November 14, 2013

Paul Tauriello  
Director, Division of Workers’ Compensation  
633 17th Street, Suite 400  
Denver, CO  80202

Re: Proposed Medical Treatment Guidelines for Cervical Spine Injury and Low Back Pain

Dear Mr. Tauriello:

The International Spine Intervention Society (ISIS) is a multi-specialty physician association dedicated to the advancement of patient care through the development and promotion of the highest standards for the performance of interventional procedures in the diagnosis and treatment of spine pain. With more than 3,000 board-certified and board-eligible physicians, ISIS membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer, or undergo more invasive and often unnecessary surgical procedures. We commend your organization on incorporating a number of the ISIS guidelines in creating draft policies addressing neck and back pain for Colorado Worker's Compensation. Before this document is finalized, we would like to offer the following comments and suggestions to further enhance these policies and ensure that they accurately reflect the current literature.

ISIS RECOMMENDATIONS BY SECTIONS:

Section E b ii:  
"All spinal injections should be preceded by an MRI." This statement is repeated multiple times. While we agree with the thought process behind this statement, unfortunately not all patients are able to undergo an MRI (e.g., those with a pacemaker). Therefore, this statement could be modified to accommodate other appropriate imaging modalities, such as CT scan. Suggest modifying recommendation to be consistent with ISIS guidelines. “All spinal epidural injections should be preceded by either an MRI or a CT scan.”

"All injections must be accompanied by active therapy." This statement is also repeated multiple times throughout the guideline. For a large variety of reasons delineated below, we would recommend changing the wording to, “All injections must be accompanied by functional goals
including a return to assisted or independent activity-based exercise, and/or provide assistance in decision making and/or diagnosis.” Despite strong general acceptance, the evidence regarding physical therapy for acute back pain is not definitive, and suggests that therapeutic exercises may not be effective nor indicated for all cases of acute low back pain. Additional literature also suggest the value of exercise for chronic low back pain is not nearly as substantial as one would believe compared to the acceptance of this treatment based on theoretical grounds. Conclusions from several systematic reviews and meta-analyses conclude: "evidence from randomized controlled trials demonstrates that there is low quality evidence for the effectiveness of exercise therapy compared to usual care" and "when all types of exercise are analyzed, small but significant reductions in pain and disability are observed compared with minimal care or no treatment". Although 18 trials on chronic low back pain reported positive conclusions in favor of exercise, only six of the 43 studies showed both clinically important and statistically significant differences in favor of the exercise groups for functional outcomes, while only four of the 43 showed differences for pain.

Conclusions of trials should be based on clinical importance and statistical validity. The reporting of confidence intervals is essential for the assessment of clinical importance and statistical significance. Of note, trials of physical therapy merely report results using mean data with standard deviations only. This method of statistical analysis is only valid assuming a normal, bell shaped distribution of pain. This is typically not the case with spine pain, in which some people resolve their pain, while others continue with significant pain. The correct statistical method in this case is reporting clinically important indicators, such as categorical data denoting 75-100% relief of pain and functional improvement. While this has never been done in the physical therapy literature, it has been done in numerous interventional outcome studies on cervical and lumbar epidural steroid injections and radiofrequency neurotomy.

Section F 3 a ii c:
“A successful block requires documentation of positive functional changes preferably by a therapist or non-injectionist physician.” This statement is also repeated numerous times elsewhere including, but not limited to, assessing pain relief following diagnostic medial branch blocks, selective nerve root blocks, sacroiliac joint injections and sacral lateral branch blocks. ISIS does recognize that, "an assessor who wants the block to work may exercise observer bias, and report as positive a block whose effect has not truly been positive, or report as completely effective a block that has been only partially effective." Accordingly, the ISIS guidelines recommend an independent assessor be used to evaluate the patient after a diagnostic block. The guidelines state, "It is imperative that the assessor be adequately trained in the documentation of relief of index pain. In some practices it may be possible to train an independent assessor specifically for this purpose. In other practices this may not be financially practical." The ISIS guidelines do not explicitly state that the independent assessor must be a therapist or a non-injectionist physician. In fact given the assessment should ideally occur immediately following the injection, thus it might be impossible for the vast majority of practices to have another physician or therapist available following the block. Therefore while we do endorse that such personnel be allowed to be assessors, we also endorse other health professionals as independent assessors, such as nurses or medical assistants. We thus recommend further modifying the guideline to state, “A successful block requires documentation of positive functional changes by trained personnel including: nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians.”
The ISIS guidelines additionally provide clarity as to the role of the assessor as follows: "The assessor evaluates the patient's response to the block, administering the instruments that have been selected for this purpose.” Appropriate assessment tools could include: pre and post procedure pain scores, the duration and magnitude of pain relief, post-procedure repetition of appropriate provocative physical exam maneuvers as determined by the pre-procedure examination, the need for break-through post-procedure pain medications, and the restoration of patient-specific functional items after the procedure.

**Section E b vi A:**
"Transforaminal injections are generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic, usually 0.5 cc, should be used to determine the level of nerve root irritation." Based upon new literature by Furman et al this volume might not be adequate to block the spinal nerve.\(^{17}\) His study showed that 1.1 mL of contrast was needed to spread to the medial aspect of the superior pedicle of the corresponding level of injection, which would be the target zone to adequately block a segmental spinal nerve. This is in contrast to medial branch blocks where 0.5 mL or less is often adequate and appropriate for a diagnostic block.\(^{18}\) The existing literature that validates lumbar spinal nerve blocks frequently use up to 1.0 cc of anesthetic, as indicated by the analysis of dynamic contrast flow and dilution patterns.\(^ {19-24}\) Therefore, we recommend the following modification to the guideline, "Transforaminal injections are generally accepted and useful in identifying the level of nerve root irritation. When performed for diagnosis, the volume of local anesthetic needed to adequately block the nerve can be estimated by the real time assessment of contrast flow patterns around the nerve prior to the application of local anesthetic. The amount of local anesthetic needed to anesthetize the nerve will generally not be more than 1.0cc."

The draft guidelines state the following sets of patients may benefit from epidural injections:

1. "When a patient with radicular findings due to herniated disc, meets all of the indications for surgery at approximately 6-8 weeks post active therapy, one epidural may be attempted at the patient's discretion… For rare, acute ruptured (herniated) disc with clear objective radiculopathy if, after one to two weeks of initial oral analgesic and conservative treatment; the patient: has continued pain interfering with most ADL function and requiring frequent opioid use; and is unable to tolerate the required movements to participate in therapy; and has pain greater in the leg than in the back, generally of 7 or greater on a VAS scale of 10; and has pain following a correlated radicular dermatome; and there is a herniated disc on the MRI at the level of subjective and objective findings; and has either: dural tension, signs of straight leg raising or slump test resulting in radicular symptoms correlating with imaging pathology; and/or one of the following documented, reproducible findings, which correlates…”

We would suggest this be changed to: “For rare, acute ruptured (herniated) disc with clear radicular pain, with or without radiculopathy if, after one to two weeks of initial oral analgesic and conservative treatment; the patient: has continued pain interfering with most ADL function and is unable to tolerate the required movements to participate in therapy; and has pain greater in the leg than in the back; and has pain with the characteristic quality of radicular pain; OR has dural tensions, signs of straight leg raising or slump test
resulting in radicular symptoms correlating with imaging pathology; OR has one of the following documented, reproducible findings, which correlates with the suspected nerve root impingement: decreased reflexes, or radicular sensation deficits, or motor weakness on testing, and there is a herniated disc on the MRI or CT at the level of subjective and objective findings…”

Note that we suggest deleting from the new coverage language the requirement for a patient to be on opioids in order to be offered an epidural, but instead recommend oral analgesics. In addition we have changed the word "and" to "or" to account for a patient with a foraminal disc herniation with intermittent but severe and disabling pain upon standing, precluding function or participation in PT, but without fixed neurological deficit or positive straight leg raise response. The last change was to remove a specific pain score (>7/10) to qualify, as pain scores vary substantially between patients. For example, if a patient meets all the other requirements (e.g. oral mediations, significant limitations of ADLs, clear pathology on MRI, unable to participate in therapy), then is it essential that their pain is an 8/10 rather than a 6/10?

2. The draft guidelines state: "The patient has documented spinal stenosis deficits, has completed 6-8 weeks of active therapy, and is unwilling to undergo a surgical procedure. There is some evidence that ESIs are associated with a less favorable clinical course in the setting of spinal stenosis, and that they may be detrimental. Therefore they are not generally recommended, although may still be considered for patients who refuse or are not surgical candidates and continue to have functionally limiting neurologic findings."

There are several potential problems with this statement. First spinal stenosis is a nonspecific imaging observation; neurogenic intermittent claudication is a defined clinical condition. Treatment guidelines should ideally be directed to well defined clinical disease processes, not radiologic findings. Also, the term “spinal stenosis” as used in the proposed Guideline is not specific enough to be of utility in a clinical setting. Stenosis can be central, foraminal, or lateral recess in nature. It can occur from various etiologies, including but not limited to: central or lateral disc herniations, facet spondylosis with superimposed herniation, spondylolisthesis with or without additional herniation, ligamentum flavum hypertrophy with or without facet hypertrophy, and disc lesions. The indications for epidural injections are dependent upon the specific pathology and clinical situation. Additionally, the approach and level of performance of the epidural steroid injection is also dependent on the specific pathology and clinical situation. Using the general term “stenosis” and limiting all epidurals in all circumstances where central, foraminal or lateral recess stenosis occurs is overly prohibitive and inconsistent with societal recommendations and the prevailing standard of care.

Enforcing such a restrictive guideline could compel more patients to undergo unnecessary surgery when, in fact, an epidural steroid injection may provide adequate pain relief and functional improvement to allow them to avoid surgery. This is evident through the literature demonstrating surgical sparing effect of epidural injections for spinal stenosis.25-27 Also other evidence-based guidelines such as the North American Spine Society (NASS) 2011 clinical guideline do suggest epidural injections may offer some pain relief in spinal stenosis. That
guidelines states, "Interlaminar epidural steroid injections are suggested to provide short-term (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy. There is, however, conflicting evidence concerning long-term (21.5-24 months) efficacy. (Grade of Recommendation: B)... "A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections is suggested to produce medium-term (3-36 months) relief of pain in patients with radiculopathy or neurogenic intermittent claudication (NIC) from lumbar spinal stenosis." (Grade of Recommendation: C)

The proposed guidelines include the statement, "...there is some evidence that ESI's are not effective for the treatment of spinal stenosis as they may result in worse outcomes when lumbar surgery is performed and do not improve long-term outcomes for non-surgical patients." This statement appears to be based upon a single reference Radcliff et al.\textsuperscript{28}

Unfortunately this study is of a very low quality and is plagued with numerous methodological flaws which include:

A) Reliance on records reviewed during the study, which were not intended to analyze the effects of epidural steroid injections. As ESIs were not the focus of the original study, the records and metrics extrapolated to evaluate ESI efficacy could be inappropriate and inaccurate.

B) Arbitrary selection of patients who had ESIs during the first three months of the surgical procedure. These patients were neither consecutively enrolled nor progressively studied, allowing for a significant bias to be introduced into this retrospective review.

C) An enormous confounder is the absence of a description of the epidural injection procedure, including the type of epidural technique used (interlaminar vs transforaminal vs caudal), and whether fluoroscopy and/or contrast was used. Descriptions of the injections also fail to articulate the basic procedural details such as the types and doses of medications used, or how many injections were performed over what period of time.

D) Multiple different operators and techniques were involved in performing the injections and no subgroup analysis based on provider was performed.

E) There is no mention of co-interventions that could affect one group's outcome data even more than the ESI. For instance, the ESI group may have been on higher doses of opioids preoperatively which has been shown to result in a poorer post-op outcome.

F) Observer bias as the authors already knew the results, the disease status, and the exposure status of patients who were later grouped for the study.

G) Post hoc questions and arbitrary sub-group analyses could readily produce misleading results, especially if there was bias introduced in group selection.
H) The authors themselves admit the possibility of selection bias in epidural injections.

I) The authors do not report on patients that were loss to follow-up. It is unlikely that this four-year study did not have any subjects that were lost to follow-up. This could dramatically de-value the results of the statistical analysis and inherently reduces the quality of the evidence.

J) SF-36 is not the ideal instrument to evaluate pain intensity, but was the basis for the evaluation for pain reduction in this study.

K) Return to work, decreased use of medication, and utilization of other health care were not analyzed.

L) The only categorical data provided were patient satisfaction, which was not statistically different between the groups at four-year follow-up.

This study is inconsistent with existing literature on this topic. In a recent well done review of the effectiveness of lumbar transforaminal injection of steroids, it was noted that the collective literature demonstrates that approximately 50% of patients with spinal stenosis with radicular pain achieve 50% pain relief for six months or more. This was based upon a comprehensive review of the available literature on transforaminal epidural injections. This literature was also noted to be universally positive. However we acknowledge more rigorous studies are lacking and no explanatory studies have reproduced the outcomes of these consistently positive pragmatic trials.

Therefore, this single significantly flawed study should not be cited as sufficient justification to deny patients with stenosis access to epidural steroid injections as part of their treatment continuum. It is highly likely that elimination of this procedure will result in more subjects undergoing more invasive spinal decompressions with greater costs, complications, and potential morbidity. Since the prevailing evidence is otherwise positive, patients should be given the option to try epidural steroid injections rather than be relegated to potentially unnecessary and expensive surgery that entails a known complication rate significantly higher than that of appropriately performed epidural steroid injections.

Section E b vi B:

"ISIS recommends that 100% of pain relief from the facet pain generator be obtained before radiofrequency neurotomy is considered." This statement is incongruent with the prevailing ISIS position as it relates to selection of patients for lumbar medial branch radiofrequency neurotomy. The more appropriate recommendation would be that there is ≥80% relief of the index pain, which is consistent with the ISIS position in the second edition of the ISIS guidelines and the validating literature. It additionally states "ISIS suggests controlled blocks – using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine) with ≥ 80% relief of the index pain" and "The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes."
Additionally, under indications for radiofrequency (RF) neurotomy, it is stated that individuals should have the following:

a. "Pain of well-documented facet origin - the physician should document pain with extension and lateral bending with referral patterns consistent with the expected pathologic level." This statement has been used for both the lumbar and cervical spine sections. We suggest deleting this requirement since a proper patient-specific functional assessment as recommend above is more thorough and appropriate. If this is retained, however, it would be better to use the terminology "pain of suspected facet origin" rather than well-documented facet origin. The specific maneuvers of extension and lateral bending are not validated methods to identify facet pain, either in the cervical or lumbar spine. There are currently no validated methods as judged against an established diagnosis derived by using controlled blocks.  

b. "Unresponsive to three months of active and manual therapy." We agree that medial branch blocks are not indicated for acute back pain. However, we question the requirement for both physical and manual therapy prior to performing these blocks in light of the fact that there is no evidence of the value of manual or physical therapy in those with established facet joint pain. While there is limited literature on chronic neck pain, there is no evidence of the value of manual or physical therapy for facet-mediated pain. This is in direct contrast to cervical and lumbar radiofrequency neurotomy, in which extensive literature has shown that large numbers of appropriately selected patients with technically sound RF lesions have definitive pain relief. Also while three months of pain is appropriate to exclude those with acute pain, patients may not need a full three months of conservative therapies as an exact duration of therapy has not been elucidated in the literature. We therefore suggest changing this statement to “Patients with at least 3 months of pain, and unresponsive to 6-8 weeks of conservative therapies”.

Section E b vi B:
"...as recommended by the ISIS guidelines, to qualify for a sacroiliac joint injection the patient must have at least 3 positive physical exam maneuvers (e.g. Patrick’s sign, Faber’s test, Gaenslen, distraction or gapping, or compression test)." Likewise this statement is repeated as one of the requirements for water-cooled RF neurotomy of the SIJ. It would be more appropriate to change this to "there are physical exam findings which can assist in the selection of patients for sacroiliac joint procedures". This statement is more consistent with the literature, which to date has not shown any one test or combination of clinical examination provocation maneuvers that can predict who has sacroiliac joint mediated pain.

Studies have shown that the provocative maneuvers of Laslett are the most predictive of identifying those that may have sacroiliac joint pain. The positive predictive value of ≥ 3/5 of the provocative maneuvers of Laslett is 77%. If all five provocative tests are negative, the negative predictive value is 100%. These provocative tests (SIJ distraction, SIJ compression, Gaenslens, sacral thrust and thigh thrust) have been shown to have adequate inter-tester reliability. Patrick's sign or Faber's test have not been shown to have the same level of PPV as the provocative tests of Laslett.
Section E b vi d:
"The discography should be performed using a manometer to record pressure. Pressure should not exceed 50 pounds per square inch (psi) above opening pressure." It is not uncommon during discography to exceed 50 psi above opening pressure. This should be rephrased to: “The discography should be performed using a manometer to record pressure. The injection may continue until either: pain is produced; contrast medium escapes from the disc; the volume of injection reaches 3mL; or a maximum pressure range of 50-75 psi over opening pressure is reached."

Section F Therapeutic Procedures #3 Injections–Spinal Therapeutic:
• "Regarding long term benefit from injections, there is strong evidence that epidural steroid injections (ESI) do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy). Therapeutic spinal injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be used in only a small subset of patients." This statement is repeated later in the guidelines under Section F 3 a. This strongly worded statement is inconsistent with recent literature.

Per the review article by MacVicar the authors concluded that in a substantial proportion of patients with lumbar radicular pain caused by contained disc herniations, lumbar transforaminal injection of corticosteroid is effective in reducing pain, restoring function, reducing the need for other health care, and avoiding surgery. More specifically, the study by Ghahreman demonstrated that up to 11% of patients had 50% relief of pain and another 14% had complete relief of pain at one year following a transforaminal epidural steroid injection in those with a symptomatic disc herniation regardless of the duration of symptoms. A very recent study by Kennedy showed that for acute disc herniations more than 70% of subjects had >50% pain reduction at six months follow-up after epidural injection of either particulate or non-particulate steroid delivered via the transforaminal route in those with a symptomatic disc herniation. This is inclusive of subjects that were either lost to follow-up or received surgery and were included as failures. In fact, the significant majority of subjects had near complete pain relief by six months. Of note over 50% of subjects received excellent relief after receiving only a single level transforaminal ESI.

• "Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology which has not improved after active engagement (6-8 weeks) of physical therapy and in patients who otherwise qualify for more invasive procedures and may need injections because they do not wish to proceed to surgery." This statement implies that patients need to have a selective nerve root block prior to any other epidural injections. This would appear to be an unnecessary step especially when the symptoms with or without signs reasonably match the imaging findings. Additionally, this draft guideline appears to recommend that a patient have surgery before considering a less invasive (and less costly) procedure in the form of an epidural steroid injection. This is not consistent with the prevailing standard of care in which all appropriate measures, including use of epidural steroid injections, are undertaken in an attempt to help patients avoid unnecessary spine surgery.
Section F 3 e i:

- The draft guideline states that "there is no justification for a combined facet and medial branch block." Intraarticular steroid injections can be carried out with steroid and no anesthetic at the same time that medial branch blocks are done without negating the diagnostic validity of the medial branch blocks. There is very little steroid used for facet blocks and this would be delivered at no additional cost (same CPT code for each). It would be reasonable to selectively use this approach of combining diagnostic medial branch blocks with the possibility of therapeutic response to intra-articular steroids in certain clinical situations.

Section F 3 e iii:

- For facet joint injection indications, the draft guideline includes "patients who have facet findings with a thoracic component." We do not understand why a thoracic component was included in the criteria as that is not a common referral zone for patients with lumbar Z (facet) joint pain.

Section F 3 f ii B:

- "Two fluoroscopically guided blocks of the appropriate branches with differing anesthetics, 80% relief of pain for the appropriate time periods, and functional improvement must be documented." This statement implies blockade of the sacral lateral branches using validated methodology, but this should be explicitly stated. Controlled multi-site, multi-depth, lateral branch blocks are the method of choice to select patients for sacroiliac joint neurotomy.

- We would also recommend controlled diagnostic intraarticular SIJ blocks be included as a method to diagnosis intraarticular sacroiliac joint pain as delineated in the Second Edition of the ISIS guidelines.

Section E, 2b Injections-Diagnostic:

“Cervical injections carry a much higher risk of injury including death and stroke than lumbar injections.” This statement implies that complications with cervical injections are common, when in fact they are exceedingly rare. Suggest changing to “Cervical epidural injections do carry additional risks of injury including death, spinal cord injury and stroke when compared to lumbar injections.”

- The second paragraph addressing cervical interventions states that "Given the lack of proof for significant long-term benefit and the risks they are rarely appropriate." ISIS disagrees with this statement, especially as it pertains to cervical radiofrequency neurotomy. Multiple independent studies have shown that the prevalence of cervical facet joint pain is of the order of 60% in patients with chronic neck pain, making facet joints the most common source of chronic neck pain. Consequently, cervical medial branch blocks should be the foremost investigation for patients with neck pain once other serious causes have been excluded. When applying the prevalence rate of 60% with the responses of a specificity of 65% and sensitivity of 100% (as noted above), an operator can be 81% certain that a positive response to comparative blocks (either concordant or discordant) is a true positive.

- For patients with positive response to cervical medial branch blocks, radiofrequency neurotomy is the treatment of choice. It is the only treatment of neck pain that has been validated in a placebo-
controlled trial;\(^4^3\) and it is the only treatment that has been shown to produce complete relief of pain\(^1^2^,1^5^,4^3^,4^4^,5^7\) along with resolution of psychological distress.\(^5^8\)

- It is stated that "therapeutic injections should only be used after imaging studies and diagnostic injections have established pathology which has not clinically improved after active engagement (6-8) weeks of physical therapy and in patients who otherwise qualify for more invasive procedures and need injections because they do not wish to proceed to surgery." It should be noted that particularly with respect to z-joint pain, imaging may not demonstrate symptomatic pathology, and it will usually either be normal, or will demonstrate irrelevant age-related changes. However, controlled diagnostic injections have been validated as a reliable means to diagnose facet related pain. As noted above, in the instance of pain related to cervical facet arthropathy, radiofrequency neurotomy is the only treatment that has been validated in a placebo-controlled trial; it is the only treatment that has been shown to produce complete relief of pain together with resolution of psychological distress. Thus, dual diagnostic medial branch nerve blocks could be considered early in the treatment algorithm for patients with non-radicular cervical pain, and if concordant relief is obtained, may be followed by radiofrequency neurotomy.

- With regard to epidural injections, observational studies are supportive of cervical epidural injection in the management of radicular pain due to cervical disc herniation and atraumatic cervical spondylotic foraminal stenosis.\(^5^9^\)\(^-^6^1\) Per the ISIS guidelines, the studies\(^5^9^\)\(^-^6^5\) show "modest effectiveness of cervical transforaminal injection of steroids... Although the success rates reported by outcome studies are modest, they are not clinically negligible. The treatment appears to offer a reasonable relief of pain."\(^1^1\) Likewise Stav et al showed conclusive evidence that epidural delivery of corticosteroid and local anesthetic is more effective than intramuscular delivery for patients with cervicobraohialgia in a patient group that had approximately 65% of patients with foraminal stenosis.\(^1^1\)

- The statement is made that "there is some evidence that ESI's are not effective for the treatment of spinal stenosis as they may result in worse outcomes when lumbar surgery is performed and do not improve long-term outcomes for non-surgical patients (Radcliff 2013). Therefore, they are not recommended for cervical stenosis patients." The study referenced is of very low quality and plagued with numerous methodological flaws which have been previously elucidated. It should also be noted that the study referenced involved the lumbar region not the cervical region, and therefore the results were inappropriately generalized to apply to the cervical region. In addition, there are multiple observational studies which do support the use of transforaminal cervical epidural injections for spinal stenosis.\(^5^9^\)\(^,6^0^\) In a randomized, controlled trial, Stav demonstrated the effects of cervical interlaminar steroid injections were clearly not related to non-specific effects of the injections or the systemic effects of corticosteroids. In stenosis patients, steroids placed intramuscularly had only 11.8% of subjects with a positive effect at one year, in contrast to 68% with good results among those that received an epidural injection.\(^1^1\)

**Section 2 b ix specific diagnostic injections:**

- Under epidural injections the draft guideline states that, "Transforaminal injections are generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic, usually 0.5 cc should be used to determine the level of nerve root irritation." As previously stated, we recommended this be changed to: "Transforaminal
injections are generally accepted and useful in identifying the level of nerve root irritation. When performed for diagnosis, the volume of local anesthetic needed to adequately block the nerve can be estimated by the real time assessment of contrast flow patterns around the nerve prior to the application of local anesthetic. The amount of local anesthetic needed to anesthetize the nerve will generally not involve more than 1.0cc."

• Under indications the draft guideline states: "Interlaminar injections should not be done above level C7-T1, nor at level of any stenosis due to the higher likelihood of neural damage." The preference of C7-T1 is noted in the ISIS guidelines; however, the ISIS guidelines also indicate that, "In some patients, prior medical imaging may demonstrate... that the epidural space is potentially capacious at higher segmental levels than C7-T1. In such cases it is possible to obtain cervical interlaminar epidural access at those levels.” However it is almost never acceptable to go higher than C6-C7. Therefore we would recommend stating that,"Interlaminar injections should not be done above level C6-C7, nor at level of any stenosis as demonstrated on pre-procedure imaging review due to the higher likelihood of neural damage."

• The proposed guidelines indicate that if “the patient has documented spinal stenosis, deficits, has completed 6-8 weeks of active therapy, and is unwilling to undergo a surgical procedure…” then "there is some evidence that ESI's are not effective for the treatment of spinal stenosis as they may result in worse outcomes when lumbar surgery is performed and do not improve long-term outcomes for non-surgical patients (Radcliff 2013). Therefore, they are not recommended for cervical stenosis patients." See comments above under Section E, 2b Injections-Diagnostic regarding this statement, as the same objections apply to its use in this instance.

• Under medial branch blocks it states, “International Spine Intervention Society (ISIS) suggests controlled blocks – using either placebo or anesthetics with varying lengths of activity (i.e. bupivacaine longer than lidocaine).” We would recommend changing this to ISIS “suggests modified controlled blocks using anesthetics of varying lengths of activity (i.e. duration of relief consistent with the anesthetic utilized).

• Under medial branch blocks blocks it states, "Additionally a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for the first 8 hours and minimally for the week following the injection." While ISIS certainly supports the use of a pain diary, the physiological effects of local anesthetic effect will have worn off well before a period of one week following an injection, so it is felt that the duration of the documentation requirement seems excessive. We would recommend “a minimum requirement of the first 8 hours post injection or until the block has clearly worn off.”

• Under medial branch block needle placement, the draft guideline states, "multi-planar fluoroscopic imaging is required for all epidural steroid injections" where it should state “…medial branch blocks”.

• Under “indications” the draft guideline refers to "pain of well-documented facet origin." The purpose of the diagnostic medial branch blocks is to determine if the pain is coming from the suspected facet joints. Therefore it would be better to use the terminology “pain of suspected
**facet origin**” rather than “well-documented” facet origin. In addition, it should be noted that numerous attempts by investigators to correlate neurophysiologic, radiologic, and physical findings, as well as other signs and symptoms with the diagnosis of facet joint pain have been unsuccessful.  

**Injections- Spinal Therapeutic**

- It is stated that the "improvement in function following a first injection needs to be documented by a therapist or a non-injectionist authorized treating physician." We can appreciate the rationale of trying to avoid bias by the assessor, however as stated above we would prefer that this be changed to “when possible, improvement in function following a first injection should be documented by trained personnel, including nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians other than the physician who performed the procedure.”

- The draft guideline states that "the following sets of patients may have epidural injections, when diagnostic epidural injections are positive". This implies that patients need to have a selective nerve root block prior to any other epidural injections. This seems like an unnecessary step especially when the symptoms with or without signs match the imaging findings. Additionally, this would prohibit the entire subset of patients who have a false negative response to the diagnostic injection from receiving potentially effective or even definitive care.

- Under “complications” it states that "spinal musculature atrophy is likely to occur especially with repeat procedures as a rhizotomy denervates the multifidus muscle in patients. For this reason, repeated rhizotomies and multiple level rhizotomies can be harmful by decreasing supportive spinal musculature.” We agree that the nerves subject to radiofrequency lesioning should be selected by the judicious performance of cervical medial branch blocks and usually not more than three nerves should be targeted. However, medial branch neurotomy denervates only one segment (i.e. 16%) of the multifidus and semispinalis cervicis per nerve coagulated. Dreyfuss et al found that following RFA of the medial branch nerves in the lumbar spine there was no discernable segmental atrophy of the multifidus at long-term follow-up on MR imaging on the side lesioned as compared to the other side of the lumbar spine that did not undergo RF neurotomy. In addition, per ISIS guidelines, "there appears to be no limit to the number of times that neurotomy might be successfully repeated. Patients have successfully undergone multiple repetitions over periods of five years or more in order to maintain complete relief of pain and complete rehabilitation."  

For diagnostic blocks, the draft document states throughout that, "fentanyl and midazolam can interfere with the injection results and are not recommended." ISIS has a position statement on the use of conscious sedation for interventional procedures. It is attached as a separate document. An excerpt states, "It is the position of the International Spine Intervention Society (ISIS) that routine use of sedation is not necessary for interventional spine procedures. There are no features of any interventional spine procedures that warrant routine use of sedation. For those procedures in which the patient and interventionalist decide that sedation will be provided (for reasons outlined in the position statement), patients should ideally remain conversant to be able to warn of adverse events. In regard to the use of sedation for diagnostic blocks, ISIS feels “patients who have undergone
diagnostic local anesthetic blocks must be aware and mobile on completion of the procedure in order to be able to report any change in symptoms that may have occurred."

Furthermore, there have been studies that look at the immediate effect of sedation on the reporting of pain in those with facet mediated pain in the pre-operative period. In a study involving the lumbar spine, with a threshold of greater than 80% relief of pain with the ability to perform prior painful movements, 5% of subjects met this threshold after administration of IV midazolam, 7% of subjects after receiving fentanyl, and 2% of those receiving normal saline (control).\(^6\) If, however, the diagnostic criteria is relaxed to 50% then this threshold is obtained in 5% of those receiving midazolam, 13% of those receiving fentanyl, and 7% of those receiving normal saline. In the cervical spine the greater than 80% threshold of pain relief is obtained in 8% receiving midazolam, 8% of those receiving fentanyl, and 5% of those receiving normal saline.\(^6\)

In summary, although sedation is not routinely needed for diagnostic blocks, if the patient and physician decide its use is appropriate, then minimal to moderate (but not deep sedation) may be used provided the patient can be aware and mobile on completion of the procedure in order to be able to report any change in symptoms that may have occurred. Sedation may reduce pain, but at the threshold recommended by ISIS for a diagnostic block to be positive (80-100% relief, with functional improvement), the use of sedation likely produces false positive results less than 8% of the time. In theory, this number would be further reduced after the procedure, as the effect of sedation would likely dissipate more rapidly than the local anesthetic. However, this has not been formally studied.

ISIS appreciates the opportunity to provide these comments. If you have any questions or wish to discuss any of our suggestions, please contact Belinda Duszynski, ISIS Director of Research and Quality Improvement, at bduszynski@spinalinjection.org or 815.200.9590.

Sincerely,

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References