ASIPP is a not-for-profit professional organization comprised of over 3,200 interventional pain physicians who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic pain.

Interventional pain management (CMS designation -09) is defined by the NUCC as, “the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.”

MedPAC defined interventional techniques as, “minimally-invasive procedures including: percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques for the diagnosis and management of chronic, persistent or intractable pain such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators.”

The following are official comments on the ACOEM Guideline process provided by ASIPP CEO Laxmaiah Manchikanti, MD

ACOEM has followed a path which included inadequate stakeholder involvement, rigor of development, application and editorial independence, identified by Cates et al in AGREE Evaluation (Spine Journal 2006; 6:72-77) and Helm (Pain Physician 2004; 7:229-238) on comparing California worker’s compensation system with occupational medicine practice guidelines and ASIPP guidelines.

Overall, the strict format has been followed along with utilizing only randomized trials. However, including Cochrane reviews, modern literature has shown different avenues for diagnostic studies (which should not be randomized), and the evidence evaluation with observational or non-randomized studies.

In AGREE Evaluation, Cates et al concluded that while ACOEM Guidelines scored highest in the dimensions that evaluated reporting of the guideline’s scope and purpose, as well as clarity and presentation, the guidelines scored much lower in the remaining areas that included stakeholder involvement (46.06), rigor of development (26.59), application (31.48), and editorial independence (29.17). Helm concluded that ACOEM Guidelines met the criteria for only 12 of the 25 key components. While the reevaluation is difficult within a short span of time provided for the comment, it appears that ACOEM Guidelines continue to be flawed and highly biased towards payor perspective.

Physician specialty societies have been developing guidelines and expanding their efforts to improve care and reduce cost through increased transparency and accountability in the delivery of medical care increasingly. However, what is odd in this era is occupational medicine guidelines, apart from occupational medicine, incorporate multiple other specialties including interventional pain management.
Consequently, with basically non-representation from interventionalists and representation from highly well-known biased stakeholders from other specialties, these guidelines appear to be totally self-serving rather than improving the quality of patient care and access. Specifically:

1. There appears to be no objective application of standard. The so-called objective standards have been applied inconsistently, subjectively.
2. Levels of evidence included in each area of the guideline are inconsistently applied. Whatever the search strategy utilized, it was highly incomplete and prejudicial.
3. Standard principles of evidence-based medicine analysis specifically in interventional pain management and guidelines development have been ignored.

Following are specific comments.

**LOW BACK PAIN SECTION**

**Discography**
The review quotes multiple references of Carragee and very old references, however, it fails to consider two systematic reviews and the evaluation of the discography in guidelines.


Further, authors of this chapter also have ignored multiple studies which contradict the so-called science developed by Carragee at times, which is highly controversial.

Thus, we recommend the panel look into lumbar discography which has been shown to have moderate evidence in systematic reviews under strict criteria of the International Association for the Study of Pain (IASP).

Based on this, the only treatments recommended should be either IDET or percutaneous automated lumbar disc decompression or laser decompression, but not fusion or disc prosthesis.

**Diagnostic Lumbar Facet Joint Nerve Blocks:**
There is significant evidence available on accuracy of diagnostic facet joint nerve blocks (not intraarticular injections).

The benefit of appropriate diagnosis of facet joint pain is that unnecessary epidural injections will be avoided. Further fusion and disc prosthesis will also be significantly reduced even though treatment with facet joint nerve blocks or radiofrequency will increase.

Since facet joint pain is shown to be prevalent in significant proportion of patients (when appropriate literature is analyzed), refusal to acknowledge facet joint pain and its management will only reduce patient access and increase worker disability, consequently increasing overall cost to the program.

There are multiple evidence based guidelines, as well as systematic reviews, performed on the accuracy of lumbar medial branch nerve blocks in the diagnosis of facet joint pain.

The articles which do not even have anything to do with diagnostic value or validity of facet joint injections has been quoted by Mayer and Birkenmaier.
Lumbar Epidural Injections
The overview of literature is good. However, authors of this document state that transforaminal injections are generally performed under fluoroscopic or CT guidance. This would be erroneous as transforaminal epidurals must never be performed without fluoroscopic or CT guidance.

Elimination of series of three is a great idea. Indications for discontinuation state that patients requesting a fourth injection should be consult for discectomy or considered to have chronic radicular symptoms for which epidural steroids are not recommended. There is no evidence that a fourth injection must not be performed. It should again be based on significant pain relief with improvement in physical and functional status.

There is no strong evidence that three epidural injections are effective. It is ironic that authors make a wonderful recommendation eliminating the series of three epidural injections, yet follow the same in their recommendations.

It appears that this may apply for all subsections of spinal stenosis, chronic low back pain, etc.

Spinal Stenosis
The recommendation should be amended to provide these treatments based on response rather than limiting it to three.

Chronic Low Back Pain without Radicular Symptoms
This is not recommended. However, even though there are no randomized trials providing any significant evidence at the present time, this would be much more cost effective for patients rather than disc replacement and lumbar fusion.

Multiple articles which are conspicuously missing in the diagnostic facet joint injection category are as follows:


Manchikanti L, Manchikanti K, Manchukonda R, Cash KA, Damron KS, Pampati V, McManus CD. Evaluation of lumbar facet joint nerve blocks in the management of chronic low back pain: A


The recommendation should be changed to include diagnostic facet joint nerve blocks to be performed utilizing IASP criteria with controlled comparative local anesthetic blocks, as placebo controlled are not feasible in the United States. The prevalence of lumbar facet joint pain has been shown to be present in 15% – 45% of the patients utilizing IASP criteria. Utilizing IASP criteria, 80% pain relief with ability to perform previously painful movements, Manchukonda et al have shown prevalence of lumbar facet joint pain in the United States. Of 27%, with a false-positive rate of 45% with a single block, Manchikanti et al also showed prevalence of 16% in post laminectomy patients, once again with the criteria of 80% pain
relief and ability to perform painful movements with a false positive rate of 49%. With regards to the diagnostic confounding factors, Manchikanti et al (Pain Physician 2004; 7:411-417) showed the following:

“The administration of sedation with midazolam or fentanyl is a confounding factor in the diagnosis of lumbar facet joint pain in patients with chronic low back pain. However, this study suggests that if strict criteria including pain relief and ability to perform prior painful movements is used as the standard for evaluating the effect of controlled local anesthetic blocks, the diagnostic validity of lumbar facet joint nerve blocks may be preserved.”

In another study (Pain Physician 2006; 9:47-52), the following was demonstrated:

“Perioperative administration of sodium chloride, midazolam, or fentanyl can confound results in the diagnosis of combined cervical and lumbar facet joint pain. False-positive results with placebo or sedation may be seen in a small proportion of patients.”

With intraarticular facet joint injections, the evidence for short- and long-term pain relief is limited for cervical pain and moderate for lumbar pain. For medial branch blocks, the evidence is moderate for short- and long-term pain relief. For medial branch neurotomy, the evidence is moderate for short- and long-term pain relief (Boswell et al Pain Physician 2007; 10:229-253).

However, authors misquote Manchikanti et al stating the periprocedure administration of sedatives may confound the results of facet joint pain.

Authors also utilized extremely old and methodologically flawed studies without rhyme or reason.

**Therapeutic Facet Joint Injections**
The authors failed to separate that therapeutic facet joint injections may be performed in the form of intraarticular injections or medial branch blocks. Authors have not even considered any evidence on medial branch blocks. There is a randomized trial, preliminary findings of which have been published and the one-year follow-up results are awaiting publication, while the study will be continued for two years.


Manchikanti L, Singh V, Falco FJ, Cash KA, Pampati V. Lumbar facet joint nerve blocks in managing chronic facet joint pain: One-year follow up of a randomized, double-blind controlled trial. 2007; submitted for publication.


We do not have any qualms with authors with regards to intraarticular injections even though the data synthesis has been poor.

Therapeutic lumbar facet joint nerve blocks with local anesthetic, with or without Sarapin or steroids, may be effective in the treatment of chronic low back pain of facet joint origin.

**Sacroiliac Joint Injections**

These are recommended only for true specific known cause of sacroiliitis, which does not occur in occupational medicine situations, as the authors have quoted in these guidelines. Utilizing IASP criteria, sacroiliac joint pain ranges from 10 – 26.6%.

Thus, the guidelines should approve appropriate sacroiliac joint pain with strict regulations.

They should be approved both for diagnostic and therapeutic injections for non-inflammatory sacroiliac joint pain. The prevalence of 10% – 26.6% is secondary to non-inflammatory sacroiliitis.

**Radiofrequency Neurotomy**

For radiofrequency neurotomy flawed methodology has been used. Authors repeatedly used poorly controlled studies such as Leclaire and Van Wijk which did not meet inclusion criteria in Boswell et al’s guidelines and other systematic reviews.


The evidence must be considered and provision should be made in appropriate low back pain diagnosed with controlled comparative local anesthetic blocks with radiofrequency neurotomy for twice a year if required and documented appropriately with 4-6 months of relief each time.

For all facet joint treatments, the cost may be reduced and appropriate controls may be introduced by paying only for the first joint and maximum of a second joint for all other additional levels.

**IDET**
The evidence must be reconsidered and IDET should be approved with strict criteria.


**Adhesiolysis**
Adhesiolysis in fact has significant evidence but this is not yet recommended. This may be performed with or without endoscopy.

The comments about Manchikanti, the studies, and the personal communication are outrageous and can serve as libel. As per the protocol, patients were enrolled if they desired into the spinal endoscopy study, even if they were in the adhesiolysis study, provided that they failed, unblinded and were withdrawn. The majority of the patients were from the control group. Thus, the authors should withdraw such an inflammatory, insulting, erroneous statement. Further, the authors translate the same philosophy to other areas by hypothesizing self-serving statements about Manchikanti et al’s studies.

Cost of adhesiolysis should not be a major concern as this is much less expensive than any other surgical modality.

The authors of this document should approve adhesiolysis in post-laminectomy syndrome patients provided it provides 8-12 weeks of relief with significant pain relief (50% or greater) with improvement in physical and functional status.

In the evidence description under randomized controlled trials, once again, the authors not only erroneously but arrogantly describe the issues of unblinding occurred in this trial, once again based on the report that patients that was not even related to this study. There were no issues of unblinding. In the preliminary report published, the results were analyzed by the statistician without unblinding.


**Spinal Fusion**  
Even though evidence is poor, the authors have recommended lumbar fusion for spondylolisthesis. It may be worthwhile and eye opening to look at the evidence synthesized by the AHRQ on the effectiveness of disc prosthesis and fusion.

**Work Conditioning/Work Hardening**  
There is significant bias in approving such a treatment without proven evidence.

**Behavioral Interventions**  
Similar to others, worker’s comp adjustors always refuse behavioral interventions. Yet, without any significant evidence, they are recommended.

**Fear Avoidance Belief Training**  
Recommended once again with very limited evidence.

**Biofeedback**  
Recommended with very limited evidence.

**Multidisciplinary Rehabilitation**  
Recommended with questionable evidence.

**Functional Capacity Evaluation**  
This is required to judge if patients are able to return to work or not, but this is not recommended.

**Failed Back Surgery Syndrome**  
Recommendations are inappropriate.

**CHRONIC PAIN SECTION**

Overall this section is similar to low back pain section. The analysis and evidence recommendations follow pretty much the low back pain with approval for multitude of techniques with very little evidence and denial with technically better evidence.

**Epidural Injections**  
The conclusions, evidence synthesis, etc. are similar to low back pain with no recommendations made for cervical spinal pain.

Authors should clarify if this evidence applies for all areas of the spine or only to the lumbar spine and adjust accordingly. Authors should reorganize and also provide with appropriate information.
Diagnostic Facet Joint Injections

In this section, surprisingly they also used nerve blocks even though there is no mention of recent literature. Comments made above about lumbar facet joint nerve blocks apply here also. Further in chronic pain section they should also utilize evidence on cervical facet joint and thoracic facet joint diagnosis.


Diagnostic facet joint nerve blocks should be recommended for cervical, thoracic and lumbar spinal pain with strict criteria, controlled comparative local anesthetic blocks and 80% relief with ability to perform multiple maneuvers along with reimbursing only for primary procedure and one additional procedure.

**Therapeutic Facet Joint Injections**

Again the recommendation and literature survey appears to be the same as in low back pain section.

No mention of cervical or thoracic pain or the evidence is revealed here. While the evidence for lumbar facet joint nerve blocks was described earlier, the cervical facet joint nerve blocks is described here.

A recent double-blind, randomized trial with publication of preliminary results and one-year follow-up in consideration for press are as follows:

Manchikant L, Singh V, Falco FJE, Cash KA, Fellows B. Cervical medial branch blocks for chronic cervical facet joint pain: A randomized, double-blind, controlled trial with 1-year follow-up; Clinical trial NCT0033272; submitted for publication.


Manchikanti L, Falco FJ, Cash KA, Pampati V, Fellows B. Psychological variables have no significant influence on the diagnosis of facet joint involvement in chronic spinal pain. 2007; submitted for publication.


Manchikanti et al (submitted for publication) showed the following:

“Therapeutic cervical medial branch nerve blocks, with or without steroids, may provide effective management for chronic neck pain of facet joint origin. Significant pain relief (> 50%) and functional status improvement was observed at 3 months, 6 months, and 12 months in over 83% of patients. The average number of treatments for 1 year was 3.5 ± 1.0 in the non-steroid group and 3.4 ± 0.9 in the steroid group. Duration of average pain relief with each procedure was 14 ± 6.9 weeks in the non-steroid group, and it was 16 ± 7.9 weeks in the steroid group. Significant relief and functional improvement was reported 46 - 48 weeks in a year.”

“Therapeutic lumbar facet joint nerve blocks, with or without steroid, may provide a management option for chronic function-limiting low back pain of facet joint origin. Based on the results of the present study, it appears that patients may experience significant pain relief 44 to 45 weeks of 1 year, requiring approximately 3 to 4 treatments with an average relief of 15 weeks per episode of treatment.”

**Rhizotomy and Facet Rhizotomy**

Radiofrequency neurotomy, while the evidence exists for this, authors have not recommended the procedure either in the cervical spine or the lumbar spine.

Comments are similar to above for low back pain. In fact, evidence is superior in the cervical spine specifically if the technique is performed as recommended by Bogduk.


**Sacroiliac Joint Injections**
Same comments as above for low back pain.

**Regional Sympathetic Blocks**
Stellate ganglion blocks and lumbar sympathetic blocks should be approved not only for acute pain but also chronic pain provided that significant improvement and response.

**Spinal Cord Stimulation**
These guidelines do not recommend spinal cord stimulators for any type of pain due to insufficient evidence. However, there is recently published evidence in the form of a randomized controlled trial on the use and effectiveness of spinal cord stimulation to treat chronic back and leg pain, accompanied by an editorial in Pain 2007 (Kumar et al, Pain 2007). In addition, there is also a newly published cost-effectiveness study related to data from a previously published non-randomized controlled trial by North et al in Neurosurgery in 2007. Since this is a surgical procedure, the authors should apply the same low level type of evidence they have utilized for other surgical interventions. Kumar et al, Pain 2007, concluded that in selected patients with failed back surgery syndrome, spinal cord stimulation provides better pain relief and improves health-related quality of life and functional capacity compared with conventional medical management alone. In the cost effectiveness study, North et al published in Neurosurgery 2007, the authors concluded that spinal cord stimulation was less expensive and more effective than re-operation in selected failed back surgery syndrome patients, and should be the initial therapy of choice. Authors also added that spinal cord stimulation is most cost-effective when patients forego repeat operation. Further, they also concluded that should spinal cord stimulation fail, re-operation is unlikely to succeed.

Spinal cord stimulation therapy should be approved under appropriate conditions with failure of injection therapy and excellent trial results.

**Intrathecal Infusion Systems**
This section was not even available for a mention in the opioid section described as a pain pump. This language is rather confusing and does disservice to implantable intrathecal drug delivery pumps.

Contrary to the opinion provided in the guidelines, there are randomized controlled trials which support use of at least certain drugs intrathecally. Further, similar to spinal cord stimulation, there are several other relevant studies of a lower level of evidence, the same level which is reviewed and included appropriately for other surgical therapies, that obviously should be included here.