January 28, 2013

John H. Armstrong, MD
State Surgeon General
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, Florida  32399-1701

Dear Dr. Armstrong:

Please accept this position statement regarding the use and practice of epidural steroid injections.  We hope this provides you and the Department of Health with insight regarding the practice of this procedure and documentation guidelines.  We are hopeful that this will mitigate concerns regarding epidural steroid injections and infectious meningitis.

Sincerely,

Sanford M. Silverman, MD

President, Florida Society of Interventional Pain Physicians
Position Statement on Epidural Steroid Injections
Florida Society of Interventional Pain Physicians

Recent events involving fungal meningitis associated with epidural steroid and other injections have prompted the Surgeon General of Florida to review existing practices in Florida regarding epidural steroid injections.

This position statement by the Florida Society of Interventional Pain Physicians (FSIPP) represents the latest evidenced based literature review regarding epidural steroid injections and spinal pain. FSIPP is the state chapter of a national organization, the American Society of Interventional Pain Physicians (ASIPP). Board certification in interventional pain medicine through the American Board of Interventional Pain Physicians (ABIPP) is recognized by the Florida Board of Medicine for board certification in pain. Interventional pain medicine (IPM) is the practice of utilizing image guided injections to provide diagnostic and therapeutic treatment of chronic pain. IPM also encompasses surgical disc procedures, vertebroplasty, kyphoplasty, and implantation of neuromodulation devices such as spinal cord stimulators and intrathecal administration systems.

FSIPP is also aware of a recent correspondence by the FMA to the Surgeon General regarding the above. In that letter, the FMA was asked to respond to the following questions:

1. What are the evidence-based indications for epidural steroid injections?
2. What are the procedural steps necessary for safe performance of epidural steroid injections?
3. What should be documented in the patient’s medical record regarding epidural steroid injection?

Dr. Constantine Sarantopoulos, MD, Professor and Chief of the Division of Pain Management in the Department of Anesthesiology at the University of Miami Miller School of Medicine crafted the response. However, we have serious concerns regarding his response in that the evidence based analysis regarding epidural steroid injections is not robust and uses studies that are in some cases decades old and whose evidence is of low quality.

Our position statement is based on the Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain published by the American Society of Interventional Pain Physicians(1).

Low Back Pain

The annual prevalence of chronic low back pain ranges from 15% to 45%, with a point prevalence of 30% (2,3,4). The studies estimated the average age related prevalence of persistent low back pain to be approximately 15% in adults and 27% in the elderly (2,4). Lawrence et al (2) estimated that among the working population (age 20 to 64), more than 26 million Americans have frequent low back pain, whereas among Americans aged 65 and older, almost 60 million have frequent low back pain.

The duration of back pain and its chronicity is controversial. It is widely believed that most low back pain, 80% to 90% resolves in about 6 weeks, regardless of the type of treatment, with only 5% to 10% of patients developing persistent back pain (5,6). However, this widely held belief has been frequently questioned since back pain tends to relapse and most patients will experience multiple episodes and long lasting back pain is common (7,8-30).

In truth, it appears that the impression that low back pain is short-lived occurs because patients simply stop seeing a doctor if they are not getting better. In 1998, Croft et al followed 463 new onset low back pain patients in a primary care office; only 32% made return appointments to the office after three months, and only 8% were still seeing the doctor for pain one year later, suggesting that patients’ low back pain had resolved. However, in telephone interviews one year later, only 21% reported resolution of their pain, with 73% still having difficulties with activities of daily living (58). It is clear that low back pain does not always go away on its own; patients just give up when they do not improve.
Diagnosis of Low back pain

Lumbar intervertebral discs, facet joints, sacroiliac joint, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the lumbar spine with resulting symptoms of low back pain and lower extremity pain (31,32).

Herniated discs

Contained herniations and extrusions can cause low back and extremity pain. The mechanisms are both mechanical and inflammatory. When released into the epidural space from the confines of the annulus, the nucleus pulposus releases arachidonic acid which initiates the inflammatory pathway involving prostaglandins. This chemical reaction is extremely irritating to neural structures, such as nerve roots and the annulus of the disc. These neural structures behave abnormally with respect to their pain and sensory thresholds, thus yielding radicular pain or radiculitis. Furthermore, there can be referred pain from the discs and facet joints to the lower extremity, which is sometimes confused with true radicular pain.

Spinal stenosis

Spinal stenosis is a degenerative condition (sometimes congenital) resulting in narrowing of the spinal canal. The neural foramen may also be narrowed (foraminal stenosis) as well. Classic spinal stenosis causes both back and leg pain, particularly with ambulation (lumbar) or with extension. In the cervical region, the same applies to the upper extremity. Spinal stenosis can be multifactorial, caused by herniated discs, degenerative disc disease, spondylolisthesis, spondylosis or all of the above.

Post laminectomy syndrome (Failed Back Surgery Syndrome, FBSS)

This syndrome can occur in a significant percentage of cases (33). Speculated causes of post-laminectomy syndrome include acquired stenosis, adjacent segment degeneration, internal disc disruption, recurrent disc herniation, retained disc fragment, spondylolisthesis, epidural or intraneural fibrosis, degenerative disc disease, radiculopathy, radicular pain, deconditioning, facet joint pain, sacroiliac joint pain, discitis, arachnoiditis, pseudoarthrosis, segmental instability, and others (34,35-39). It is an extremely painful and disabling disease. In fact, FBSS is considered to be the major disadvantage of surgical intervention on the lumbar spine with the addition of 80,000 or so patients a year with continued chronic disabling back pain (33). In this review (33), it has been pointed out that there were at least 392,000 surgeries to treat low back pain in 2000 and the rate of spine surgery has continued to rise since then.

Epidural fibrosis may occur following an annular tear, disc herniation, hematoma, infection, surgical trauma, vascular abnormalities, or intrathecal contrast media (40-46). There may be a final common pathway with all these etiologies, which results in peripheral and central facilitation potentiated by inflammatory and nerve injury mechanisms (40-46).

Epidural Steroid Injections

The use and efficacy of epidural steroid injection varies not only for the disease state, but the technique utilized. This concept has been ignored in older studies and evidenced-based analyses of epidural steroid injections.

The statement “the sole indication for epidural injection of steroids is radicular pain (i.e. sciatica)” is outdated, dogmatic and inaccurate. It is based on outdated evidence that utilizes the construct that nerve root pain is caused solely by pressure from discs and intervertebral structures. However, chronic spinal pain may have multiple etiologies, which impact symptomatology such as leg and back pain. Although the nerve root is responsible for true “radicular” pain, identical pain can be referred to the extremity from the discs, the disc material, facet joints, sacroiliac joints, and muscles; all modulated through different anatomic structures.

The methodology of injecting steroids into the epidural space is also quite variable, since the space can be accessed via the caudal canal, the intervertebral space (interlaminar approach), and through the neural foramen (transforaminal approach).
approach). Furthermore, evidence from the 1960’s-1990 did not account for image guided injections utilizing fluoroscopy; accounting only for blind, interlaminar epidural and caudal injections.

There are differences in both technique and efficacy with regard to the three approaches to the lumbar epidural space: caudal, interlaminar, and transforaminal approaches. The interlaminar approach tends to be more closely directed to the assumed pathology and is easily performed with or without fluoroscopy. The caudal approach is technically simple with minimal risk of dural puncture. The transforaminal approach is quite specific; requiring image guidance in targeting specific nerve roots using small volumes, with the ultimate goal of reaching the ventrolateral epidural space.

Thus far, the literature has been more favorable to lumbar transforaminal epidurals, followed by caudal epidural and cervical interlaminar epidural injections, with limited evidence for blind lumbar interlaminar epidural injections and no evidence available either for thoracic interlaminar or for thoracic and cervical transforaminal epidural injections (1).

Since there is considerable variation in technique, advantages, disadvantages and outcomes, these different techniques (for lumbar, thoracic and cervical) must be considered separate entities. Multiple factors must be taken into consideration to include pathology. The response to epidural injections is different for various pathological conditions. The most commonly utilized indications are disc herniation and/or radiculitis, discogenic pain without disc herniation, spinal stenosis, and post-surgery syndrome.

To summarize, the evidence for epidural injections should therefore be evaluated by:

- Technique
- Use of imaging
- Disease state treated
- Region of the spine treated (lumbar, thoracic, cervical)

Level and grading of evidence

Evidence is based on evaluation of multiple studies. The level of evidence for example is very high for randomized controlled double blind studies. Systematic reviews, observational studies, physiologic studies and case reports follow in descending order of quality. The grading of such evidence is based on criteria developed by Guyatt et al (47) and ultimately used in the review by ASIPP (tables 1 and 3).

It should also be noted that evidence based medicine (EBM), while the current rage in the medical community and regulatory agencies, and is often plagued by the proverbial “devil in the details”. For example, it is well established that randomized double blind controlled placebo studies (RCT’s) are of high quality evidence, however they cannot always be performed. There is considerable expense involved in performing RCT’s and there also may be ethical considerations. For example, determining whether a new cardiac bypass procedure is beneficial, when compared to a placebo or sham procedure would be considered unethical and unreasonable. In pain medicine, it may also be very impractical to employ sham procedures when injecting the central neuraxis. Therefore, lower level evidence may have to suffice. Furthermore the studies that are published in medical journals may not be representative of all the studies that are completed on a given topic (published and unpublished) or may be misleading due to conflicts of interest. Despite these limitations, EBM is often considered the gold standard by insurance carriers and regulatory bodies to deny medical care and control costs.
Caudal steroid injections involve injection of steroid into the spinal canal via the caudal canal, which is relatively easy to access. Larger volumes of injectate are usually necessary to push the medication cephalad into the lumbar epidural space, which is contiguous with the caudal canal.

Caudal epidural steroid injections are indicated for:

1. Chronic low back pain which has failed to respond to conservative modalities of treatments.
2. Patients who are negative for facet or sacroiliac joint pain or who have at least a combination of discogenic component with facet joint pain.
3. Treatment for lower lumbar and sacral involvement, in postsurgical patients, and in patients with bilateral involvement or multilevel involvement for which transforaminal epidurals will require multiple procedures at multiple levels.
The evidence is based on randomized trials and observational studies utilizing the USPSTF criteria (48). Tables 5-8 illustrate the results of effectiveness of caudal epidural injections.

- The evidence is Level I for short- and long-term relief in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis and discogenic pain without disc herniation or radiculitis.
- The evidence is Level II-1 or II-2 for caudal epidural injections in managing low back pain of post-surgery syndrome and spinal stenosis.

### Table 5. Results of randomized trials of effectiveness of caudal epidural steroid injections in managing pain of lumbar disc herniation/radiculitis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>Manchikanti et al 2008 (247)*</td>
<td>RA, DB</td>
<td>72</td>
<td>84</td>
<td>81%</td>
<td>86%</td>
</tr>
<tr>
<td>Dasfield et al 2005 (248)*</td>
<td>RA, DB</td>
<td>50</td>
<td>Caudal = 30</td>
<td>SI</td>
<td>SI</td>
</tr>
<tr>
<td>Bush and Hillier 1991 (238)</td>
<td>RA, DB</td>
<td>55</td>
<td>23</td>
<td>SI</td>
<td>NSI</td>
</tr>
<tr>
<td>Mathews et al 1987 (249)</td>
<td>RA, DB</td>
<td>62</td>
<td>C = 34</td>
<td>SI</td>
<td>SI</td>
</tr>
<tr>
<td>Hasla and Breivik 1979 (251)</td>
<td>RA, DB</td>
<td>58</td>
<td>69 patients: crossover design</td>
<td>77% vs 25%</td>
<td>59% vs 25%</td>
</tr>
<tr>
<td>Breivik et al 1976 (250)</td>
<td>RA, DB</td>
<td>68</td>
<td>C = 19</td>
<td>20% vs 30%</td>
<td>20% vs 50%</td>
</tr>
</tbody>
</table>

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; C = control; T = treatment; NA = not available; SI = significant improvement; NSI = no significant improvement; vs = versus; P = positive; N = negative


### Table 6. Results of randomized trials in managing low back pain of post-surgery syndrome with caudal epidural injections.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>Manchikanti et al 2008 (252)*</td>
<td>RA, DB</td>
<td>70</td>
<td>40</td>
<td>65% to 70%</td>
<td>60%</td>
</tr>
<tr>
<td>Revel et al 1996 (253)</td>
<td>RA</td>
<td>62</td>
<td>Forceful injection = 29; Regular = 31</td>
<td>NA</td>
<td>49% vs 19%</td>
</tr>
<tr>
<td>Hasla and Breivik 1979 (251)</td>
<td>RA, DB</td>
<td>58</td>
<td>69 patients: crossover design</td>
<td>77% vs 25%</td>
<td>59% vs 25%</td>
</tr>
</tbody>
</table>

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; NA = not available; vs = versus; P = positive; N = negative

Interlaminar Epidural Injections

- The indicated evidence based on USPSTF criteria (48) is Level II-2 for blind lumbar interlaminar epidural injections for short-term relief in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis.

- The evidence is Level III for blind lumbar interlaminar epidural injections in managing low back pain of spinal stenosis, and chronic low back pain of discogenic origin with-out disc herniation or radiculitis.

- The indicated evidence for cervical interlaminar epidural steroid injections is Level II-1.
Table 9. Results of randomized trials of effectiveness of blind lumbar interlaminar epidural injections in managing disc herniation and radiculitis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 3 mos.</td>
<td>3 mos.</td>
</tr>
<tr>
<td>Wilson-MacDonald et al 2005 (295)</td>
<td>RA</td>
<td>68</td>
<td>43</td>
<td>SI</td>
</tr>
<tr>
<td>Arden et al 2005 (294)</td>
<td>RA,DB,PC</td>
<td>86</td>
<td>228</td>
<td>75%</td>
</tr>
<tr>
<td>Cazzati et al 1997 (239)</td>
<td>RA,DB,PC</td>
<td>77</td>
<td>C = 80</td>
<td>T = 78</td>
</tr>
<tr>
<td>Cazzati et al 1985 (240)</td>
<td>RA,PC</td>
<td>60</td>
<td>C = 31</td>
<td>T = 42</td>
</tr>
<tr>
<td>Snook et al 1977 (293)</td>
<td>RA</td>
<td>72</td>
<td>C = 24</td>
<td>T = 27</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; PC = placebo controlled; C = control; T = treatment; SI = significant improvement; SIT = significant improvement in treatment group; NSD = no significant difference; P = positive; N = negative


Table 10. Results of published studies of the effectiveness of blind lumbar interlaminar epidural injections in managing spinal stenosis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 3 mos.</td>
<td>3 mos.</td>
</tr>
<tr>
<td>Cazzati et al 1985 (240)</td>
<td>RA,DB</td>
<td>60</td>
<td>37</td>
<td>NSD</td>
</tr>
<tr>
<td>Wilson-MacDonald et al 2005 (295)</td>
<td>RA</td>
<td>68</td>
<td>32</td>
<td>SI</td>
</tr>
<tr>
<td>Campbell et al 2007 (308)</td>
<td>O</td>
<td>53</td>
<td>84</td>
<td>NA</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; O = observational; SI = significant improvement; NSD = no significant difference; NA = not available; P = positive; N = negative


Table 11. Results of published studies of effectiveness of cervical interlaminar epidural injections.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>Castagnera et al 1994 (311)</td>
<td>RA</td>
<td>55</td>
<td>14</td>
<td>79%</td>
</tr>
<tr>
<td>Stav et al 1993 (310)</td>
<td>RA</td>
<td>50</td>
<td>C = 17</td>
<td>T = 25</td>
</tr>
<tr>
<td>Pasqualucci et al 2007 (312)</td>
<td>RA</td>
<td>56</td>
<td>Single = 20</td>
<td>Continuous = 20</td>
</tr>
</tbody>
</table>

RA = randomized; C = control; T = treatment; vs = versus; P = positive; N = negative; NA = not available

Lumbar Transforaminal Epidural Steroid Injections

This modality is considered a target specific approach to spinal pain, requiring image guidance. Table 12 illustrates the results of randomized trials of effectiveness of lumbar transforaminal epidural injections. The indicated evidence for lumbar transforaminal epidural steroid injections is Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain based on the USPSTF criteria (48).

Table 12. Results of randomized trials of effectiveness of lumbar transforaminal epidural injections.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Short-term relief (\leq 6) mos</th>
<th>Long-term relief (&gt; 6) mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karppinen et al 2003/2001 (44,349)</td>
<td>RA, DB</td>
<td>81</td>
<td>C = 80 T = 80</td>
<td>SICH</td>
<td>NSI</td>
<td>NSI</td>
</tr>
<tr>
<td>Jeong et al 2007 (348)</td>
<td>RA, DB</td>
<td>63</td>
<td>239</td>
<td>PG 99 of 112 G 90 of 127</td>
<td>PG 84 of 106 G 78 of 116</td>
<td>NA</td>
</tr>
<tr>
<td>Vad et al 2002 (351)</td>
<td>RA</td>
<td>58</td>
<td>38</td>
<td>NA</td>
<td>NA</td>
<td>48% vs. 84%</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; P = prospective; C = control; T = treatment; PG = prediscogenic; SICH = significant improvement in contained disc herniation; NSI = no significant improvement vs. = versus; NA = not available; P = positive; N = negative.


Algorithmic approach to chronic spinal pain

Figures 3, 5, 7 are algorithms for approaches to chronic low back, cervical, and thoracic pain. With the exception of low back pain, epidural steroid injections are recommended for discogenic thoracic and cervical pain (57).

![Algorithmic approach to chronic spinal pain](image-url)

Fig. 3. A suggested algorithm for therapeutic interventional techniques in the management of chronic low back pain.

* Not based on evidence
Steroids and frequency of injections

The most commonly used formulations of long-acting steroids include methylprednisolone (Depo-Medrol), triamcinolone acetonide (Aristocort or Kenalog), and betamethasone acetate and phosphate mixture (Celestone Soluspan) (49, tables 32-33).

The chemistry of neuraxial steroids has taken center stage in recent years due to the devastating complications following epidural injections, specifically transforaminals. Steroid particle embolization of small radicular arteries is
believed to be an important causative factor (50-53). Tiso et al (54) and Benzon et al (55) extensively evaluated chemical properties and their relationship to IPM.

The frequency and total number of injections have been considered important issues, even though controversial and poorly addressed. These are based on flawed assumptions from non-existing evidence. Over the years, some authors have recommended one injection for diagnostic as well as therapeutic purposes. Some have preached 3 injections in a series irrespective of a patient’s progress or lack thereof, whereas others suggest 3 injections followed by a repeat course of 3 injections after 3-, 6-, or 12-month intervals. There are also proponents who propose that an unlimited number of injections with no established goals or parameters should be available. A limitation of 3 mg per kilogram of body weight of steroid or 210 mg per year in an average person and a lifetime dose of 420 mg of steroid also has been advocated; however, with no scientific basis (1).

The comprehensive review of the literature in preparation of these guidelines (1) and review of all the systematic reviews has not shown any basis for the above reported assumptions and limitations. The administration of epidural steroids must be based solely on patients’ response, safety profile of the drug, experience of the patient, and pharmacological and chemical properties such as duration of action adrenal suppression.

Table 32. Formulations of commonly used epidural steroids.

<table>
<thead>
<tr>
<th></th>
<th>Depo-Medrol</th>
<th>Kenalog</th>
<th>Celestone</th>
<th>Decadron</th>
<th>Non-particulate Celestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triamcinolone acetonide</td>
<td>40 mg/mL</td>
<td>80 mg/mL</td>
<td>40 mg/mL</td>
<td>6 mg/mL</td>
<td>4 mg/mL</td>
</tr>
<tr>
<td>Betamethasone preservative free</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone sodium phosphate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone sodium phosphate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of steroid</td>
<td>40 mg/mL</td>
<td>80 mg/mL</td>
<td>40 mg/mL</td>
<td>6 mg/mL</td>
<td>4 mg/mL</td>
</tr>
<tr>
<td>Polyethylene glycol 3350</td>
<td>29.1</td>
<td>28.2</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>1.94</td>
<td>1.88</td>
<td>0.4</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Monobasic sodium phosphate</td>
<td>6.8</td>
<td>6.59</td>
<td>—</td>
<td>3.4</td>
<td>3.0</td>
</tr>
<tr>
<td>Benzy1 alcohol</td>
<td>9.16</td>
<td>8.8</td>
<td>9</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Diabetic sodium phosphate</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>7.1</td>
<td>6.0</td>
</tr>
<tr>
<td>Eudate disodium</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.1</td>
<td>—</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.2</td>
<td>—</td>
</tr>
<tr>
<td>Sodium sulfate</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1 mg</td>
<td>—</td>
</tr>
</tbody>
</table>

Table 33. Profile of commonly used epidural steroids.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Equivalent Dose</th>
<th>Epidural Dose</th>
<th>Anti-Inflammatory Potency</th>
<th>Sodium Retention Capacity</th>
<th>Duration of Adrenal Suppression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone</td>
<td>20 mg</td>
<td>N/A</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Depo-Methylprednisolone (Depo-Medrol)</td>
<td>4 mg</td>
<td>40-80 mg</td>
<td>5</td>
<td>0.5</td>
<td>1-6 weeks 1-3 weeks N/A</td>
</tr>
<tr>
<td>Triamcinolone acetonide (Kenalog)</td>
<td>4 mg</td>
<td>40-80 mg</td>
<td>5</td>
<td>0</td>
<td>2-6 weeks N/A 2-3 months</td>
</tr>
<tr>
<td>Betamethasone (Celestone Solupan)</td>
<td>0.6 mg</td>
<td>6-12 mg</td>
<td>33</td>
<td>0</td>
<td>1-2 weeks N/A N/A</td>
</tr>
<tr>
<td>Dexamethasone (Decadron)</td>
<td>0.75 mg</td>
<td>8-16 mg</td>
<td>27</td>
<td>1</td>
<td>N/A</td>
</tr>
</tbody>
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N/A = Not available

Procedural steps and documentation of Epidural Steroid Injections

Epidural steroid injections are considered surgical procedures. In 2009, the America Society of Interventional Pain Physicians published guidelines for documenting these procedures (56). These guidelines are considered the standard of care in the specialty. Below is a version of these guidelines adapted specifically for epidural steroid injections.

The following are considered the requirements for procedural documentation:

- History and physical
- Indications and medical necessity
- Intra-operative procedural description
- Post-operative monitoring and ambulation
- Discharge/disposition

History and Physical

The physician’s history should include the following elements:

- Documentation of the signs and symptoms warranting the epidural steroid injection.
- A listing of the patient’s current medications including dosages, route, and frequency of admission.
- Documentation of allergies (if the patient has no history of allergies or adverse reactions, this should be noted in a prominent place)
- Any existing co-morbid conditions and previous surgeries.
- Documentation of any social history or conditions which would have an impact on the patient’s care upon discharge from the facility following the procedure.

Medical necessity must be established for each and every procedure. In a well documented chart, an auditor or anyone reviewing the chart should be able to find indications and medical necessity for that particular procedure easily.

General documentation requirements for epidural steroid injections including both indications and medical necessity are as follows:

1. Complete initial evaluation including history and physical examination.

2. Physiological and functional assessment, as necessary and feasible.

3. Definition of indications and medical necessity, as follows:

- Suspected organic problem.
- Non-responsiveness to conservative modalities of treatment.
- Pain and disability of moderate-to-severe degree.
- No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
- Responsiveness to prior epidural steroid with improvement in physical and functional status
- Repeating epidural steroid injections only upon return of pain and deterioration in functional status.
The physician’s physical examination should not only reflect the procedure planned, but also the type of anesthesia planned. Generally, for epidural steroid injections, if no anesthesia is to be administered, the physical examination is limited to the assessment of the patient’s mental status and an examination specific to the proposed epidural, including any co-morbid conditions. However, if intravenous sedation or any other type of anesthesia is planned, the physical examination should also include documentation of the results of an auscultatory examination of the heart and lungs, and an assessment and written statement about the patient’s general health, in addition to the assessment of mental status and an examination specific to the proposed procedure and any co-morbid conditions.

Documentation of the Epidural Steroid Injection Procedure

This includes description of the procedure which entails documentation of consent, diagnosis, monitoring, sedation, positioning, site preparation, fluoroscopy, drugs utilized, needle placement, and complications. In addition, the description should also include postoperative monitoring, and finally, discharge/disposition.

**Informed Consent:** There should be an informed consent for all epidural steroid injections. This consent should describe the alternatives available and complications in detail. Generally, for epidural steroid injections, this consent must always be signed by the patient. In rare situations, another person may sign the consent for the patient.

The names of all the personnel during the procedure assisting or monitoring must be documented.

**Diagnosis:** The diagnosis should match the procedure performed.

**Physiologic Monitoring:** Appropriate and at least basic monitoring should be applied in all cases of epidural steroid injections if a patient is sedated. This should include at minimum, monitoring of cardiac rhythm, heart rate, blood pressure, and continuous pulse oximetry.

**Description of Sedation:** Type of drug, the volume, and dosage must be documented.

**Patient Positioning:** Positioning for each procedure performed should be described in the procedure description note.

**Sterile Field Preparation:** The type of preparation and agent utilized should be described.

**Fluoroscopic Visualization:** Should include the name of the technologist and time of exposure in seconds.

**Antibiotic Administration:** If an antibiotic is administered prior to or during the procedure, it should be documented.

**Local Anesthesia:** It should be mentioned if local infiltration or anesthesia is provided.

**Description of Intravenous Access:** The type of intravenous access, the size of cannula, and the fluid administered must be documented.

**Needle Placement:** It should include the type, size, and gauge of the needle. You may also describe under fluoroscopic guidance, the direction of the needle, etc., and the final anatomic placement. This is generally performed under fluoroscopy with or without contrast injection.

**Description of Injectate:** Type of drug, the volume, and dosage must be documented.

**Complications:** Any and all complications must be described.

**Condition Following the Procedure:** The condition of the patient at the end of the epidural, as well as mode of transportation from the operating room to the recovery room should be documented.
**Postoperative Monitoring:** This should include not only the monitoring, but all the complications during the procedure or if any additional parts of the treatments are provided in this phase.

**Discharge/Disposition:** The discharge and disposition also should be documented appropriately, including the instructions provided to the patient.

**Fungal meningitis outbreak and steroid use**

Unfortunately, there is no FDA-approved steroid for epidural use, and there is evidence that non-depo-steroids do not offer long-term relief (59). All of the commercially available depo-steroids contain preservatives that theoretically could cause neurotoxicity if injected unexpectedly into the intrathecal space. Therefore, a group of interventional pain physicians approached compounding pharmacies to provide preservative free deposteroids. It is tragic that one manufacturer used unacceptably lax manufacturing techniques, which resulted in contaminated medication. However, it is inappropriate to respond to this tragedy by banning the medication or the procedure. This contamination is exactly analogous to the deadly melamine contamination of baby formula, which resulted in several deaths, but not the banning of baby food.

In light of the recent outbreak of fungal meningitis, FSIPP recommends the additional documentation requirements:

**Use of Compounded Medications:** The manufacturer, lot number, and expiration date of any compounded medication should be documented in the medical record.

In conclusion, FSIPP’s recommendations are:

1. **Patient selection regarding epidural steroid injections** should follow the evidenced based guidelines outlined in this position statement.
2. The **lot number, manufacturer and expiration date of any compounded medication** should be documented in the medical record.
3. **Regulations for Florida state compounding pharmacies** should be reviewed. These regulations should be consistent and provide strict requirements for plant operations, preparation and distribution.
References


57. Laxmaiah Manchikanti, MD, Standiford Helm, MD, Vijay Singh, MD, Ramsin M. Benyamin, MD, Sukdeb Datta, MD, Salim M. Hayek, MD, PhD, Bert Fellows, MA and Mark V. Boswell, MD, PhD; An Algorithmic Approach for Clinical Management of Chronic Spinal Pain; Pain Physician 2009; 12:E225-E264 • ISSN 2150-1149
