Member Groups Requesting Changes:

Midwest Spine Institute
Mayo Clinic
Marshfield Clinic

Member Groups that Reviewed the Guideline, No Changes Requested:

CentraCare Health System
Hudson Physicians

Member Groups that Responded but the Guideline Does Not Pertain to Practice:

None

Sponsoring Health Plans Requesting Changes:

Medica
HealthPartners

Sponsoring Health Plans that Reviewed the Guideline, No Changes Requested:

None

GENERAL COMMENTS:

1) It would be helpful if ICSI included both the procedure and diagnosis codes that are used in their guideline measures. (HealthPartners)

   Thank you for the comment. The range of possible codes for low back pain is large. We have opted to allow readers to choose which codes to track for measurement.

2) The ICSI LBP guideline is used as resource in addition to other evidence-based guidelines such as those from MASS, ISIS, etc. (Midwest Spine Institute)

   Thank you for the comment. This is great to hear!

3) I love, love, love the ability to navigate through the guideline with a single mouse click. It makes the document much more user friendly. Major Kudos! (Mayo Clinic)

   Thank you for the compliment!
4) I don’t see a lot of change in this guideline compared to the last version, but I think this document is more direct about the recommendations. Below, I copied the recommendations that I’d love to see really adopted and used by the local Practice. If we had a spine specialist, we could limit lumbar MRIs to that person/group and thus decrease unnecessary lumbar MRI. (Mayo Clinic)

(Aims in document)

• **Reduce or eliminate imaging** for non-specific low back pain diagnosis in patients 18 years and older in the absence of "red flag" indicators.

• **Delay imaging** in patients with radicular pattern pain until after six weeks to allow for resolution that usually occurs within this period.

• Increase the use of a core treatment plan as first-line treatment. This includes activity, heat, education, exercise and analgesics for patients 18 years and older with low back pain diagnosis.

• Limit the use of opioids to the appropriate management of acute or subacute low back pain.

• Increase the utilization of validated pain and function scales to help differentiate treatment approaches in order to improve the patient’s ability to function. (Mayo Clinic)

*Thank you for the comment and support of the guideline recommendations.*

5) Recommendations Table, page 7- The recommendations table on page 7 would be more useful if the recommendations were listed in order of strength from strongest to weakest, then the provider could see what evidenced based recommendations are more favorable at a quick glance. (Marshfield Clinic)

*Thank you for the comment. There are multiple ways the recommendations table could be formatted. We have opted to list the recommendations in alphabetical order. The strength of the recommendations is determined by the balance between desirable and undesirable consequences of alternative management strategies, quality of evidence, variability in values and preferences, and resource use. Therefore, weak recommendations are as favorable as strong recommendations.*

6) As an aside, does ICSI ask Guideline workgroup members for potential conflicts of interest? If not, should this be done? If it is done, should it be published with the Guideline, or should readers of the Guideline be offered a link to the authors’ disclosure statements? (Mayo Clinic)

*Thank you for your comment. ICSI requires all work group members to disclose potential conflicts of interest. These are published in the guideline along with a link to our Conflicts of Interest policy.*

**MEDICAL CONTENT:**

7) Definitions, page 11- Spinal Manipulative Therapy – This includes spinal mobilization and these interventions are usually applied with the aim of inducing intervertebral movement by directing forces to the vertebrae and include spinal manipulation and mobilization. Since this includes spinal mobilization consider changing the title to “Manual Therapy of the Spine.” As reported in Medicine & Health Journal February 2009, from research taken from Cochrane Database Systematic Review (2004 & 2005),
"Exercise and manual therapy including spinal manipulation, have been shown to benefit many patients." (Marshfield Clinic)

Thank you for your comment. The topic of spinal manipulative therapy was discussed and reviewed by the work group extensively. This is the terminology used to encompass both mobilization and manipulation interventions. See also the more current Cochrane review by Assendelft 2008, “Spinal Manipulative Therapy for Low-Back Pain.”

8) Algorithm Box# 2a and 2b: Algorithm boxes 2a and 2 b call for using the Oswestry Disability Questionnaire, yet it no available as a tool in the guideline. Can it be added as a tool in the appendix? (Marshfield Clinic)

Thank you for your comment. The Oswestry Disability Questionnaire is not included in the guideline due to copyright restraints for publication. However, the tool is available for use to clinicians at http://www.mapitrust.org/services/questionnairelicensing/cataloguequestionnaires/128-odi.

9) Regarding the psychological or psychosocial component associated with back pain; Most back pain is likely organic in nature as there are various inflammatory mediators in disc and other anatomic structures associated with pain. Certainly psychological factors may impact the severity of perceived pain however, in most cases, psychological factors do not cause it. (Midwest Spine Institute)

Thank you for your comments regarding psychological and psychosocial components.

10) Annotation #2a: Would note that ODI is related to pain and function, and not to performance, not to range of motion, and not to neurological findings. Diagram of dermatome patterns incomplete/not completely accurate. References- Please see attached dermatome pattern body map/chart (Midwest Spine Institute)

Thank you for your comment. We agree that the dermatome pattern diagram in the document is incomplete. However, we are utilizing a simplified form that looks at patterns in order to assist the primary clinician in identifying the common forms.

11) The annotation for diamond #5 in the middle of page 1 and the box 29 on the top of page 3 need revision. Both imply that pain must go below the knee in order to be deemed radicular. This is incorrect. L5 and S1 radiculopathies can cause referred pain that does not extend below the knee, and certainly upper lumbar radiculopathies (e.g., L3, L4) frequently do not radiate below the knee. (Mayo Clinic)

Thank you for your comment. We agree with your assessment of box #29 and have changed it to read “Radicular pain diagnosed.” We have reviewed box #5 “Presence of radicular pain, not simply radiating pain past knee?” and believe that this box includes all patients with radicular pain and is not limiting.

12) The annotation of diamond #6 (on page 1) which is on page 16 states “Diffuse or not organic sensory or strength changes are not considered radicular and if noted should be treated as nonspecific low back pain.” This does not recognize the possibility that diffuse weakness and/or widespread sensory impairment in one lower extremity may be
secondary to myelopathy. Compression of the lower thoracic spinal cord can also cause lower limb pain in addition to nonradicular sensory loss and/or weakness. (Mayo Clinic)

*Thank you for your comment. We have modified the annotation to read “diffuse or NON-organic sensory” and have added a statement indicating that in rare cases it may represent myelopathy or higher cord lesions.*

13) Annotation #6, page 16: Third sentence: “Diffuse or not organic sensory or strength changes are not considered radicular and if noted should be treated as non-specific low back pain.” Should “or not” be removed from the sentence? (Marshfield Clinic)

*Thank you for your comment. We have modified the annotation to read “diffuse or NON-organic sensory.”*

14) Annotation #11 on page 17 (and elsewhere) is excessively restrictive in its recommendation for use of opioid analgesic therapy. The sentence should read, “Opioid analgesic therapy may be considered for patients with severe disabling pain not controlled with acetaminophen and NSAIDS.” When used, opioid analgesics should not be “rarely used” but used as needed with an appropriate interval between dosing, and they should be used in an effective dose, not a “minimum dose.” Perhaps, the sentence should read, “…used at the minimum effective dose.” There are many recent references supporting the use of opioid analgesics for acute and some for chronic low back pain. 3,4,5,6,7,8,9,10 (Mayo Clinic)

*Thank you for your comments. The annotation content and the recommendation for opioids has been revised.*

15) On page 19, there is a statement, “The evidence of effectiveness of opioids on acute low back pain is inconclusive,” quoting Chou from 2007. I was not certain whether the Guideline was quoting Chou and Huffman (your Ann Intern Med 2007a)9 or Chou, Qaseem, Snow, et al (your Ann Intern Med 2007c),11 but both articles state that opioids are effective for low back pain: “Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled…with acetaminophen and NSAIDS.”11 and “We also found fair evidence that opioids, tramadol…are effective for pain relief.” (Mayo Clinic)

*Thank you for your comments. The annotation content and the recommendation for opioids have been revised.*

16) Annotation #11 Regarding Core Treatment Plan: In Non-specific Low back Pain Algorithm: Would ask the question as to why physical therapy is excluded from the core treatment plan? Would suggest that primary care provider has sufficient training to make a judgment and be able to refer to physical therapy before referring to medical spine specialist. In Radicular Pain Algorithm Consideration of anti-neuropathic medications as part of core treatment (Midwest Spine Institute)

*Thank you for your comment. The core treatment plan is utilized throughout the course of treatment for acute low back pain. The document then describes the additional pieces that are included along the course of acute/subacute low back pain. This includes spinal manipulative therapy, which includes all modalities, and is introduced in the early acute
phase. We have focused on the options and not the specific practitioner choices that are available under spinal manipulative therapy.

17) **Regarding Imaging:** For non-specific LBP consideration of plain films after 2 weeks if not improving/responding to core treatment plan. For severe radicular pain consideration of HT/advanced imaging after 2 weeks or after 6 weeks if not improving/responding to core treatment plan. Rationale: to move to diagnosis more quickly to evaluate/initiate appropriate treatment options. (Midwest Spine Institute)

*Thank you for your comment. Based on evidence, imaging is not recommended for non-specific low back pain regardless of the duration. In addition, the data does not support the use of plain films in adding additional value to diagnosis or treatment. Imaging is not recommended in the first six weeks of radicular pain, with the exception of advancing neurologic deficits and severe unrelenting pain, as it is not supported by evidence.*

18) **Annotation #11 Core Treatment Plan: Interventions – Manual Therapy**

Clinicians should consider utilizing thrust manipulative procedures to reduce pain and disability in patients with mobility deficits and acute low back and back-related buttock or thigh pain. Thrust manipulative and non-thrust mobilization procedures can also be used to improve spine and hip mobility and reduce pain and disability in patients with subacute and chronic low back and back-related lower extremity pain. References: Low Back Pain Guidelines 2012 Journal of Orthopaedic & Sports Physical Therapy Volume 42, Number 4, April 2012. (Medica)

*Thank you for your comment. Spinal manipulative therapy includes all modalities, both thrust and non-thrust. We have focused on the option and not the specific practitioner choices or modality choices that are available under spinal manipulative therapy. The clinician and the patient can discuss options through shared decision-making.*

19) **Annotation #11 Core Treatment Plan: Interventions – Trunk Coordination, Strengthening, and endurance exercises**

Clinicians should consider utilizing trunk coordination, strengthening, and endurance exercises to reduce low back pain and disability in patients with subacute and chronic low back pain with movement coordination impairments and in patients post-lumbar microdiscectomy. (Medica)

*Thank you for your comment. The work group has thoroughly reviewed the evidence on exercise and low back pain. The evidence shows that exercise is recommended, however, the use of any specific type of exercise is not supported by quality evidence.*

20) **Annotation #11 Core Treatment Plan: Interventions – Centralization and directional preference exercises and procedures**

Clinicians should consider utilizing repeated movements, exercises, or procedures to promote centralization to reduce symptoms in patients with acute low back pain with related (referred) lower extremity pain. Clinicians should consider using repeated exercises in a specific direction determined by treatment response to improve mobility and reduce symptoms in patients with acute, subacute, or chronic low back pain with mobility deficits. (Medica)

*Thank you for your comment. The work group has thoroughly reviewed the evidence on exercise and low back pain. The evidence shows that exercise is recommended, however, the use of any specific type of exercise is not supported by quality evidence.*
21) Annotation #11: Inconsistency with Core Treatment Plan (listed on page 1) and annotation 11, expanded explanation on Page 17-18:

• A bullet point for exercise is included on page 18 but is not listed in Core Treatment Plan on page 1.
• “Return to work.” is mentioned in the Core Treatment Plan on page 1 but not in the expanded “core” treatment of annotation 11. (Possibly one may consider just putting this under the bullet point that patients should “stay active”?)

Imaging is a diagnostic modality and not a treatment modality. Imaging should be addressed separately and not be included with treatment recommendations. (Midwest Spine Institute)

Thank you for your comments. We have added a bullet point for exercise to the Core Treatment Plan box on the algorithm. Return to work is discussed in the annotation #11 and is under “Return to work assessment.” The work group agrees that imaging is a modality but is part of the treatment even though it is a recommendation against the procedure. We have changed the wording for the core treatment plan to read “no imaging for non-specific low back pain.”

22) Annotation #11, page 17: First dot point: “No standardized form of education is suggested.” This statement contradicts what is said in the discussion about education on page 19. Please see the patient education recommendations in the 2012 APTA Low Back Pain clinical practice guideline. Delitto, 2012. The same recommendation for the second dot point on top of page 18 which reads: “Exercise is recommended to reduce the recurrence of low back pain, however, no specific exercise is preferred.” The statement that “no specific exercise is preferred” is misleading. According to the 2012 APTA Low Back Pain Guidelines, the recommendation is: Clinicians should consider utilizing trunk coordination, strengthening, and endurance exercises to reduce low back pain and disability in patients with sub-acute and chronic low back pain with movement coordination impairments and in patients post–lumbar microdiscectomy. Physical therapists should have a significant role in the education component of the initial treatment. (Marshfield Clinic)

Thank you for your comment. The work group has thoroughly reviewed the evidence on education and exercise for low back pain. The evidence shows that education and exercise are recommended, however, the use of any specific type of exercise or education is not supported by evidence.

23) Annotation #11, Page 17: Physical therapy is already involved in at least 6 of the 9 aspects of the Core Treatment Plan. Physical therapy should not only be specifically considered to be included in referral for the management of low back pain, physical therapists should also be considered in an expanded role for the primary management of this condition due to efficacy and cost effectiveness of interventions including treatment and education. (Marshfield Clinic)

Thank you for your comment. Spinal manipulative therapy includes all modalities, both thrust and non-thrust. We have focused on the option and not the specific practitioner choices or modality choices that are available under spinal manipulative therapy. The clinician and the patient can discuss options through shared decision-making.
24) On page 21, regarding the annotation for box 12 “Reassess as Needed,” which occurs on page 1, the patient should also be instructed to return to their care provider if they note increasing or severe lower limb weakness. (Mayo Clinic)

Thank you for your comment. We agree and have added weakness of the leg to this list of instructions for returning to the clinician in annotation #12.

25) Annotation #16 and #17: Aspects of PT intervention should be emphasized in the early and late acute phase of low back pain. Spine Journal, 2012 concluded that "There was a lower risk of subsequent medical service usage among patients who received PT early after an episode of acute low back pain relative to those who received PT at later times. Medical specialty variations exist regarding early use of PT, with potential underutilization among general specialties." References: Spine 2012 4(20); 37(9) 775-82, (Marshfield Clinic) Gelhorn, 2012

Thank you for your comment. Spinal manipulative therapy includes all modalities, both thrust and non-thrust. We have focused on the option and not the specific practitioner choices or modality choices that are available under spinal manipulative therapy. The clinician and the patient can discuss options through shared decision-making.

26) Annotation #17, p. 25 consider referral to medical spine specialist: In the second sentence it states, “The patient and/or clinician should request a trained non-surgical spine specialist who demonstrates competency in providing therapies…” This statement is also repeated in annotation # 18, p. 26 under medical spine specialist, and in annotation # 43, p. 32 under medical spine specialist. This statement seems to be making assumptions that the patient is knowledgeable of techniques in the literature and this guideline. Is this statement realistic, especially regarding patient knowledge? Suggest rephrasing e.g., “The provider should be knowledgeable of trained non-spine specialists who provide therapies such as education, exercise programs, and appropriate use of manipulative therapies as outlined in this guideline.” “Then, the patient and provider can discuss the appropriate options that are available.” (Marshfield Clinic)

Thank you for your comment. We appreciate your suggested rephrasing, however, we have opted to leave the statement as is.

27) Annotation #16: A broad question; At the onset of low back pain, can a recommendation be made for physical therapy versus chiropractic-one over the other and how should the primary care physician decide which is preferable? It would be great to provide some guidance as to which to select and how one should arrive at that decision. If there is no clear evidence that physical therapy or chiropractic is preferred over the other then should this be stated directly up front?

May consider adding formal physical therapy in addition to spinal manipulation. Patients may potentially prevent recurrences and benefit by decreasing pain with early intervention and education regarding appropriate home exercises and management techniques.
Comment: On Page 21-22, regarding annotation 16, it discusses the clinical prediction rule and is given a weak recommendation due to low quality evidence. Suggest that there is consideration this be moved to the appendix region. If in a year or two from now the evidence is stronger, then it could be considered to be put back into the main body of the guideline in a future revision. The concern is that if the guideline is based upon weak recommendation due to low quality evidence is there enough support to have a guideline? The strength of the document depends on having recommendations based upon high quality evidence. The same statement could be made for the “delayed recovery risk assessment.” This is also noted to be a weak recommendation with low quality evidence. Consider this be moved to appendix region until at some future review/revision there is more evidence supporting this concept. (Midwest Spine Institute)

Thank you for your comment. The term spinal manipulative therapy includes all modalities of mobilization and manipulation. We have focused on the treatment option and not the specific practitioner choices or modality choices, including physical therapy, that are available under spinal manipulative therapy. The clinician and the patient can discuss options through shared decision-making. The work group evaluated the evidence for clinical prediction rule and delayed recovery risk assessment, and although the evidence is of low quality with weak recommendations, it is consensus of the group that this is an important strategy to consider in evaluating patients with low back pain.

28) Annotation #18, p.25 and 26: Consider adding assessment to rule out inflammatory back pain. At times it may be difficult to differentiate mechanical vs. inflammatory back pain. Axial spondyloarthritis refers to a form of spondyloarthritis in which the predominant symptom is back pain. Although this may be rare, it most commonly occurs in males < 40 years of age. Rx and prognosis is very different, so we recommend including in the initial assessment to rule out the possibility, and consider if symptoms continue to the late sub-acute phase. Information and considerations regarding inflammatory back pain could potentially be considered under the delayed recovery assessment discussion. Please see attached articles. (Marshfield Clinic)

Thank you for your comments. The work group feels this assessment is an ongoing assessment done by the practitioner. The subacute phase would be the likely time the condition is suspected. However, we have made a notation to think about this condition. See the Main Algorithm.

29) I propose that the red flags section includes another diamond with appropriate links: seronegative spondyloarthropathy. As per recent literature, the algorithm for diagnosing this has been updated and is simpler. Here are the references listed below that include straightforward algorithms for work up. But essentially the authors argue the spondyloarthropathy incidence is probably about 5% of chronic LBP patients. If the patient fits the definition of "inflammatory" back pain (4 out of 5 including age< 40, pain duration > 3 months, insidious onset, morning stiffness, improvement with exercise), then an HLA-B27 blood test is run. If that is positive, then an MRI of the pelvis with specific protocol to assess inflammation of the sacroiliac joints is ordered (garden variety "pelvis MRI scan " will not be as sensitive at picking this up. I'm a bit unsure where this might fit in the guideline given the > 3 months criteria for inflammatory back pain…? In actual red flag section (my personal choice) or in the subsequent re-evaluation section.
4. Poddenuyy et al. J Rheum 2011, 2452-60 (Mayo Clinic)

Thank you for your comments. The work group feels this is a condition that is out of the scope of this guideline and does not fall into the red flags algorithm. In addition, the practitioner, based on symptoms for each specific patient scenario, best decides specific blood tests.

30) Annotation #20, page 27: The current statement in the guideline is, “Uncommon but serious causes for back pain include infection.” “A spinal infection such as vertebral osteomyelitis or spinal epidural abscess can give chronic back pain with fever, an elevated white count, and elevated erythrocyte sedimentation rate.” Consider including CRP. In many instances of spinal infection, WBC’s will not be elevated. If the workgroup keeps elevated WBC’s, then please consider including a discussion that WBC’s may not be elevated. Please see attached article. (Marshfield Clinic) Cleveland Clinic article

Thank you for your comment. We have removed references to specific testing as the work group feels the clinician should determine appropriate diagnostic testing for each type of suspected infection.

31) In the “Red Flags Algorithm” on page 2, severe or progressive lower limb motor weakness is not listed as a red flag, which it should be. (Mayo Clinic) Bigos and Chou 2011

Thank you for your comment. Chou 2011 lists severe or progressive lower limb motor weakness as a reason for imaging, but not as a red flag. This finding would lead the examiner off into the Radicular Pain portion of the algorithm where this evaluation is discussed.

32) On pages 27 and 28, “Red Flags Algorithm Annotations,” for cancer and evaluation of fracture, evaluation should include recommendation for MRI of the spine. (Mayo Clinic)

Thank you for your comment. Evaluating for cancer and for fracture are stopping points of the algorithm. At that point, the specific care is specialized. Therefore, specific details in the evaluation for cancer are outside the scope of the guideline.

33) Annotation 27 on the top of page 28 is misleading, if not inaccurate. All patients with back pain, and especially those with sciatica, should be examined for bilateral lower limb weakness, decreased leg (really lower limb) deep tendon reflexes, and perineal numbness, not just those with urinary retention which can be a very late manifestation of cauda equina syndrome. In fact, urinary retention is an indication for emergent MRI in the patient with low back and/or lower limb pain. (Mayo Clinic)

Thank you for your comment. We agree that all patients should be examined as described. The intent of this section and annotation is to give specific direction for further evaluation of red flag symptoms. These are stopping points in the algorithm and...
would take the patient out of the care of this guideline. In following the flow of the algorithms, the patient is evaluated for these symptoms at the first visit, and if present, is taken immediately to the red flag algorithm and corresponding annotations.

34) Algorithm Box #29: Leave out “past the knee”. It should just state radicular pain diagnosed. Presentation of anterior or anterolateral thigh pain/paresthesias and groin pain may also be radicular symptoms. The knee is neither a dermatome nor is the knee a muscle group. It is a joint. We believe this only adds confusion. (Midwest Spine Institute)

Thank you for your comment. The work group agrees and has removed the wording.

35) “Radicular Pain Algorithm Annotations” #31 on page 29 states “No Imaging First Six Weeks with Radicular Pain…” This does not accurately quote the literature. The recent Chou et al recommendations state “for persistent radicular symptoms…advanced imaging should be performed after a one-month trial of therapy…”2,11 The older Bigos AHCPR also indicates a four-week interval of conservative treatment before advanced imaging is considered.1 The recommendation to wait at least six weeks is questioned. (Mayo Clinic)

Thank you for your comments. Some evidence cites four weeks and others at six weeks. Six weeks is based on evidence and work group consensus.

36) Annotation #31: Referencing paragraph with statement.... “...with this in mind, in the face of radiculopathy there is no benefit and there is possible harm.” (Chou 2011)

This is a bold statement supported by a single study with a known bias by the author. The point in algorithmic annotation #31 can be accomplished without that sentence. Our concern is with guideline recommendation based upon only one study. Regarding this annotation, it discusses a “progressive neurological deficit or a weakness that is worsening.” This could be further defined. Presumably the patient had no neurological deficit or weakness prior to the onset of his radicular symptoms, and thus by the time he is found to have a neurological deficit or a weakness that would be a change or worsening or progression. Question: At what interval(s) would the patient need to be reexamined to see if there are additional changes after a presenting neurological deficit? Would support primary care guidelines on evaluating/rating severity of neurologic deficit so appropriate referral to spine specialist may be made.

Additionally in regard to this particular annotation, the primary care provider needs to be aware that there is going to be a delay in treatment due to the time it takes to get an MRI scan performed, the information relayed back to the primary care physician, then a referral made to a spine specialist, and then finally another referral made to a spine surgeon if needed. Although mild deficits can be tolerated over quite a bit of time prior to definitive treatment, significant deficits are thought to be best treated in a timely fashion. There are no large scale studies that have sufficient numbers of patients with profound neurological deficits to make this conclusion statistically significant. These studies all had a “beta” error in their statistical analysis. (Midwest Spine Institute)
Thank you for your comments. We are unaware of the bias stated in the Chou article. Regarding progressive neurological deficits, it is up to the clinician to educate the patient on when to come back related to additional changes. It is also up to the clinician to determine that there is a progressive neurological deficit. These conditions would be out of the scope of this guideline. In regards to MRI and delay of treatment, the work group feels that imaging and follow up treatment is readily available through well set up health care systems.

37) Also on page 29, under annotation #34, the need to perform advanced imaging before an epidural injection should be included in the “Recommendations” rather than delayed to the “Patient Selection for Epidurals” section. Perhaps the first bullet under “Recommendations” on page 29 could be amended to read, “Imaging MUST be OBTAINED to rule out underlying pathology for those patients who are considering surgery or epidural steroid injection.” Patients cannot have surgery or an epidural steroid injection without an advanced imaging study. (Mayo Clinic)

Thank you for your comment. We have changed the wording from “may consider” to “should be done” and have added epidural steroid injections as a condition for imaging.

38) Algorithm Box #34 Would suggest consideration of referral to spine specialist and consideration of HT/advanced imaging for patient with severe radicular pain >2 weeks or after 6 weeks of radicular pain if no improvement with core treatment plan. (Midwest Spine Institute)

Thank you for your comment. Based on evidence, imaging is not recommended for non-specific low back pain regardless of the duration. In addition, the data does not support the use of plain films in adding additional value to diagnosis or treatment. Imaging is not recommended in the first six weeks of radicular pain as it is not supported by evidence.

39) Box 34 on page 3 states “…discussing options of imaging, epidurals or continuing a core treatment plan” is misleading. Imaging is required prior to an epidural injection. The sentence should read “…imaging, epidural injection preceded by imaging, or continuing a core treatment plan.” Annotation 34 on page 29 should also clarify the requirement that patients undergo advanced imaging before an epidural injection can be offered. (Mayo Clinic)

Thank you for your comment. Box 34 text lists imaging prior to epidural. More specific information on the use of imaging prior to epidural is presented under “patient selection for epidurals.”

40) At the top of page 31, the two paragraphs after the hyphen are confusing. They currently read, “No history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogrel.” and beneath that “Allow the patient to “drift” to the lowest effective international normalized ratio (INR), prior to the procedure. Consult with the individual performing the procedure for appropriate anticoagulation guidelines.” Are patients on warfarin or clopidogrel prohibited from having epidural steroid injection? I think not. I presume that the second paragraph refers to patients who are on warfarin. I believe there is a risk of spinal epidural hematoma if patients on warfarin are maintained at the “lowest
effective international normalized ratio (INR)” prior to epidural steroid injection. I believe that their INR should be close to normal before undergoing this procedure. I believe the patients on clopidogrel should stop the medication for one week before undergoing an epidural steroid injection, if acceptable from a cardiac viewpoint. Patients who are currently taking clopidogrel should not undergo spinal epidural injection. Resumption of warfarin or clopidogrel after the injection might be mentioned and depends, in part, on the underlying medical condition for which they are receiving the blood-thinning medication. (Mayo Clinic)

Thank you for your comment. We have modified the verbiage in this annotation as follows: “Epidural injections carry a higher risk of bleeding. Patients taking antithrombotics have an increased risk and the standard protocols for these patients should be followed. Guidelines have been developed to limit the risk. Assessment of the risk versus benefit needs to be done prior to the procedure.”

41) Annotation #34: Would suggest consideration of additional literature review related to efficacy by approach (caudal, interlaminar, transfemoral) ESI for LBP. References: See attached studies/articles (Midwest Spine Institute)

Thank you for your comment. The work group has reviewed the different approaches related to epidural steroid injection. This guideline is for the primary care clinician, therefore, we have determined that the approach is up to the radiologist providing the service and is beyond the scope of this guideline.

42) On pages 32 and 33, Annotation #34 indications for referral to a medical spine specialist should also include severe or progressive lower limb weakness. Referral to a surgical spine specialist for “cauda equina syndrome” needs to be done emergently, and this should be stipulated. The last two references in this section are very old (18 and 25 years). (Mayo Clinic)

Thank you for your comment. Chou 2011 lists severe or progressive lower limb motor weakness as a reason for imaging, but not as a red flag. This finding would lead the examiner off into the Radicular Pain portion of the algorithm where this evaluation is discussed.

43) Indications for specialty referral, top of page 33: 1st dot point: Remove the dot point from medical spine specialist. This should be the heading. (Marshfield Clinic)

Thank you for your comment. We have removed the bullet point “medical spine specialist.”

44) Appendix B – On pages 68 and 69 the title of the appendix is the Roland-Morris Disability Questionnaire, but the information relates to MRI imaging. Does this information belong with appendix G? (Marshfield Clinic)

Thank you for your comment. This information regarding MRI imaging has been removed.
45) Appendix C - seems to be out of place. It is mixed in with the assessment/screening tools. It would be more appropriately placed either before the assessment tools or after. (Marshfield Clinic)

Thank you for your comment. Our appendices are listed in the order they are referenced within the guideline and not by order of relevance or topic.

46) Appendix C on page 70, I disagree with the statement that “Acute radiculopathy is low back pain that also lasts for six weeks or less, but the pain extends below the knees.” First, it should be “knee,” but more importantly, radicular pain need not radiate below the knee. This is true for some L5 and S1 radiculopathies and characteristically true of L2, L3, and L4 radiculopathies. While typically true, the old adage that pain must go below the knee to be radicular is ridiculous. Incidentally, acute lumbosacral radiculopathy need not be accompanied by low back pain. (Mayo Clinic)

Thank you for your comment. We certainly appreciate your concern regarding the use of the term Acute Radiculopathy and how it is defined. So while it is true that one can have radicular pain involving these levels that occur above the knee, there has been no literature to guide this type of subgrouping. In addition, this is a term included in the patient education tool and has been simplified for use by the patient.

47) In Appendix G and Appendix H on pages 83 through 85, there is extensive referencing of “open upright” MRI. The inclusion of this information is inappropriate as it relates to the routine investigation of low back pain with or without radiculopathy. Upright MRI has been advocated for patients with lumbar spinal stenosis but not for severe claustrophobia, poor patient fit, or patients who cannot lie flat because of severe pain. The additional comments about axial loading also pertain to lumbar spinal stenosis or spondylolisthesis and not low back pain with radiculopathy. Most of the references listed are more than 10 years old, and most refer to lumbar spinal stenosis, not acute lumbar radiculopathy. Open upright MRI is not mentioned in the recent Chou et al article, “Diagnostic Imaging for Low Back Pain: Advice for High-Value Health Care from the American College of Physicians.” Pages 83 through 85 should be stricken. Am I correct that there was no radiologist on the workgroup for this Guideline? (Mayo Clinic)

Thank you for your comments. We have removed the appendix on Open Upright MRI and have reduced the statement in Appendix G.

48) Appendix G: Some information you may find interesting and might want to consider adding to appendix G. Virginia Mason in Seattle has an approach that has saved employers significant amounts of time and money in the care of back pain. With a large national employer, Virginia Mason conducted a Back Pain Collaborative that analyzed the care for patients seeking treatment of back pain. A key finding was that overutilization of MRIs for back pain treatment accounted for a substantial proportion of unnecessary costs for employers - at about $1,000 per test. Interestingly, medical evidence indicates that an MRI of the spine is generally indicated for a short list of conditions, including trauma, weakness, onset of bowel or bladder dysfunction, evidence of systemic illness or unremitting pain. With none of these conditions present, an MRI is unlikely to help.
In the Back Pain Collaborative, what was identified as medically helpful to patients is same-day Physical Therapy. A model was designed that provided same-day access for a combined appointment with both a physical therapist and a physical medicine physician. Those patients who do require emergency or complex care have prompt access to advanced imaging, neurosurgery consultation, and rehabilitation and pain specialists. Unnecessary MRIs were avoided by designing a system that required evidence-based indicators to schedule the test.

Results of the Collaborative included:
- Elimination of 23 percent of all MRIs of the lower back
- Increase in same-day access with patients seen promptly and returning to work quickly
- Very high patient satisfaction scores
- Greater reduction in pain, greater improvement in function and greater perceived improvement - with fewer MRIs and less physical therapy
- Reduced cost to purchasers for uncomplicated back pain

For more information: http://www.virginiamasoninstitute.org/back-pain-collaborative#ixzz1syFHVd49 (Marshfield Clinic)

Thank you for your comments. Regarding the use of MRI’s, the work group and guideline support the judicious use of advanced imaging including MRI. With regards to the information from the Virginia Mason Institute’s Back Pain Collaborative, the work group has reviewed this information, however, we would not make an endorsement in this evidence based guideline.

PRIORITY AIMS AND SUGGESTED MEASURES:

49) For measurement rates, ICSI often uses a “low is better” scale, which can be somewhat confusing. We recommend that the “higher rate” be used consistently to indicate the desired outcome. Sometimes a guideline has both a “lower is better” and “higher is better” for separate measurements in the same guideline. (HealthPartners)

Thank you for your comment. We will take this into consideration as we continue to look at the formatting of our measures.

50) On page 36, “opiates” should be “opioids.” (Mayo Clinic)

Thank you for your comment. This has been corrected.

51) Aims & Measures #5a-pg.46: Improvement is noted as a decrease in the rate. If the measure where the inverse, a higher rate would be viewed as better. (HealthPartners)

Thank you for your comment. We will take this into consideration as we continue to look at measurements.

SUPPORT FOR IMPLEMENTATION:
None