

# Lumbar Transforaminal Epidural Steroid Injections

**Review & Recommendation Statement**

January 2013



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# Lumbar Transforaminal Epidural Steroid Injections

## Review & Recommendation Statement

January 2013

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The evidentiary tables developed by the authors are available in a separate document titled *Lumbar Transforaminal Epidural Steroid Injections: Review and Recommendation Statement Evidentiary Tables*, and can be accessed at:

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/ScientificPolicyComments/Default.aspx>.

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## **Introduction**

Lumbar transforaminal epidural steroid injection (LTFESI) is used to treat lumbar radicular pain and radiculopathy. The condition can be associated with significant pain and disability. Patients who are candidates for TFESI typically have not responded to some form(s) of medical treatment and have often had recent cross sectional imaging studies that correlate with their clinical findings.

This statement is intended to present the current state of the evidence for the use of TFESI in treating lumbar radiculopathy/radiculitis resulting from herniated disc or spinal stenosis and provide evidence-based recommendations regarding their use in treating lumbar radicular pain.

This document supersedes any other existing NASS documents, with the exception of current clinical guidelines.

## **Topic Questions**

The work group identified and has attempted to address the following five key clinical questions in this review and recommendation statement:

1. What are the prognostic indicators that predict which patients are likely to benefit from lumbar transforaminal epidural steroid injections (LTFESI)?
2. What is the reported efficacy of TFESI in the treatment of radicular pain from lumbar spinal stenosis and lumbar disc herniation?
3. What are the reported complications of lumbar TFESI?
4. What is a reasonable maximum number of therapeutic lumbar TFESI that a patient should receive within a six month period to treat lumbar radicular pain?
5. What is the value (eg, cost per QALY) of TFESI in the treatment of lumbar radicular pain?

## **Revision Date**

This statement will be reviewed no more than two years following publication.

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Speaking and/or Teaching Arrangements: Oakstone Medical Publishing (Financial, Level A honorarium for videotaped lecture for video textbook entitled "Comprehensive Review of PM&R"); Grants: Bob Doctor Grant (Level B, Paid directly to institution/employer), American Physical Therapy Association (Level D, Paid directly to institution/employer); Other: PM&R Journal Senior Editor (Financial, less than Level B), VA Merit Grant Reviewer (Financial, Expenses and Level A honorarium).

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Nothing to disclose.

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Nothing to disclose.

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Board of Directors: First Choice Insurance Group (Financial, Pain Management representative to the Board. There is a Level A remuneration for each Board meeting attended during weekdays. In the past year, I have been paid Level A), International Spine Intervention Society (ISIS) [Nonfinancial, I am on the ISIS Board of Directors. I also serve as Treasurer. Travel expenses (airfare, hotel and parking) are provided when traveling to a Board meeting (official business only)].

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Range Key:

Level A. \$100 to \$1,000

Level B. \$1,001 to \$10,000

Level C. \$10,001 to \$25,000

Level D. \$25,001 to \$50,000

Level E. \$50,001 to \$100,000

Level F. \$100,001 to \$500,000

Level G. \$500,001 to \$1M

Level H. \$1,000,001 to \$2.5M

Level I. Greater than \$2.5M

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# Methodology

## ■ Step 1: Identification of Work Groups

A multidisciplinary team was identified and assigned to a work group. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the development process that a cross-section of the NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized. Work group participants were required to have participated in evidence analysis training or have passed a proficiency test in assigning levels of evidence (*Appendix A*).

## ■ Step 2: Identification of Clinical Questions

The NASS Review and Recommendation Statement Oversight Committee developed the list of clinical questions that the statement addresses. Individual committee members submitted questions which were compiled into a master list and circulated to each committee member with a request that they independently rank the questions in order of importance for consideration. The most highly ranked questions, as determined by the participants, served to focus the statement.

## ■ Step 3: Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (*Appendix B*) which has been followed to identify literature for evaluation in review and recommendation statement development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices (*Appendix C*).

## ■ Step 4: Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

## ■ Step 5: Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members identified the *best research evidence available* to answer the targeted clinical questions. That is, if Level I, II and or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

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#### ■ Step 6: Evidence Analysis

Members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence.

As a final step in the evidence analysis process, members identified and documented gaps in the evidence to educate readers about where evidence is lacking and help guide further needed research.

#### ■ Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held Web casts to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this statement very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

#### Consensus Development Process

Voting on recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (“extremely inappropriate”) to 9 (“extremely appropriate”). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, statement content was developed, addressing the literature which supports the recommendations.

#### ■ Step 8: Submission of the Draft Review and Recommendation Statement for Review/Comment

The statement was submitted to the Review and Recommendation Statement Oversight Committee and the full NASS membership for review and comment. *Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence, where evidence exists.*

#### ■ Step 9: Submission for Board Approval

Once any revisions were incorporated by the work group and Oversight Committee, the statement was submitted for NASS Board review and approval. *Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence, where evidence exists.*

#### ■ Step 10: Dissemination

Once Board-approved, the statement was shared with the NASS membership and made available via posting on the NASS Web site.

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■ Step 11: Review and Revision Process

The recommendations will be reviewed *at least* every two years by a multidisciplinary team and the statement will be revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the review and recommendation statement.



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# Review and Recommendations

## What are the prognostic indicators that predict which patients are likely to benefit from lumbar transforaminal epidural steroid injections?

In patients treated with TFESI in the setting of disc herniation, effectiveness was more likely if the disc herniation was “contained” or abutted the nerve root and less likely if the nerve root was displaced or entrapped. The presence of stenosis, size of herniated intervertebral disc (HIVD), type of HIVD and hydration of HIVD do not predict outcome with LTFESI.

### Level of Evidence: III

Choi et al<sup>1</sup> described a retrospective case control study investigating the relationship between magnetic resonance imaging (MRI) findings and the clinical outcome after treatment with lumbar transforaminal epidural steroid injections (LTFESI). The study included 91 consecutive patients with lumbar herniated intervertebral disc (HIVD) who received LTFESI (40 mg triamcinolone with 0.5% Marcaine). Outcome measures included a five grade patient satisfaction scale and a numeric rating scale (NRS). Follow-up ranged from seven days to 22 months with a mean follow-up of 2.7 months. Of the 27 patients who experienced unsatisfactory results, 14 underwent subsequent surgical treatment. There was no significant difference between patients who experienced a satisfactory result and those who did not relative to the type, hydration and size of the HIVD, or an association with spinal stenosis ( $p > 0.05$ ). However, the location of the HIVD and the grade of nerve root compression was significantly different between the two groups ( $p < 0.05$ ). In critique, the study had less than 80% follow-up. This study provides Level III prognostic evidence that presence of stenosis, size of HIVD, type of HIVD and hydration of HIVD do not predict outcome with LTFESI, but suggest that unsatisfactory results are statistically more likely in patients with higher grade herniation (displacement and entrapment of nerve root rather than abutment) and subarticular location of disc herniation.

**Patients with lumbar scoliotic stenosis and radiculopathy experience significantly higher success rates if their symptoms were present for less than three months.**

### Level of Evidence: IV

Cooper et al<sup>2</sup> reported results of a retrospective case series evaluating the effectiveness of LTFESI in 52 nonconsecutive patients with degenerative lumbar scoliotic stenosis and radiculopathy. Patients received, on average, 1.3 injections of 80 mg triamcinolone with 1.5 cc of 2% lidocaine and were followed for an average of 85.5 weeks (range of 20-152 weeks). The study utilized several validated and nonvalidated measures including the NRS, NASS Patient Satisfaction Index and adapted Stucki Outcome Questionnaire pain and function scores. Successful outcome was defined as a patient satisfaction index of one or two, greater than two point improvement on the NRS along with the summary pain and function scores. A successful post-injection

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outcome occurred in 59.6% at one week, 55.8% at one month, 44.2% at three months, 37.2% at one year and 27.3% at two years ( $p < 0.01$  vs. no success). There was a statistically significant difference for patients with acute symptoms to experience higher success rates than those with symptoms greater than three months in duration. This study provides Level IV prognostic evidence that successful outcomes are less likely in patients with protracted symptoms. In retrospective analysis, the degree of scoliotic curve, prior surgery, previous unsuccessful caudal injections, age, gender, level, side and type of insurance did not predict outcome. Subjects with more chronic symptoms tended to have worse outcomes than those with acute symptoms (less than three months of pain prior to LTFESI). At the 24-month outcome period, this difference was statistically significant.

**There is no significant difference between EMG positive and negative groups in terms of pain difference, but a mild functional improvement in EMG positive patients undergoing a LTFESI.**

**Level of Evidence: IV**

Fish et al<sup>3</sup> described results from a retrospective case-control study assessing whether electromyographic (EMG) diagnostic evaluation is predictive of functional outcome in patients undergoing LTFESI. The study included 39 consecutive patients assessed via the Verbal Rating Scale (VRS) and the Oswestry Disability Index (ODI) prior to injection and followed for an average of 3.9 weeks. Pretreatment ODI scores were not significantly different between groups showing positive (72.3 SD +/- 12.7) and negative (65.9 SD +/- 18.6,  $p > 0.05$ ) EMG findings. There was significantly greater improvement of ODI for EMG positive radiculopathy (7.11 SD +/- 9.5) compared with negative EMG (3.2 SD +/- 17.4,  $p < 0.05$ ). Positive radiculopathy subjects complained of more pain by VRS before ESI than subjects with negative EMG findings, 8.1 SD +/- 1.0 and 7.3 SD +/- 0.8, respectively, which was not significant ( $p > 0.05$ ). VRS mean improvement was not significantly different in the positive EMG group (1.8 SD +/- 1.2) compared with a negative EMG (1.2 SD +/- 1.2,  $p > 0.05$ ). The authors concluded that patients undergoing LTFESI, who have a positive radiculopathy by EMG before injection, will have significant improvement in functional outcome as assessed by ODI. This correlation was not found with current pain intensity assessed by VRS. In critique, patients were not consecutively assigned, the diagnostic method was not stated and the protocol for EMG diagnosis of radiculopathy was not articulated. Because of these limitations, this potential Level III study provides Level IV prognostic evidence that there is no significant difference between the EMG positive and negative groups in terms of pain difference, but a mild difference is noted in functional status improvement in EMG positive grouped subjects undergoing LTFESI. It should be noted that this study may not have external validity due to subjects having extremely high initial disability scores.

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**Patients with radicular pain from an HIVD or central stenosis and/or lateral recess stenosis at the supra-adjacent intervertebral disc, obtain significant relief from a preganglionic LTFESI irrespective of age, gender, level of injection, symptom duration and pain intensity.**

#### **Level of Evidence: IV**

Kabatas et al<sup>4</sup> presented a retrospective case series analyzing the efficacy of fluoroscopically-guided LTFESI using a preganglionic approach in 40 patients with foraminal stenosis due to lumbar spinal stenosis and lumbar discogenic pain with radiculopathy. Patients were followed for an average of nine months (range of 4-14 months) via Visual Numeric Pain Scale (VNS) and NASS Patient Satisfaction Score. When the VNS and NASS were evaluated with respect to the age of the patients, level numbers, gender, preprocedure symptom duration and pre-procedure VNS, no significant differences were found. A reduction by 50% or more in VNS and NASS Patient Satisfaction Scores was 77.8% (N/n: 40/31) at one month, 67.2% (N/n: 40/27) at six months, and 54.8% at 12 months. The authors concluded that the age of the patient, gender, level of injection, duration of symptoms and initial pain intensity were not predictive of the outcome of LTFESI. This study provides Level IV prognostic evidence that age, gender, level of injection, duration of symptoms and initial pain intensity are not predictive of the outcome of LTFESI.

#### **Future Directions for Research**

A prospective study of all consecutive patients with documented single-level lumbar radiculopathy or radicular pain treated with image-guided TFESI, in which potential determinants of outcome could be correlated with outcome of treatment. Follow-up data should be obtained at four weeks and six months after final TFESI. The sample sizes of patients exhibiting potential indicators of interest and the number of successful and unsuccessful responses to treatment for each indicator should be sufficiently large to either validate or refute the indicator. Multivariate analysis should be applied to test and control for potential covariates such as nature of pathology, symptom severity, symptom duration, number of injections and concomitant treatment.

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## What is the reported efficacy of transforaminal epidural steroid injections in the treatment of radicular pain from lumbar spinal stenosis and lumbar disc herniation?

**TFESI is recommended to provide relief of radicular pain related to lumbar disc herniation. TFESI has been found to be effective in providing pain relief for at least one month in more than fifty percent of patients, with half of these patients continuing to benefit from treatment for a year or more. Treatment can be repeated in those patients whose pain recurs.**

### **Grade of Recommendation: A**

Ghahreman et al<sup>1</sup> performed a prospective randomized controlled trial (RCT) assessing the efficacy of lumbar transforaminal epidural steroid injection (LTFESI) for radicular pain secondary to disc herniation. Of the 150 consecutively assigned patients included in the study, 28 received LTFESI with triamcinolone. Outcomes were assessed at one month and one year via the Visual Analog Scale (VAS), SF-36 (version 1), Roland Morris Disability Questionnaire (RMDQ) and the Patient-Specified Functional Outcome instrument. Additionally work status and other health care services being utilized were assessed. The authors found that a significantly greater proportion of patients treated with transforaminal injection of steroid (54%) achieved pain relief compared to patients treated with transforaminal injection of local anesthetic (7%), transforaminal injection of saline (19%), intramuscular steroids (21%) or intramuscular saline (13%). Pain relief was corroborated by significant improvements in function and disability and reductions in use of other health care services. Outcomes were equivalent for patients with acute or chronic radicular pain. Over time, the number of patients who maintained relief diminished. Only some maintained relief beyond 12 months. The proportions of patients doing so were not statistically significantly different between treatment groups.

This study provides Level I therapeutic evidence that for patients with lumbar disc herniation: (1) LTFESI provides greater than 50% relief of pain for 54% of patients at one month after treatment; (2) LTFESI is significantly more often effective than sham and other treatments, with a number needed to treat (NNT) of three; (3) relief of pain is associated with restoration of function and virtual elimination of the need for other health care; (4) 25% of patients undergoing LTFESI have relief that persists for at least 12 months, without repeat treatment; and (5) LTFESI substantially reduces the need for surgery. Additionally, duration of symptoms does not prejudice response to treatment.

Karpinnen et al<sup>2</sup> conducted a prospective RCT describing the cost-effectiveness of periradicular infiltration with steroid in subgroups of patients with sciatica. Of the 160 consecutively assigned patients, 18 patients with bulging discs received LTFESI while 11 were injected with saline; 24 patients with contained herniated intervertebral disc (HIVD), defined as “broad-based herniation not extending through the posterior longitudinal ligament,” received LTFESI while 26 received saline injection; and 38 patients with extrusions, defined as “herniation extruding through the posterior longitudinal ligament,” received LTFESI while 43 were injected with saline. All patients received one injection. Follow-up assessments were conducted at two weeks, one month, three months, six months and one year. Outcomes were assessed by VAS (leg pain primary), ODI and Nottingham emotional scores. The authors found that there were no significant differences in outcomes for the

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patients with bulging discs, but in patients with contained HIVD, scores for leg pain were significantly better for patients receiving LTFESI at two and four weeks. At six months, leg pain, disability and Nottingham emotional scores were significantly better for saline. At one year, treatment effects were null. For patients with extrusions, leg pain was significantly better in the saline group at six months. The authors concluded that LTFESI for contained HIVD is superior to saline in terms of leg pain and medical costs and possibly prevents operative treatment. At one year, 42% of patients in the saline group compared to only 20% of patients in the LTFESI group underwent surgery, although this was not statistically significant. For extrusions, use of corticosteroids appears countereffective. This study provides Level I therapeutic evidence that: (1) at four weeks after treatment, LTFESI achieves significantly greater improvements in pain and disability than a credible sham treatment in patients with contained herniations, but not in patients with extrusions; and (2) for providing at least 75% relief of radicular pain, LTFESI is more often effective (0.44) than sham treatment (0.21) with an NNT of five. However, this difference is not statistically significant because of the small sample sizes and low success rates encountered in the study.

Riew et al<sup>3</sup> performed a prospective RCT to determine the effectiveness of selective nerve root injections (SNRI) in obviating the need for an operation in patients with lumbar radicular pain due to lumbar disc herniation or foraminal stenosis, who were otherwise considered to be patients facing surgery. Of the 55 consecutive patients, 27 were randomly assigned to receive bupivacaine alone and 28 received bupivacaine with betamethasone. At mean follow-up of 23 months (13-28 months) following the first injection, outcomes were assessed using the NASS Low Back Questionnaire and numeric rating scale (NRS). Nineteen patients received more than one injection: 10 had two injections, six had three injections and three had four injections. Thirteen of the 19 patients who had multiple injections did not undergo operative treatment. Among patients with foraminal stenosis who avoided surgery, there was a significant decrease in neurological symptoms and low back pain on final evaluation. HIVD patients who avoided surgery showed a trend toward decreased back pain. The difference in operative rates between the two groups was significant with 67% of local anesthetic patients undergoing surgery compared to only 29% of corticosteroid plus anesthetic patients ( $p < 0.004$ ). The authors concluded that SNRI with corticosteroid are significantly more effective than those with local anesthetic alone in obviating the need for operative care for 13-28 months following the injections in operative candidates. This study provides Level I therapeutic evidence that LTFESI is more effective than transforaminal injection of bupivacaine for reducing the need for surgery at 12 months in patients with lumbar radicular pain due to lumbar disc herniation or foraminal stenosis.

Ng et al<sup>4</sup> conducted a prospective RCT to determine the treatment effect of corticosteroids in periradicular infiltration for chronic radicular pain from HIVD and foraminal stenosis (FS). Of the 86 consecutively assigned patients included in the study, 43 were randomly assigned to receive LTFESI (bupivacaine + corticosteroid) and 43 received injections of bupivacaine alone. Outcomes were assessed at three months using the VAS and ODI along with patient satisfaction and change in walking distance. Intent-to-treat analysis did not demonstrate a statistically significant difference in Oswestry scores between the two treatment groups. Pathology (HIVD/FS) subgroup analysis did not demonstrate a statistically significant difference between the treatment groups. The duration of symptoms had a statistically significant negative effect on ODI. The authors concluded that clinical improvement occurred in both groups of patients and corticosteroid did not provide additional benefit. In critique, this was a small study which was insufficiently powered to be an equivalence study. Because of these limitations, this potential Level I study provides Level II therapeutic evidence that corticosteroid provides no additional benefit compared with local anesthetic alone. The authors failed to find a

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difference in outcome between the two types of injections, however, the study was not adequately powered to serve as an equivalence study.

Riew et al<sup>5</sup> described a prospective comparative study presenting five year follow-up data assessing the efficacy of nerve root blocks for the treatment of lumbar radiculopathy. Of the 29 consecutively assigned patients included in the study, eight were lost to final follow-up. Of the remaining 21 patients, nine received bupivacaine injections and 12 received bupivacaine and betamethasone injections. Of the 21 patients available at five year follow-up, 17 avoided surgery and experienced a significant decrease in neurologic symptoms and back pain as assessed by the NASS Low Back Pain Questionnaire. Patients with FS had a significant decrease in neurologic symptoms and patients with HIVD had a significant decrease in back pain. There was a significant decrease in back pain in the HIVD subgroup treated with bupivacaine and betamethasone. Of the four patients who proceeded to surgery, three had FS and one had HIVD. The authors concluded that the majority of patients with lumbar radicular pain who avoid surgery for at least one year after receiving a nerve root block of local anesthetic with or without corticosteroid will continue to avoid operative intervention for a minimum of five years. The majority of patients with lumbar radicular pain who avoid an operation for at least one year after receiving a nerve root injection with bupivacaine alone or in combination with betamethasone will continue to avoid operative intervention for a minimum of five years. In critique, neither the patients nor the reviewers were masked, and there was less than 80% follow-up. This study provides Level II therapeutic evidence that LTFESI is more effective than transforaminal injection of bupivacaine in reducing the need for surgery five years after treatment.

Vad et al<sup>6</sup> conducted a prospective RCT to assess the efficacy of LTFESI in patients with lumbar radiculopathy secondary to HIVD. Of the 50 consecutively assigned patients, 25 received LTFESI and 25 received paravertebral trigger point injections. Outcomes were assessed using a patient satisfaction scale, Roland Morris Low Back Pain Questionnaire and a visual numeric pain scale. Successful outcomes required a patient satisfaction score of good or very good, a five point or better improvement on the Roland Morris score and pain reduction greater than 50% at least one year following treatment. After an average follow-up period of 16 months, the group receiving LTFESI had a success rate of 84% as compared to 48% of the group receiving trigger-point injections. In critique, neither the reviewers nor patients were masked to treatment, thus, the quality of the placebo control was compromised (ie, trigger point injections were performed at office visit). This study provides Level II therapeutic evidence that for patients with HIVD, LTFESI is more often effective (84%) than trigger point injections (48%) in providing at least 50% relief of radicular pain at 16 months.

Ackerman et al<sup>7</sup> described a prospective comparative study assessing the efficacy of LTFESI in patients with lumbar disc herniations. Of the 90 patients included in the study, 30 received LTFESI, 30 received caudal epidural steroid injections and 30 were treated with interlaminar epidural steroid injections (ILES). Outcomes were assessed via the VAS and ODI at three weeks, 12 weeks and 24 weeks. At 24 weeks, 3% (1/30) of patients receiving caudal injections reported complete pain relief, 53% (16/30) reported partial pain relief and 43% (13/30) reported no relief. For the interlaminar group, 10% (3/30) reported complete pain relief, 50% (15/30) reported partial relief and 40% (12/30) reported no relief. In the transforaminal group, 30% (9/30) reported complete pain relief, 53% (16/30) reported partial pain relief and 17% (5/30) reported no relief. The

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authors concluded that pain relief was significantly more effective with transforaminal injections. This study provides Level II therapeutic evidence that at 24 weeks after treatment, LTFESI is more effective than caudal ESI or ILESi in reducing pain. It provides Level IV evidence regarding efficacy of LTFESI alone and suggests that 30% of patients can expect complete relief after transforaminal injection with a further 53% achieving partial relief.

Lee et al<sup>8</sup> described a retrospective comparative study assessing the effectiveness of translaminar, caudal and transforaminal techniques with small and large volume of injectate in the treatment of lumbosacral HIVD or spinal stenosis. Of the patients included in the study, 54 received caudal injections, 64 received ILESi and 115 received LTFESI. Outcomes were assessed at two weeks, one month and two months using the VAS pain score, Patient Satisfaction Index (PSI) and Roland Five Point Pain Scale. A higher ratio of successful results was found for translaminar and transforaminal techniques than caudal technique in VAS in the HIVD group and in VAS and PSI in the stenosis group. Reduction of Roland score was maintained until two months in all techniques in the HIVD and stenosis groups. In the stenosis group, transforaminal groups showed more reduction of Roland score than caudal approach. No difference was found between small and large volume of transforaminal techniques. The authors concluded that the translaminar and transforaminal approaches were more effective than the caudal approach for HIVD and stenosis groups. Effectiveness of the transforaminal approach was more prominent in the stenosis group as compared with the HIVD group. This study provides Level III evidence that LTFESI is significantly more often effective than fluoroscopically-guided caudal injections, but is not significantly more often effective than fluoroscopically-guided interlaminar injection. It provides Level IV evidence that LTFESI provides at least 50% relief at two months after treatment in 66% of patients with radicular pain due to disc herniations and in 53% of patients with spinal stenosis.

Thomas et al<sup>9</sup> performed a prospective RCT to determine the first-line injection procedure to recommend for treatment of lumbar radiculopathy secondary to a disc herniation. Of the 31 consecutively assigned patients included in the study, 15 were treated with LTFESI and 16 received blind ILESi. Patients were assessed at six months with the VAS, RMDQ and Dallas Pain Questionnaire. Compared to the ILESi group the LTFESI patients had statistically significantly greater improvement in VAS at 30 days and six months, and daily activities, work and leisure activities, anxiety and depression and RMDQ scores at six months. The authors concluded that the efficacy of LTFESI is greater than ILESi for the relief of lumbar radicular pain at 30 days and six months. This small study provides Level I therapeutic evidence that LTFESI is more effective than ILESi for reducing pain and improving disability at six months. The study does not provide data on success rates for LTFESI, but implies a non-zero success rate. It provides Level IV evidence regarding the efficacy of LTFESI alone.

**There is insufficient evidence to make a recommendation for or against the efficacy of TFESI in the treatment of lumbar radicular pain in the setting of foraminal stenosis.**

### **Grade of Recommendation: I (Insufficient Evidence)**

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Although several studies enrolled and treated patients with foraminal stenosis along with patients with herniated discs, no study provided outcome data stratified by pathology. Therefore, the outcomes for this condition are unknown.

**There is insufficient evidence to make a recommendation for or against the efficacy of TFESI in the treatment of lumbar radicular pain in the setting of central stenosis.**

**Grade of Recommendation: I (Insufficient Evidence)**

Lee et al<sup>8</sup> described a retrospective comparative study assessing the effectiveness of interlaminar, caudal and transforaminal techniques with small and large volume of injectate in the treatment of lumbosacral HIVD or spinal stenosis. Of the patients included in the study, 54 received caudal injections, 64 received ILESI and 115 received LTFESI. Outcomes were assessed at two weeks, one month and two months using the VAS pain score, Patient Satisfaction Index (PSI) and Roland Five Point Pain Scale. A higher ratio of successful results was found for interlaminar and transforaminal techniques than caudal technique in VAS in the HIVD group and in VAS and PSI in the stenosis group. Reduction of Roland score was maintained until two months in all techniques in HIVD and stenosis groups. In the stenosis group, transforaminal groups showed more reduction of Roland score than caudal approach. No difference was found between small and large volume of transforaminal techniques. The authors concluded that the interlaminar and transforaminal approaches were more effective than the caudal approach for HIVD and stenosis groups. Effectiveness of transforaminal approach was more prominent in the stenosis group as compared with the HIVD group. This study provides Level III evidence that LTFESI is significantly more often effective than fluoroscopically-guided caudal injections, but is not significantly more often effective than fluoroscopically-guided interlaminar injection. It provides Level IV evidence that LTFESI provides at least 50% relief at two months after treatment in 66% of patients with radicular pain in the setting of disc herniations and in 53% of patients with spinal stenosis.

**Future Directions for Research**

A randomized controlled trial assessing the efficacy of transforaminal epidural steroid injections compared with a control group for patients with lumbar radiculopathy in the setting of foraminal and central stenosis would provide Level I evidence with regard to efficacy in these patient populations. Appropriate subgroup analyses must be documented for the foraminal and central stenosis subgroups.

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**Transforaminal lumbar epidural steroid injection is generally a safe procedure with minor transient side effects; however, spinal cord injury is a rare but catastrophic complication that can result from the vascular injection of *particulate* steroids.**

### **Level of Evidence: IV**

#### *Transient Side Effects*

A variety of side effects associated with lumbar transforaminal epidural steroid injections (LTFESI),<sup>1-3</sup> such as vasovagal reactions and nausea, can occur but are not specific to LTFESIs. These side effects occur with many invasive medical procedures in awake patients. Similarly, LTFESI is associated with venous uptake of injectate<sup>4-6</sup> which can occur in any injection procedure and is considered neither a side effect nor a complication if recognized and responded to by repositioning of the needle and reassessing for the avoidance of repeated venous injection. If not recognized, the potential effects of venous uptake are twofold: systemic administration of agents subsequently injected, which may or may not cause side effects; and a false-negative response to treatment because the agent is quickly removed from the intended site of action.

#### *Technical Risks*

A technical hazard of LTFESI is unintended injection into an intervertebral disc.<sup>7,8</sup> This should not be considered either a side-effect or a complication if recognized. However, the theoretical risk applies of causing an infection (discitis).

#### *Catastrophic Complications*

A catastrophic complication of lumbar TFESI is spinal cord infarction,<sup>9-12</sup> which ostensibly occurs when particular steroids are injected into a reinforcing radicular artery. In order to avoid this complication, some recommend that (1) close attention be paid for any intra-arterial uptake during the injection of contrast medium, prior to the administration of any corticosteroids; (2) a test-dose of local anesthetic be administered and the patient assessed for onset of any neurologic features before any injection of corticosteroid. Digital subtraction imaging has been recommended to look for injection into radicular arteries which may be difficult to recognize on conventional fluoroscopy. Others emphasize that LTFESI under computerized tomography (CT) guidance precludes the identification of intra-arterial injection and does not provide for these safety measures due to arterial flow out of the plane of view.

### **Future Directions for Research**

Due to the nature of the question posed, descriptive case series represent the best evidence available to describe the complications resulting from LTFESI. Higher level evidence is not achievable to address questions related to description of complications. Future research may address the impact of strategies

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designed to prevent complications. Comparative studies assessing complication rates with and without such measures (eg, particulate vs. nonparticulate injections) would yield higher level evidence related to the prevention of complications. The work group suggests that future research and evidence-based statements examine the question of which strategies can be implemented to reduce the risk of complications.

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## What is a reasonable maximum number of therapeutic transforaminal epidural steroid injections that a patient should receive within a six month period to treat lumbar radicular pain?

In the absence of sufficient evidence regarding a reasonable maximum number of lumbar transforaminal epidural steroid injections (LTFESI), it is the opinion of the work group that: (1) no more than two injections be used to attempt to achieve a beneficial response in the first instance, and (2) thereafter, it seems reasonable to use up to three injections in a six month period to reinstate and maintain benefit once it has been achieved. In order to justify repeat treatment, benefit should be evident in the form of reduced pain and/or improved function, along with reduced need for other health care.

### Work Group Consensus Statement

The available evidence indicates that favorable outcomes for LTFESIs reported in the literature were achieved most often using one or two injections. Rarely did investigators require three or more injections to achieve an outcome. The rarity of using more than two injections precludes statistically valid conclusions, but the trend in the available literature suggests that if a favorable outcome is not achieved after one or two injections the yield of further injections is small. The literature also suggests that the benefit of TFESIs may diminish with time. If a response has been achieved, but pain recurs, it seems reasonable to offer the patient the possibility of reinstating relief by repeating the treatment. The relief should be of sufficient magnitude and duration to justify repeat treatment. Treatment with TFESIs should at least reduce the need for other health care and preferably should improve function as well as reduce pain. If such gains are achieved and maintained, repeating treatment is professionally and morally defensible.

If the potential need for injections exceeds four per year, the management of the patients should be reviewed. Large numbers of injections increase the steroid and radiation exposure to the patient and suggest that any beneficial effect is insufficiently durable to justify persisting with this form of treatment. Alternative treatment should be considered. This evidence review and resulting recommendation are relevant to patients with radiculopathy resulting from compressive disc pathology for which surgery would potentially be a viable treatment option. Only in exceptional circumstances would persevering with LTFESI be justified, such as patients who are unable to use opioids and not suitable for surgery.

It should be noted that our review addressed therapeutic injections only, and the number of injections recommended does not include injections *that may be* performed for diagnostic purposes.

### Future Directions for Research

A randomized controlled trial assessing efficacy of specific LTFESI protocols (ie, single injection vs. series of two injections vs. series of three injections) in specific subgroups of patients that are appropriately stratified

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based upon symptom severity and duration would provide Level I evidence to support a recommendation regarding a maximum number of injections that will yield maximum therapeutic benefit.

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## What is the value (eg, cost per QALY) of transforaminal epidural steroid injections in the treatment of lumbar radicular pain?

**In those patients with contained disc herniations not extending through the posterior longitudinal ligament, lumbar transforaminal epidural steroid injections (LTFESI) are substantially cost-effective compared with sham treatment. For all other indications, there is insufficient evidence to make a specific recommendation regarding cost-effectiveness of TFESI in the treatment of lumbar radicular pain.**

### **Grade of Recommendation: I (Insufficient Evidence)**

Karpinnen et al<sup>1</sup> conducted a prospective RCT describing the cost-effectiveness of periradicular infiltration with steroid in subgroups of patients with sciatica. Of the 160 consecutively assigned patients, 18 patients with bulging discs received LTFESI while 11 were injected with saline; 24 patients with contained herniated intervertebral disc (HIVD), defined as “broad-based herniation not extending through the posterior longitudinal ligament,” received LTFESI while 26 received saline injection; and 38 patients with extrusions, defined as “herniation extruding through the posterior longitudinal ligament,” received LTFESI while 43 were injected with saline. Patients were followed for one year and outcomes were assessed by VAS (leg pain primary), ODI and Nottingham emotional scores. The authors found that there were no significant differences in outcomes for the patients with bulging discs, but patients with contained HIVD scores for leg pain experienced significantly better outcomes for LTFESI at two and four weeks. At six months, leg pain, disability and Nottingham emotional scores were significantly better for saline. At one year, treatment effects were null. For patients with extrusions, leg pain was significantly better in the saline group at six months. The authors concluded that LTFESI for contained HIVD is superior to saline in terms of leg pain and medical costs and possibly prevents operative treatment. For extrusions, corticosteroid appears countereffective. This study provides Level I therapeutic evidence that: (1) at four weeks after treatment, LTFESI achieves significantly greater improvements in pain and disability than a credible sham treatment in patients with contained herniations, but not in patients with extrusions; and (2) for providing at least 75% relief of radicular pain, LTFESI is more often effective (0.44) than sham treatment (0.21) with an NNT of five. However, this difference is not statistically significant because of the small sample sizes and low success rates encountered in the study. Nevertheless, LTFESI is substantially and significantly more cost effective than sham treatment since it can prevent more costly surgical treatment.

### **Future Directions for Research**

An additional RCT or prospective comparative study is needed to determine whether the conclusions of the Karpinnen<sup>1</sup> study are reliable. If results of another high quality study examining this question are consistent, the grade of recommendation could be significantly higher.

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## Practice and Coverage Considerations

Due to the prevalence of lumbar radicular pain, the increasing use of lumbar transforaminal epidural steroid injections (LTFESI) and the potential confusion regarding appropriate patient selection, NASS proactively performed a comprehensive literature review to provide evidence-based recommendations regarding the use of LTFESI in the treatment of lumbar radiculopathy/radiculitis resulting specifically from herniated disc or spinal stenosis.

The work group identified and attempted to address the following five key clinical questions in this review and recommendation statement:

1. What are the prognostic indicators that predict which patients are likely to benefit from lumbar transforaminal epidural steroid injections (LTFESI)?
2. What is the reported efficacy of LTFESI in the treatment of radicular pain from lumbar spinal stenosis and lumbar disc herniation?
3. What are the reported complications of lumbar TFESI?
4. What is a reasonable maximum number of therapeutic lumbar TFESI that a patient should receive within a six month period to treat lumbar radicular pain?
5. What is the value (eg, cost per QALY) of TFESI in the treatment of lumbar radicular pain?

**Based on this review, LTFESI is recommended to provide relief of radicular pain related to lumbar disc herniation with good evidence identified to support this recommendation.** Although evidence for the benefit of LTFESI in the setting of central spinal stenosis was identified, available studies do not allow sufficient stratification of data for a specific recommendation to be formed on the use of these procedures in patients with central canal or foraminal stenosis. From a practice standpoint, the data are generally supportive of the use of LTFESI for radicular pain, although more research is recommended to clarify the relative benefits of the procedure in specific patient groups.

The review concluded that a minimum of one or two LTFESIs would be very appropriate in the treatment of a specific episode of lumbar radicular pain, with a maximum of three injections within six months, assuming there was a positive response and improvement seen with the previous injections (eg, decreased pain, reduced the need for other health care, improved function, etc.). Review of the management of the patient is advised if the potential need for LTFESI exceeds four per year.

It should be noted that there are circumstances to which this specific recommendation regarding a maximum number of injections may not be appropriate and may need to be exceeded. For instance, this review only addressed the therapeutic aspect of LTFESI, and the number of injections recommended does not include injections that may be performed for diagnostic purposes. Selective or diagnostic spinal nerve blocks (DNRB) are performed in a manner similar to LTFESI and utilize the same CPT codes (64483-64484). Additionally, there may be infrequent cases in which a new, separate radicular problem develops which may cause the total number of CPT codes submitted to exceed these recommended amounts. As mentioned in the review, other exceptional but justified circumstances may exist for utilizing LTFESI with a frequency that may exceed the limits recommended. Given these factors, an absolute limit of four LTFESIs per year may be inappropriate in some cases and could overly restrict some patients from receiving necessary and reasonable care.

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The review found that LTFESI is generally a safe procedure and that catastrophic complications, such as spinal cord injury, are rare but can result from intra-arterial injection of particulate corticosteroids. The appropriate use of contrast medium, digital subtraction imaging, a test-dose of local anesthetic and/or non-particulate corticosteroids all may potentially reduce this risk.

This review is specific to the use of LTFESI for the indications noted, and there are limitations to the scope of the findings. This review did not address the use of LTFESI in the treatment of axial low back pain, sympathetic pain or other causes of radiculopathy/radiculitis such as inflammation from a viral or immune-mediated origin, synovial cysts or epidural fibrosis. The use of caudal or lumbar interlaminar epidural steroid injections was also not part of this review.

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# Appendices

**Appendix A: Levels of Evidence/Grades of Recommendation**

**Appendix B: Linking Levels of Evidence to Grades of Recommendation**

**Appendix C: NASS Protocol for Literature Searches**

**Appendix D: LTFESI Literature Search Parameters**

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# APPENDIX A: Levels of Evidence/Grades of Recommendation

## Levels of Evidence For Primary Research Question<sup>1</sup>

As Adopted by the North American Spine Society January 2005

Types of Studies				
	<b>Therapeutic Studies –</b> Investigating the results of treatment	<b>Prognostic Studies –</b> Investigating the effect of a patient characteristic on the outcome of disease	<b>Diagnostic Studies –</b> Investigating a diagnostic test	<b>Economic and Decision Analyses –</b> Developing an economic or decision model
Level I	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic Review<sup>2</sup> of Level I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>
Level II	<ul style="list-style-type: none"> <li>Lesser quality RCT (e.g. &lt; 80% follow-up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level II studies or Level 1 studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (e.g. patients enrolled at different points in their disease or &lt;80% follow-up.)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>Case control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Case control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>Study of non-consecutive patients; without consistently applied reference “gold” standard</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	Case Series <sup>8</sup>	Case series	<ul style="list-style-type: none"> <li>Case-control study</li> <li>Poor reference standard</li> </ul>	<ul style="list-style-type: none"> <li>Analyses with no sensitivity analyses</li> </ul>
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

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1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; eg, failed total arthroplasty, are compared to those who did not have outcome, called “controls”; eg, successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

### **Grades of Recommendation for Summaries or Reviews of Studies As Adopted by the North American Spine Society January 2005**

- A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.
- B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.
- C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.
- I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

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## APPENDIX B: Linking Levels of Evidence to Grades of Recommendation



Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
B	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
C	May be considered; is an option	One Level I, II or III study with supporting Level IV studies	Two or more consistent Level IV studies
I (Insufficient or Conflicting Evidence)	Insufficient evidence to make recommendation for or against	A single Level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*
*Note that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.			

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## APPENDIX C: Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities. It is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

NASS research staff will work with the requesting parties and the NASS-contracted medical librarian to run a comprehensive search employing *at a minimum* the following search techniques:

1. A comprehensive search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to research staff to facilitate this search.
  - Time frames for search
  - Foreign and/or English language
  - Order of results (chronological, by journal, etc.)
  - Key search terms and connectors, with or without MeSH terms to be employed
  - Age range
  - Answers to the following questions:
    - o Should duplicates be eliminated between searches?
    - o Should searches be separated by term or as one large package?
    - o Should human studies, animal studies or cadaver studies be included?

This search will encompass, at minimum, a search of PubMed, EMBASE, Cochrane and Web of Science. Additional databases may be searched depending upon the topic.

2. Search results with abstracts will be compiled by the medical librarian in Endnote software. The medical librarian typically responds to requests and completes the searches within two to five business days. Results will be forwarded to the research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff has access to EndNote software and will maintain a database of search results for future use/documentation.)
3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review.
4. NASS research staff will work with Galter library to obtain requested full-text articles for review.
5. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

Following this protocol will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in EndNote for future use or reference.

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## **APPENDIX D: LTFESI Literature Search Parameters**

### **Databases Searched for All Questions**

- PubMed
- Cochrane
- EMBASE Drugs and Pharmacology
- Web of Science

### **Search Parameters for All Questions**

- Time frames for search: 1966-November 2010
- ENGLISH ONLY
- Age range: 18+
- HUMAN STUDIES ONLY

### **Search Strategy Implemented**

((("lumbosacral region"[MeSH Terms] OR ("lumbosacral"[All Fields] AND "region"[All Fields]) OR "lumbosacral region"[All Fields] OR "lumbar"[All Fields]) OR lumbosacral[All Fields]) AND (transforaminal[All Fields] AND epidural[All Fields]) AND (("steroids"[MeSH Terms] OR "steroids"[All Fields] OR "steroid"[All Fields]) OR ("steroids"[MeSH Terms] OR "steroids"[All Fields])) AND (("injections"[MeSH Terms] OR "injections"[All Fields] OR "injection"[All Fields]) OR ("injections"[MeSH Terms] OR "injections"[All Fields])) AND (English[lang] AND ("1966"[PDAT] : "3000"[PDAT])))

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