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AAPM&R Guideline Review

Guideline Title: Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain

Guideline Sponsors/Authors: North American Spine Society (NASS)

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AAPM&R Clinical Practice Guideline (CPG) Committee Reviewers: Aaron E. Bunnell, MD; David W. Lee, MD; Armando S. Miciano, Jr., MD; K. Rao Poduri, MD; and Jeffrey Radecki, MD

AAPM&R Clinical Domain Expert (CDE) Reviewer: David W. Lee, MD; John M. Lesher, MD, MPH; Christopher J. Standaert, MD; and Santhosh A. Thomas, DO, MBA

Overview/Summary: This guideline was created to provide evidence-based recommendations to address key clinical questions regarding the diagnosis and treatment of adult patients with nonspecific low back pain. This guideline is based upon a systematic review of the clinical evidence available as of February 2016. The goal of the guideline recommendations is to assist in delivering optimum, efficacious treatment and functional recovery from nonspecific low back pain. NASS notes that this guideline does not represent a "Standard of Care." AAPM&R is acknowledged as a Contributing Society and several physiatrists served as authors and contributors to this guideline.

AAPM&R CPG AGREE II Tool Review: To determine endorsement of this guideline, the CPG Committee Members evaluated the guideline according to the Appraisal of Guidelines for Research & Evaluation (AGREE) II. This tool allows reviewers to assess the methodological rigor and transparency in which a guideline is developed. It provides a framework to assess the qualities of the guideline, provide a methodological strategy for the development of the guideline, and informs what information and how information should be reported in the guideline. This guideline received an overall AGREE average rating of 5.8 out of 7 by reviewers. As the AGREE II Tool does not asses the content of the guidelines, elements of the GuideLine Implementability Appraisal (GLIA) v. 1.0 have been adapted to assist reviewers in the assessment of the recommendations include within this guideline.

AAPM&R Endorses the NASS Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain

Physiatry Recommendation Summary:

- 1. The following Recommendations have been identified by the CPG or CDE as relevant to the practice of physiatry and do not constitute the entirety of this guideline. Each recommendation is followed by the grade and quality of evidence as cited in the published guideline.
- 2. The Recommendations consider the factors of Decidability (precisely under what circumstances to do something), Executability (exactly what to do under the circumstances defined), Measurable Outcomes (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation), and Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence). Comments discuss implications for Physiatry practice and any barriers or challenges that could be encountered in implementation of the recommendation. Note strengths

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of the recommendation. These factors have been adapted from the <u>GuideLine Implementability Appraisal</u> (GLIA) v. 1.0

- 3. Special emphasis is placed on review of potential barriers to implementation and ideas/opportunities to overcome those barriers and challenges. The CPG and CDEs feel these barriers offer an opportunity for quality improvement in the field.
- 4. Grades of Recommendation

A: Good evidence (Level I studies with consistent findings) 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.



Recommendation #1: Aerobic exercise is recommended to improve pain, disability and mental health in patients with nonspecific low back pain at short-term follow-up. Grade of Recommendation: A

Summary of Decidability (precisely under what circumstances to do something):

Physiatrists should not encounter difficulty, nor confusion, recommending aerobic exercise as part of treatment program for low back pain. This recommendation applies to low back pain which is considered as a single condition for this recommendation as opposed to other back related conditions. Providers should be able to reasonably identify exceptions where applicable clinically.

Summary of Executability (exactly what to do under the circumstances defined):

The detail on the specific type of aerobic exercise is not elucidated. Some studies recommend high intensity aerobic exercise based on heart rate parameters, but this is not a universal recommendation from the guidelines. Therefore, the recommendation for aerobic exercise is a general directive and will most likely encompass numerous types of treatment depending on availability, patient and physician interest and cost. The lack of specificity addressed in the guideline leaves providers room for interpretation when implementing this clinically.

Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):

Options of measurability include subjective self-reporting, objective testing, accelerometers, step counters, etc. If the participant has a wearable tracking device or remote health monitoring system, data could relay criteria listed above to the electronic medical record system. Other objective measures may include the patient's ability to complete specific exercises, as well as tolerance to certain durations and frequencies of aerobic activity.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

The referenced literature supports aerobic exercise as a treatment for low back pain. The recommendation has a broad scope and may be tailored accordingly.

Recommendation #2: Cognitive behavioral therapy is recommended in combination with physical therapy, as compared with physical therapy alone, to improve pain levels in patients with low back pain over 12 months. Grade of Recommendation: A

Summary of Decidability (precisely under what circumstances to do something):

This recommendation applies to those patients that have low back pain and are being referred for physical therapy for treatment. Physiatrists should be able to reasonably distinguish when to utilize cognitive behavioral therapy (CBT) and physical therapy (PT) individually, or in combination in most cases. This recommendation supports the combined use in patient with low back pain over 12 months.

Summary of Executability (exactly what to do under the circumstances defined):

Based on the guideline, there is substantial evidence to support the use of CBT in combination with physical therapy compared to physical therapy alone to improve disability and return to work. There is, however, limited guidance regarding executability and it is very much left open-ended. Additional concern is the access to CBT in certain areas, which may impede its use as a treatment option. However, the recommendation highlights that health care providers be trained to incorporate CBT into PT care and office visits with clinicians to provide an integrated approach.

Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):



This recommendation is one where CBT is incorporated with PT for treatment of the LBP and is not easily measurable by an electronic health record (EHR) system. Measurability would be subjective. However, indicators such as pain, depression, anxiety, etc., can be measured and tracked via EHR. The NASS work group did recommend future studies to identify what types of psychosocial interventions are the most effective, the appropriate frequency, various combinations of therapy to improve treatment of LBP.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

The recommendation is open-ended and leaves room for individual interpretation and decision-making for the clinician. Based on this recommendation, it is clear that CBT should be incorporated in the PT approach. CBT has been shown to enhance outcomes of PT. The largest challenge will be to find way to integrate CBT on a consistent basis with PT.

Recommendation #3: For patients with acute low back pain, spinal manipulative therapy (SMT) results in similar outcomes to no treatment, medication or modalities. Periodically, short-term improvement is statistically better, but clinical significance is uncertain. Grade of Recommendation: A

Summary of Decidability (precisely under what circumstances to do something):

This review examined only evidence in the subset of patients with acute axial low back pain without radiating pain. For those patients in an acute setting, where spinal manipulative therapy (SMT) was applied, the evidence was not consistent. Certain studies do show statistically significant improvements short-term with SMT without substantial evidence or long-term pain relief or clinical significance. The guidelines themselves read, "Therefore, a definitive statement of SMT in all patients with LBP cannot be made." In this respect, the clinical efficacy of SMT is not clear. The wording of the recommendation implies that it is non-superior to the use of modalities, medications or no treatment.

Summary of Executability (exactly what to do under the circumstances defined):

Given the long-standing beliefs that manual manipulation helps with acute low back pain real world application of SMT may be varied. Additionally, patients also may have preference for manual manipulation either through physical therapy, osteopathic manipulative therapy or more commonly perhaps, chiropractic manipulation.

<u>Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):</u>

This recommendation involves making a clinical decision when deciding on treatment of the LBP patient, and not that of which is easily integrated by electronic record keeping system. Although data elements are not extractable from the recommendation, outcomes of SMT could be hypothetically measured by functional and standardized scores (VAS, NRS, Oswestry, SF-36). There will be some aspect of subjectivity, and placebo cannot be ruled-out.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

The recommendation is clear, suggesting that SMT not be used in acute low back pain patients. The recommendation reflects the clinical intent and outcome. Long-standing belief that manipulation helps in acute low back pain may be a difficult hurdle to overcome without constant reinforcement. As the evidence does not prove SMT to be uniquely helpful for low back pain treatment, eliminating it as a treatment option in this specific LBP patient population would likely save both patient time and financial resources.



Recommendation #4: Treatments targeting fear avoidance combined with physical therapy are recommended compared to physical therapy alone to improve low back pain in the first six months. Grade of Recommendation: A

Summary of Decidability (precisely under what circumstances to do something):

The evidence suggests that acute and subacute low back pain patients could benefit from fear avoidance treatment in combination with physical therapy. Determining the beginning of low back pain and knowing when the "first six months" has transpired may present some challenges for providers.

Summary of Executability (exactly what to do under the circumstances defined):

Cognitive based therapy (CBT) focused on treating fear avoidance will be variable in different practice settings. This recommendation highlights the need to routinely incorporate psychologically-based treatments and exercises early on in the course of low back pain. Use and knowledge of appropriate screening tools may help identify patients that might be prone to long-term psychological sequelae. The interventions could be reasonably led by a physiatrist, psychologist or therapist with special training in CBT. Proficiency in CBT/fear avoidance treatments will be variable in different clinical and geographic settings. An additional concern is that it is unclear what exactly is meant by "treatments targeting fear avoidance"- no examples are given. Fear avoidance is a psychological construct and subjective in this respect.

Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):

Baseline pain, psychiatric and/or pain catastrophizing scores could be collected and reassessed at different time points during the patient's treatment. The data (i.e. fear avoidance scores, pain scores, functional improvement scores) could be collected with an electronic health record system longitudinally.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

CBT aimed at improving fear avoidance and decreasing low back pain is valid and supported by the literature, but there is no consensus on the best means of addressing fear avoidance in routine practice nor a practice that most spine practitioners consciously do routinely. There is a high likelihood that treatments will be variable based on provider proficiency, availability, reimbursement and patient engagement.

Recommendation #5: Thermal radiofrequency ablation is suggested as a treatment for patients with low back pain from the zygapophyseal joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these injections is durable for at least 6 months following the procedure. Grade of Recommendation: B

Summary of Decidability (precisely under what circumstances to do something):

Most evidence for the use of radiofrequency ablation is in patients that have a failed conservative course of physical therapy, modalities, medication management. Diagnostic blocks are requisite prior to radiofrequency ablation. Medical appropriateness for repeatability is addressed with at least 6 months between radiofrequency ablation procedures.

Summary of Executability (exactly what to do under the circumstances defined):

Clinicians should be able to execute these recommendations consistently. The only ambiguity here is the "diagnostic criteria" that the recommendation alludes to. Most insurance coverage recommends anywhere from single- to double-block paradigm of >50% temporary relief. The double-block was specifically recommended due to reduction in the placebo effect prior to radiofrequency ablation procedure.

Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):

Documentation needs to indicate that percentage relief from diagnostic blocks. Additionally, tracking how long of relief is equally important as radiofrequency ablation procedure often need to be repeated, and at no earlier than 6 months. An option of measurability would be to document the results in the electronic health record system making it accessible for the provider.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

The recommendation is supported by clinical evidence, though it is extremely general, simply stating that radiofrequency ablation for LBP patient is efficacious when zygapophyseal joints are identified as the pain generator. The details of diagnostic procedures are not enumerated and details of the radiofrequency procedure itself are not detailed. However, this lends to flexibility to account for variability in patient and clinical/non-clinical factors.

Recommendation #6: It is suggested that the use of opioid pain medications should be cautiously limited and restricted to short duration for the treatment of low back pain. Grade of Recommendation: B

Summary of Decidability (precisely under what circumstances to do something):

Providers should clearly understand the intent and message of this recommendation – that opioid medications should be limited in the treatment of low back pain patients. The words "limited" and "short duration" are relative terms and may be interpreted differently by providers. One limitation of this particular recommendation is that it is only focused on low back pain, not radicular/sciatica type pain.

Summary of Executability (exactly what to do under the circumstances defined):

Short duration" of treatment is not defined but most likely represents three (3) months of treatment or less. Additionally, recommendations on specific opiate usage are not defined though the majority of studies described in the guidelines reference the use of tramadol in patients with chronic low back pain. Physiatrists, with or without pain medicine subspecialty training/certification, who regularly treat patients with chronic low back pain should have the clinical proficiency in the short-term use of opiate medications.

Summary of Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation):

Opiate medication usage may be easily tracked thru prescription databases as well as electronic prescribing software.

Summary of Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence):

Although not implicitly stated in this recommendation, the guidelines allow for non-opiate medications and other non-pharmacological treatments to be used for patients with low back pain. There is flexibility to allow for this. It is clearly supported by the literature and but could be further emphasized.

ADDAE



Reviewers of this guideline would also like to acknowledge the following recommendations that are relevant to physiatrists:

Therapies and Modalities:

- Back school is recommended to provide improvements in pain and function when compared with general medical care, modality care or a simple handout at 6-12 months' follow- up for chronic low back pain. Grade of Recommendation: A
- In patients with chronic low back pain, addition of acupuncture to usual care is recommended for short-term improvement of pain and function compared to usual care alone. Grade of Recommendation: A
- Laser acupuncture provides no short-term or medium-term benefit over sham treatment for patients with chronic low back pain. Grade of Recommendation: A
- In patients with subacute or chronic low back pain, traction is not recommended to provide significant improvement in pain or function. Grade of recommendation: A
- In the long term, it is suggested that the addition of massage to an exercise program provides no benefit when compared to an exercise program alone. Grade of recommendation: B
- It is suggested that, for patients with acute low back pain, those that exercise more at baseline and use exercise to facilitate recovery are predicted to have better functional outcomes over time than patients who do not exercise or use bed rest to help with recovery. Grade of Recommendation: B
- It is suggested that the use of heat for acute low back pain results in short term improvements in pain. Grade of Recommendation: B
- It is suggested that there is no short-term benefit of laser therapy (low-level or high level) when compared with exercise alone. Grade of Recommendation: B
- It is suggested that a specific stabilization exercise program is equivalent to a general exercise program. Grade of Recommendation: B
- There is insufficient evidence to make a recommendation for or against lumbar stabilization in patients with chronic low back pain. Grade of Recommendation: I
- McKenzie method is an option for the treatment of chronic low back pain. Grade of recommendation: C

Interventional Procedures:

- There is high-level evidence that provocative discography without manometric measurements correlates with pain reproduction in the presence of moderate to severe disc degeneration on MRI/C discography. Grade of Recommendation: A
- Intradiscal electothermal annuloplasty is suggested to provide improvements in pain and function at up to two years. This treatment is limited in its effectiveness with roughly 40-50% of patients receiving a 50% reduction in pain. Grade of recommendation: B
- Intradiscal steroids are suggested to provide short-term improvements in pain and function in patients with Modic changes. Grade of Recommendation: B
- Cooled radiofrequency ablation of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with sacroiliac joint pain diagnosed with dual diagnostic blocks. Grade of Recommendation: C

Pharmacotherapy:

- Topical capsicum is recommended as an effective treatment for low back pain on a short-term basis (3 months or less). Grade of Recommendation: A
- It is suggested that the use of oral or IV steroids is not effective for the treatment of low back pain.
 Grade of Recommendation: B



Pain Psychology:

 It is recommended that psychosocial factors and workplace factors be assessed when counseling patients regarding the risk of conversion from acute to chronic low back pain. Grade of Recommendation: A