphoplasty may seal osseous defects and venous pathways, thereby preventing cement from leaking (42).

The patient's overall health and comorbid conditions will affect the type of sedation required to perform vertebral augmentation. Many patients can tolerate vertebral augmentation with the use of sedation alone; however, those with poor cardiopulmonary status or those undergoing vertebral augmentation of cervical vertebrae may require general anesthesia.

Adjunctive procedures have been applied to patients with malignancy. Radiation therapy has been used in patients with spinal metastasis. In some cases, tumors are unresponsive, or patients are not offered vertebroplasty until they receive maximal radiation. There are those who advocate vertebral augmentation before radiation therapy as it has been shown that treatment of neoplasms is not affected by the presence of cement, nor is cement affected by radiation (43). In fact, it has been shown using a human cadaver model that the delivered dose to the vertebral body is increased after vertebroplasty (44). Small series have included adjunctive procedures such as radiofrequency ablation for patients with spinal metastasis (45,46). The use and benefit of these procedures requires further study because additional treatments may increase costs.

### Recommendations

The imaging modalities used to perform vertebral augmentation should

be described. Patient positioning, the route/approach, and the point of needle entry into the vertebral body should be described. The number of needle placements for each vertebra and the use of unipedicular, bipedicular, or extrapedicular approaches must be reported. The type, size, method of use, and manufacturer of all devices used, including needles, catheters, and balloons, must be reported. The type of sedation used and patient monitoring should be reported. When general anesthesia is used, the reason for its use should be described. The manufacturer of the cement, composition of the cement, method of delivery, working time, use of additives (eg, to increase opacity), and volume delivered must be reported. The methods used to choose technical and procedural aspects and endpoints (eg, approach to the vertebra, amount of cement injected, detection of cement leakage, degree of balloon inflation) must be specified. Procedural elements (eg, patient positioning, imaging modality) may influence the overall procedure time and fluoroscopy time (as well as radiation dose), and these should be documented (47). The number of levels treated as well as their location must be reported. Objective measurements of kyphosis and vertebral body height improvement should be reported according to accepted measures such as the Cobb angle and Genant score (23). Adjunctive procedures such as epidural or sacroiliac joint injections, radiofrequency ablation, and radiation therapy, when used in conjunction with vertebral augmentation, should be reported. Use of local and systemic medications, such as intravenous antibiotics, should be reported. Whether patients were treated according to the originally intended protocol should be reported.

### OUTCOMES ASSESSMENT

The goal of vertebral augmentation is to improve patients' quality of life by relieving pain and returning patients to their baseline level of activity before the onset of pain related to a vertebral compression fracture or neoplastic/tumoral destruction of a vertebral body. As a result of the differing underlying disease processes (eg, osteoporosis, malignancy, hemangioma), outcome measures will be different and the follow-up of these patients may be limited by life expectancy. To fully evaluate the out-

**Table 2**  
**Summary of Reporting Standards**

Category	Recommendation
<b>Population description</b>	
Basic demographic data	Required
Etiology of fracture	Required
Purpose of treatment	Required
Grade of vertebral compression fracture	Required
Treatments before vertebral augmentation	Required
Symptom duration before vertebral augmentation	Required
Pain assessment	Required
Disability evaluation (eg, VAS, ODI, RMDQ, SF-12, SF-36)	Required
Quality of life	Recommended
Risk factors/comorbidities	Required
Imaging modalities for workup	Required
Inclusion/exclusion criteria	Required
Method of treatment assignment	Required
<b>Treatment description</b>	
Imaging equipment	Required
Patient position	Required
Sedation/general anesthesia	Required
Route/approach to vertebra	Required
Devices used, including manufacturer	Required
Location and number of levels treated per session	Required
Procedure time	Required
Type of cement and additives	Required
Method of cement injection	Required
Amount injected per level	Required
Adjunctive procedures	Required
<b>Outcomes assessment</b>	
Technical and clinical success	Required
Imaging follow-up: type, timing, and results	Required
Clinical follow-up: type, timing, and results	Required
Complications, classified by SIR outcomes scale	Required
Pain assessment	Required
Disability evaluation	Required
Quality of life	Recommended
Height restoration and kyphosis improvement	Recommended
New compression fractures and locations	Required
<b>Analysis</b>	
Study design	Required
Data collection	Required
Institutional review board approval	Required
Statistical analysis	Required
Intent to treat/per protocol	Required
Cost analysis	Recommended

Note.—ODI = Oswestry Disability Index; RMDQ = Roland Morris Disability Questionnaire; SF-12 = Short Form-12; SF-36 = Short Form-36; VAS = visual analog scale.

comes of vertebral augmentation, it is necessary to assess the safety and efficacy of vertebral augmentation, as well as resource utilization.

The Society of Interventional Radiology (SIR) Quality Improvement Guidelines for Percutaneous Vertebroplasty provide and list of complications associated with vertebroplasty and suggested thresholds. Described complications include death, paralysis, hypotension, bleeding, infection, device breakage, ce-

ment leakage (including location of leakage), and pulmonary embolism (including fat and cement). Major complications occur in fewer than 1% of patients treated for compression fractures secondary to osteoporosis and in fewer than 5% of treated patients with metastatic involvement (48). Published rates may vary with patient selection, as well as the methods used to detect complications: for example, routine use of postoperative chest CT may increase re-

ported rates of cement embolism (49). Methods used to diagnose complications (ie, imaging and/or clinical methods) should be reported. The type of imaging equipment employed during performance of vertebral augmentation, cement properties, number of levels treated, and underlying disease process have all been implicated in contributing to complications. SIR standards of practice for classification of complications by outcome provide a uniform means for classifying and reporting complications (Table 1). Adverse events should be recorded at standard intervals such as 24 hours and 30 days. All complications, both symptomatic and asymptomatic, must be classified and reported.

Technical success should be considered placement of the needle and/or device into the vertebral body with injection of enough cement to stabilize the vertebral body. As this last element is subjective, it will vary with each level treated and will be influenced by the size of the vertebral body. It is therefore important to define technical success and document this on a per-procedure basis. Clinical success is defined as the achievement of significant pain relief and/or improved mobility as measured by validated measurement tools. Threshold rates for clinical success have been suggested as 80% for patients with osteoporosis and 50%–60% for patients with neoplastic lesions (48). Definitions of technical and clinical success were specified in the studies of Knight (50) and Kallmes et al (51); authors may choose to use these.

The immediate and short-term (<1 year) benefit of vertebroplasty (52–54) and kyphoplasty (4) have been shown by several studies. Postprocedural pain, disability, and quality of life should be measured with repetition of the preprocedural validated tools to compare clinical status before and after treatment with vertebral augmentation. These measures should be administered at set time intervals after vertebral augmentation as specified in the study protocol.

Obtaining information about the cost of a procedure is typically limited to hospital charges. Unfortunately, this does not take into account the productivity lost by patients and their immediate families if they are the primary caretakers. Most patients undergo several weeks of medical therapy before vertebral augmentation. Cost savings may be

found because of the shorter recovery period associated with a minimally invasive procedure compared with medical or surgical treatments. Rigorous analysis of costs should include in-hospital costs, costs of complications, and costs of long-term care, monitoring, and treatment.

### Recommendations

Technical/anatomic success must be defined and rates reported. Complications should be defined as minor or major and reported at standardized intervals, on a per-patient basis, according to the SIR criteria. Treatment efficacy, including the primary outcome measure(s), must be defined and rates reported. Improvement in patient pain, disease/symptom severity, disability, and quality of life are key elements in reporting outcomes after vertebral augmentation. Quantitative and clinically meaningful measures of these outcomes must be used. Authors should specify which outcomes measures were collected prospectively and which were collected retrospectively. The follow-up protocol should specify the type and timing of follow-up imaging, and the timing and nature of clinical follow-up and personnel responsible for this. Suggested follow-up intervals are short-term (ie, <1 year), midterm (ie, 1–3 y), and long-term (ie, >3 y).

### COMPARISON BETWEEN TREATMENT GROUPS

The randomized clinical trial is the criterion standard of clinical research and is the methodology of choice for determining the safety and efficacy of vertebral augmentation treatments and for comparing them with other percutaneous, surgical, and medical therapies (55). However, it is recognized that most studies will be of lesser methodologic rigor as a result of practical reasons such as cost, patient recruitment, and/or ethical considerations. Randomized trials should be performed in accordance with the guidelines described by Begg et al (55).

Reports must indicate whether a study is single-center or multicenter and sponsored, and if so, by whom and whether it was performed under the aegis of the United States Food and Drug Administration or another regulatory body. The role of the sponsor in funding, data management, and data analy-

sis, among other functions, should be described. The institutional review board status must be provided. The study design, sample size, statistical power, and statistical analyses must be reported. Consultation with a statistician in the methodology of the study design and statistical analysis is recommended before starting the study.

Primary statistical analyses should be reported based on intent-to-treat and per-protocol analyses. With an intent-to-treat approach, subjects are analyzed with the group to which they were randomized whether they received the treatment or dropped out of the study. A per-protocol analysis considers only those patients who actually received the intended treatment. Discussions of significance should incorporate the study design limitations. If the study conclusions are based on analysis of surrogate outcomes, they should be tempered accordingly. Authors should avoid drawing conclusions not clearly supported by the data; if alternate interpretations of the data are possible, they should be discussed.

### CONCLUSION

Published studies on vertebral augmentation have been limited by non-standardized reporting, lack of long-term follow-up, and use of surrogate outcome measures. It is the purpose of these reporting standards to bring greater uniformity to vertebral augmentation research reported in the radiology literature. A summary of the requirements and recommendations for reporting are provided in **Table 2**. Some of these requirements and recommendations may be more applicable to large trials than small case series. Authors are also encouraged to consult the guidance for vertebral augmentation published by the United States Food and Drug Administration in 2004 (56).

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.