

Low back pain and sciatica

Consultation on draft guideline – deadline for comments **5pm on 5 May 2016** email: LBPUpdate@nice.org.uk

				<p>Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.</p> <p>We would like to hear your views on these questions:</p> <ol style="list-style-type: none"> 1. Do any recommendations represent a substantial increase in costs, and do you consider that the reasons given in the guideline are sufficient to justify this? 2. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) <p>See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.</p>
Stakeholder organisation(s) (or your name if you are commenting as an individual):				<u>Spine Intervention Society</u>
Name of commentator (leave blank if you are commenting as an individual):				<u>John MacVicar, MB ChB, SIS President</u>
Comment number	Document (full version1, full version 2 short version or the appendices)	Page number Or 'general' for comments on the whole document	Line number Or 'general' for comments on the whole document	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	Full	General	General	Evidence Base: The authors did not clearly define study inclusion criteria. Some, but not all, studies aimed at treating facet related pain were included as pertaining to the non-specific low back pain category. High quality observational studies were omitted

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				that would have shed light on the effectiveness of the different treatment options. The exclusion of high quality observational studies of clinical effectiveness removes important information and context from a synthesis of the literature. While some may argue that there are ample randomized controlled trials (RCTs) for analysis, and examination of observational trials is unnecessary, many of the RCTs included patients selected only by symptoms or failure to utilize image guidance. These failings make such trials irrelevant to current clinical practice and not unexpectedly show poor outcomes. Judging current practice of precise needle placement to a 1 - 2mm target zone in three dimensional space with confirmation of medication distribution by real-time observation of contrast flow by using data from blind injections into an unknown tissue compartment has no validity. There are very few RCTs that utilize current practice standards. Hence, examination of current large observational studies adds important information that is relevant to current standards of practice.
2	Full	General	General	<p>Terminology – Sciatica:</p> <p>As explained on Page 18, line 9, the term “sciatica” is in common use: “Sciatica’ is a term that patients and clinicians understand and one that is used widely in the literature to describe neuropathic leg pain secondary to compressive spinal pathology.”</p> <p>The problem is that radicular pain may be caused by nerve root irritation, and not compression. Besides, quite often the nature of leg pain that accompanies back pain is somatic referred (non-radicular). There should be some explanation/discussion about the distinctions between radicular pain, somatic referred pain, and radiculopathy. It's not just semantics; the diagnostic and therapeutic options differ for each entity.</p>
3	Full	General	General	<p>Diagnosis of Non-Specific Low Back Pain:</p> <p>It is imperative that the guideline promote identification of a proper diagnosis. The term Non-specific Low Back Pain (LBP) implies that it is impossible to diagnose a specific etiology of this condition, which in turn may restrict the ability to treat LBP, depending on its origin. This term is an old misconception that was utterly disproved by a plethora of studies showing that in the majority of cases, the source of LBP (i.e. facet joints, intervertebral discs, SI joints) can be diagnosed.</p> <p>References:</p> <ol style="list-style-type: none"> Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. Spine 1995;20:1878–83. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine (Phila Pa 1976). 1995 Jan 1;20(1):31-7. Maigne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine (Phila Pa 1976). 1996 Aug 15;21(16):1889-92.

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				<ol style="list-style-type: none"> 4. Schwarzer AC1, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine (Phila Pa 1976). 1994 May 15;19(10):1132-7. 5. Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: an evaluation of prevalence and false-positive rate of diagnostic blocks. J Spinal Disord Tech. 2007 Oct;20(7):539-45 6. Schwarzer AC1, Wang SC, Bogduk N, McNaught PJ, Laurent R. Prevalence and clinical features of lumbar zygapophysial joint pain: a study in an Australian population with chronic low back pain. Ann Rheum Dis. 1995 Feb;54(2):100-6. 7. Laslett M1, McDonald B, Aprill CN, Tropp H, Oberg B. Clinical predictors of screening lumbar zygapophysial joint blocks: development of clinical prediction rules. Spine J. 2006 Jul-Aug;6(4):370-9. 8. DePalma MJ1, Ketchum JM, Saullo TR. Multivariable analyses of the relationships between age, gender, and body mass index and the source of chronic low back pain. Pain Med. 2012 Apr;13(4):498-506. 9. Katz V, Schofferman J, Reynolds J. The sacroiliac joint: a potential cause of pain after lumbar fusion to the sacrum. J Spinal Disord Tech. 2003 Feb;16(1):96-9. 10. Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. Eur Spine J. 2005 Sep;14(7):654-8. Epub 2005 Mar 11. 11. DePalma MJ1, Ketchum JM, Saullo TR. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011 May;12(5):732-9 12. Depalma MJ, Ketchum JM, Trussell BS, Saullo TR, Slipman CW. Does the location of low back pain predict its source? PM R. 2011 Jan;3(1):33-9 13. Laslett M, Oberg B, Aprill CN, McDonald B. Centralization as a predictor of provocation discography results in chronic low back pain, and the influence of disability and distress on diagnostic power. Spine J. 2005 Jul-Aug;5(4):370-80. 14. Hancock MJ, Maher CG, Latimer J, Spindler MF, McAuley JH, Laslett M, Bogduk N. Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain. Eur Spine J. 2007 Oct;16(10):1539-50. 15. Laslett M, Aprill CN, McDonald B, Young SB. Diagnosis of sacroiliac joint pain: validity of individual provocation tests and composites of tests. Man Ther. 2005 Aug;10(3):207-18.
4	Full	General	General	<p>Diagnosis of Non-Specific Low Back Pain: “Non-specific low back pain” presents a symptom, not a diagnosis. A good comparison would be an example of “cough” as a symptom. The actual diagnosis can vary from bronchitis to lung cancer, but both can present with cough, and the treatment approaches for those two conditions would substantially differ. “Non-specific low back pain” should</p>

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				be reserved for patients for whom every effort has been made to identify the pain generator and define the proper diagnosis. Low back pain is not non-specific until appropriate diagnostic testing has been employed and has failed to yield a diagnosis.
5	Full	General	General	Inadequate Subgroup Analysis: Stratification of studies according to their technical approach and quality of evidence has not been done. Different types of treatments (e.g. caudal, interlaminar, and transforaminal epidural steroid injections) have been lumped into a category despite the fact that their technical approach may influence outcomes as supported in literature.
6	Full	General	General	Exclusion of Sacroiliac Joint Pain: It is unclear why sacroiliac joint pain has been excluded. It is a well-proven, common cause of low back pain. Investigation of the sacroiliac joint should be included in the algorithm, when there has been an inadequate response to conservative treatment. The data have already been reviewed, and the effectiveness of sacroiliac joint injections was confirmed with a number needed to treat (NNT) of 2 for 50% pain relief. Reference: Kennedy DJ, Engel A, Kreiner DS, Nampiaparampil D, Duszynski B, MacVicar J. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. <i>Pain Med.</i> 2015 Aug;16(8):1500-18.
7	Full (Non-Invasive)	15	Algorithm	The algorithm suggests that patients with acute low back pain and radiculopathy should go through a very conservative pathway (e.g. group exercise, psychological therapies) before considering epidural steroid injections (ESIs). As a matter of fact, the best indication for ESIs based on current evidence is acute radicular pain, and these injections should be considered before psychological therapies in acute radicular pain cases, in hopes of preventing costly surgical interventions and use of other healthcare resources. Reference: Rathmell JP. The proper role for epidural injection of corticosteroids. <i>Anesthesiology.</i> 2014;121(5):919-21.
8	Full (Non-Invasive)	15	Algorithm	A major flaw is that leaving box B does not consider discogenic pain or sacroiliac joint pain. It only considers lumbar facet pain- one of the least common sources of axial pain- and “non-specific low back pain”. This is in keeping with one of the key recommendations: Do not offer injections for non-specific low back pain. If there is an inadequate response to treatment in box B, then there should be consideration of diagnostic modalities aimed at determining a pain generator, with a selection based on likely etiology. The guideline authors should consider low back pain to be non-specific only if a thorough investigation fails to reveal its cause. Reference:

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				Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.
9	Full (Non-Invasive)	15	Algorithm	<p>The American College of Radiology, American Pain Society, and American College of Physicians have developed evidence-based recommendations for the use of imaging in spine pain patients. (1-3) These recommendations are based on risk stratification regarding the likelihood of underlying systemic disease as the cause of the patient’s back or limb pain. This stratification is based on signs, symptoms, and historical features (red flag features) which identify risk of neoplasm, infection, traumatic injury or inflammatory spondyloarthropathy. The draft guideline acknowledges this (page 150) but chooses to purposely avoid the discussion. This is to dismiss the crux of the matter. One can include this implicitly, perhaps, in the “will it change management “ rubric, but is a disservice to the reading physicians not to provide this established guidance from the literature.</p> <p>Once the criteria for imaging are met, then the utility of imaging in planning subsequent interventional procedures is paramount. Image-guided spinal interventions must be directed toward specific anatomic targets deemed likely pain generators; this is not possible without pre-intervention imaging.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Davis PC, Wippold FJ II, Brunberg JA, et al. ACR appropriateness criteria on low back pain. J Am Coll Radiol 2009;6:401–7. 2. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007;147:478–91 3. Chou R, Qaseem A, Owens DK, et al. Diagnostic imaging for low back pain: advice for high-value health care from the American College of Physicians. Ann Intern Med 2011;154:181–9.
10	Full (Non-Invasive)	15	Algorithm	Epidural steroid injections in patients with sciatica should only be performed after adequate imaging of the lumbosacral spine is obtained via magnetic resonance imaging (MRI) or computed tomography (CT). In addition to ruling out other causes, imaging can better localize the site of pathology so that a targeted epidural steroid injection can be performed. A rare but serious complication can be avoided if imaging is performed before epidural injections in cases when spinal tumors (e.g. ependymoma), or spinal hematoma are a cause of the patient’s pain. In addition, epidural steroid injections should only be performed with image guidance, as widely documented in literature. This is not addressed in the algorithm.
11	Full (Non-Invasive)	15	Algorithm	Surgical decompression should be performed only if mechanical compression of a nerve root by a large disc herniation is proven to be the cause of this pain. Several authors reported significantly worse outcomes after discectomy in those with small, contained disc herniations, and some even excluded from surgical consideration patients with small sized

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				<p>lumbar disc herniations. This recommendation should also caution that surgical results are better if performed within 6 months, as per North American Spine Society guidelines.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Carragee EJ, Han MY, Suen PW, Kim D. Clinical outcomes after lumbar discectomy for sciatica: The effects of fragment type and anular competence. <i>J Bone Joint Surg Am</i> 2003;85(1):102–8. 2. Dewing CB, Provencher MT, Riffenburgh RH, Kerr S, Manos RE. The outcomes of lumbar microdiscectomy in a young, active population: Correlation by herniation type and level. <i>Spine (Phila Pa 1976)</i> 2008;33(1):33–8. 3. Folman Y, Shabat S, Catz A, Gepstein R. Late results of surgery for herniated lumbar disk as related to duration of preoperative symptoms and type of herniation. <i>Surg Neurol</i> 2008;70(4):398–401. 4. Mysliwiec LW, Cholewicki J, Winkelpleck MD, Eis GP. MSU classification for herniated lumbar discs on MRI: Toward developing objective criteria for surgical selection. <i>Eur Spine J</i> 2010;19(7):1087–93. 5. North American Spine Society (NASS). Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. Burr Ridge (IL): North American Spine Society (NASS); 2012.
12	Full (Non-Invasive)	15	Algorithm	<p>In terms of therapeutic non-invasive modalities, the authors have stripped therapy down to manipulation and exercise therapy. They recommend against traction, ultrasound, transcutaneous electrical nerve stimulation (TENS), and acupuncture. While these modalities do not change long-term outcome, they are palliative and one must remember that initial back pain therapy “is” palliative therapy in many cases.</p>
13	Full (Non-Invasive)	15	Algorithm	<p>The guidelines make pharmacological recommendations. We agree with using the lowest effective dosage of non-steroidal anti-inflammatories. The guidelines recommend “weak” opioids if non-steroidal anti-inflammatory drugs (NSAIDs) are contraindicated. The guidelines then recommend against selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and anti-convulsants. While the evidence for the use of other medications is not convincing, strong evidence supporting opioid use to treat chronic pain lasting > 3 months is lacking. Offering only an opioid alternative may propagate further expansion of opioid use that has already resulted in accidental overdoses and deaths resulting in an opioid crisis of enormous proportions over the last two decades. In fact, the U.S. Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids emphasize that, “of primary importance, nonopioid therapy is preferred for treatment of chronic pain.” (http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm) Physicians need options, and patients require effective treatment with safe therapeutic indices. The guidelines include psychotherapy in their algorithm, but discount the use of other medications for treating pain. Anticonvulsants like gabapentin and pregabalin are known to be very effective in the treatment of sciatica. Cymbalta is an SNRI shown to be effective in the treatment of musculoskeletal pain. These drugs are opioid alternatives with acceptable therapeutic indices,</p>

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				<p>References:</p> <ol style="list-style-type: none"> 1. McCleane GJ. Does gabapentin have an analgesic effect on background, movement and referred pain? A randomized, double-blind, placebo controlled study. <i>Pain Clinic</i> 2001;13:103-7. 2. Yildirim K, Sisecioglu M, Karatay S, et al. The effectiveness of gabapentin in patients with chronic radiculopathy. <i>Pain Clinic</i> 2003;15:213-8. 3. Romano CL, Romanò D, Bonora C, et al Pregabalin, celecoxib, and their combination for treatment of chronic low-back pain. <i>J Orthopaed Traumatol</i> 2009;10(4):185-91. 4. Baron R, Martin-Mola E, Müller M, et al. Effectiveness and safety of tapentadol prolonged release (PR) versus a combination of tapentadol PR and pregabalin for the management of severe, chronic low back pain with a neuropathic component: a randomized, double-blind, phase 3b study. <i>Pain Pract</i> 2014;10.1111/papr.12200 5. Baron R, Freynhagen R, Tölle TR, et al; A0081007 Investigators. The efficacy and safety of pregabalin in the treatment of neuropathic pain associated with chronic lumbosacral radiculopathy. <i>Pain</i> 2010;150:420-7.
14	Full (Non-Invasive)	16	8	The guideline states, "explain to people with low back pain with or without sciatica that if they are being referred for a specialist opinion, they may not need imaging" but at the same time suggests to "consider imaging in a specialist care setting for people with low back pain with or without sciatica only if the result is likely to change management". This approach may produce negative patient bias towards specialists.
15	Full (Invasive)	11	30-31	Authors are evaluating "what is the clinical and cost effectiveness of spinal injections in the management of non-specific low back pain". As stated above, the entity "non-specific low back pain" presents a symptom, not a diagnosis.
16	Full (Invasive)	11	28-29	In the introduction to the review section, the authors note that, "The GDG agreed that the main uncertainty ...was the effectiveness of various agents, rather than the route or mode of administration." As a result, no consideration is given to the proper diagnosis of the low back condition prior to assessing an intervention for that particular condition. In essence, as previously mentioned, the review lumps all forms of back pain (except lumbar facet pain) in one basket, and assesses their treatments together by considering manuscripts that have not identified a specific etiology of the LBP. Since many different etiologies may account for "non-specific low back pain" obviously there is substantial, unaccounted heterogeneity. There was also heterogeneity in the procedures performed for non-specific etiologies: intra-articular facet injections, peri-capsular injections, peri-facet injections, intra-discal injections, nerve blocks, caudal epidurals, interlaminar epidurals, EMG-guided trigger point injections, spinal ligament injections, spinal ligament injections and non-image guided paraspinal injections. The SIS guidelines adequately describe evidence-based methodologies for stratifying low back pain patients based on etiology. Stratification based on cause then allows a meaningful analysis of various types of treatment. The authors would find that quality evidence based data already exists in this realm. The flaws in this analysis render the authors' conclusions equally flawed.

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				Reference: Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.
17	Full (Invasive)	42	12	Two Manchikanti references are given with respect to prevalence of facet joint pain. The first (98) is a study of adhesiolysis and seems to be included here in error. Manchikanti L, Pampati V, Bakhit CE, Pakanati RR. Non-endoscopic and endoscopic adhesiolysis in post lumbar laminectomy syndrome: a one-year outcome study and cost effectiveness analysis. Pain Physician. 1999; 2(3):52-58
18	Full (Invasive)	42	12	The prevalence of 25-40% quoted from Manchikanti is higher than that from other studies, particularly for younger people. We recommend reviewing and revising this per the findings of Schwarzer and DePalma. These studies suggest a prevalence of facet joint pain in younger people of 10-15%, and Schwarzer's data, in particular, are likely to be an overestimate, as a criterion of 50% relief from a single block was used. References: 1. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine 1994;19:1132-1137. 2. DePalma MJ, Ketchum JM, Saullo TR. Multivariable Analyses of the Relationships Between Age, Gender, and Body Mass Index and the Source of Chronic Low Back Pain. Pain Medicine 2012; 13: 498–506.
19	Full (Invasive)	43 and Appendix D (p. 63)	Table	Regarding study inclusion criteria for radiofrequency denervation, the guideline stipulates, "RCTs and SRs will be included in the first instance. If insufficient RCT evidence to form a recommendation is found, non-randomised studies will be included." The critical analysis of all of the quoted studies (with the exception of a more recent one by Civilek) was provided by Bogduk et al. (2009). The Civilek study, which wasn't included in the Bogduk et al. appraisal, has a number of flaws but most importantly, the technique itself appears to be invalid. Civilek's supplied images seem to indicate that the needle was placed in an anteroposterior (AP) view onto the superior articular process along a portion of the course of the nerve. Because the lateral view was not obtained, the needle tip could therefore lie on the nerve but is as likely to still be on the SAP. At best, this would create a pinpoint lesion of 1-2 mm, resulting in a short-term response. The radiofrequency (RF) technique is too poor to justify further analysis of the study. The controlled trials are sufficient to demonstrate efficacy, but not to optimize the technique. It is imperative to review high quality prospective studies that implement appropriate technique (e.g. Dreyfuss 2000, MacVicar 2013). The best practices document from the British Pain Society in the reference list refers to the SIS Guidelines as the correct methodology for both medial branch blocks and radiofrequency neurotomy.

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				<p>References:</p> <ol style="list-style-type: none"> 1. Bogduk, Nikolai, Paul Dreyfuss, and Jayantilal Govind. "A Narrative Review of Lumbar Medial Branch Neurotomy for the Treatment of Back Pain: Narrative Review of Lumbar Medial Branch Neurotomy." <i>Pain Medicine</i> 2009; 10(6): 1035–45.. 2. MacVicar, John, James M Borowczyk, Anne M MacVicar, Brigid M Loughnan, and Nikolai Bogduk. "Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand." <i>Pain Medicine</i> 2013; 14(5): 639–45. 3. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. <i>Spine (Phila Pa 1976)</i>. 2000 May 15;25(10):1270-7. 4. "mbb_2013_-_FINAL.pdf." Accessed April 25, 2016. https://www.britishpainsociety.org/static/uploads/resources/files/mbb_2013_-_FINAL.pdf.
20	Full (Invasive)	59	Table	<p>"Only do radiofrequency denervation after a positive response to a diagnostic medial branch block for people with chronic non-specific low back pain with suspected facet joint pain."</p> <p>We are pleased to see support for radiofrequency denervation, but have concerns about a relying on results of a single positive response to a diagnostic lumbar medial branch block. Single medial branch blocks have a credibility of 50% when 100% relief is considered a positive response. (Engel 2016)</p> <p>The combination of the low prevalence of the condition and the known risk of false positive responses to medial branch blocks means that a single block will identify far too many patients who do not have the condition as appropriate for treatment. Giving physicians permission to treat people who have had a response to a single block will result in a large number of failed treatments, and harm the reputation of the procedure. RF should only be recommended when there have been positive responses to two sets of medial branch blocks. The criterion for a positive response to medial branch blocks should be 80-100% relief of the index pain.</p> <p>Reference: Engel AJ, Bogduk N. Mathematical Validation and Credibility of Diagnostic Blocks for Spinal Pain. <i>Pain Med</i>. 2016 Mar 19. pii: pnw020. [Epub ahead of print]</p>
21	Full (Invasive)	64-65	Table	<p>Regarding longer-term outcomes, MacVicar has clearly shown exceptional durability of response from this procedure. If the placebo rate from lumbar and cervical medial branch blocks is the same, the NNT for complete relief is 3. We recommend a controlled trial using the optimal technique and selection criteria as described in the SIS guidelines and implemented by MacVicar, 2013.</p> <p>References:</p>

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				<ol style="list-style-type: none"> 1. Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013. 2. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. Pain Med. 2013 May;14(5):639-45.
22	Full (Invasive)	55	15-17	<p>"The probability of a positive response to the diagnostic block was based on a study included in the clinical review. Due to a lack of data, all other probability data in the model were based on GDG opinion". The algorithm used to diagnose facet pain failed to include several high quality studies addressing the validity of diagnostic blocks and made recommendations based on one study and biased opinions.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Kaplan M, Dreyfuss P, Halbrook B, Bogduk N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. A physiologic challenge. Spine 1998;23:1847–52. 2. Schwarzer AC, Aprill, CN, Derby R, et al. The falsepositive rate of uncontrolled diagnostic blocks of the lumbar zygapophysial joints. Pain 1994;58:195–200. 3. Manchikanti L, Pampati V, Fellows B, Bakhit CE. The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or without adjuvant agents. Curr Rev Pain 2000;4:337–44. 4. Bogduk N, Holmes S. Controlled zygapophysial joint blocks: The travesty of cost-effectiveness. Pain Med 2000;1:24–34.
23	Full (Invasive)	55	20-36	<p>The patients in the sham arm had already had usual care. Therefore, adding the sham placebo effect to the baseline to simulate the effect of usual care does not make sense. The effectiveness of the RF neurotomy should be compared to the baseline scores as stated in lines 23-24. The GDG notes on page 63 that the patients studied had pain from between 3-5 years. It is unlikely that spontaneous remission would occur in this group, and no citation is provided to justify this supposition. In addition, the cost analysis control group was given the placebo effect but no cost associated with it. Comparing RF to baseline would provide an improved cost efficiency factor.</p>
24	Full (Invasive)	67	1-30	<p>Stratification of studies according to their technical approach and quality of evidence was not adequately addressed. Caudal, interlaminar, and transforaminal epidural steroid injections were all lumped in a same category despite the fact that their technical approach may influence outcomes as supported in literature.</p>
25	Full (Invasive)	120	Table	<p>"Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis." If patients have central canal stenosis with neurogenic claudication, and ESIs are being considered for treatment of neurogenic claudication for the established diagnosis, the recommendation does not pertain to non-specific LBP.</p>
26	Full (Invasive)	120	Table	<p>The authors recommend ESI and local anesthetic in patients with acute sciatica. They recommend against the use of ESI in neurogenic claudication and central stenosis. When one reviews the evidence, 2 papers are excluded for risk of</p>

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				<p>bias. It is unclear if the analysis includes 2 or 3 papers. These papers are not cited, disallowing an independent review of the results. The authors thus deprive patients with stenosis, a condition known to be poorly responsive to conservative care, of any alternative but surgery (surgery for stenosis was not assessed in the guidelines).</p>
27	Full (Invasive)	123	Table	<p>Research Recommendations:</p> <p>“There is a rationale that transforaminal epidurals might be most effective, by ensuring delivery of corticosteroids directly to the region in which the nerve root might be compromised. However, transforaminal epidural injection requires imaging, usually within a specialist setting, potentially limiting treatment access and increasing costs. Caudal epidural injection might be undertaken without imaging, or with ultrasound guidance in a non-specialist setting, but, it has been argued, the drug might not reach the affected nerve root and therefore this approach might not be as effective as would be transforaminal injection. Empirical evidence that 1 approach is clearly superior to the other is currently lacking. Access to the two procedures varies between healthcare providers, and people who do not respond to caudal corticosteroid injection might subsequently receive image guided epidural injection. People with sciatica might therefore currently experience unnecessary symptoms at unnecessary cost to the NHS than would be the case if the most cost effective modes of delivering epidural corticosteroid injections were used.”</p> <p>The techniques utilized in the administration of epidural steroids are also critical. No randomized studies examined the use of image guidance as a variable. This has, however, been well examined in non-randomized studies demonstrating that up to 74% of “epidural” steroid injections performed without image guidance either deposit medication external to the epidural space or do not reach the targeted pathology within the ventral epidural space. (1-4).</p> <ol style="list-style-type: none"> 1. Fredman B, Nun MB, Zohar E, Iraqi G, Shapiro M, Gepstein R, Jedeikin R. Epidural steroids for treating "failed back surgery syndrome": is fluoroscopy really necessary? <i>Anesth Analg</i> 1999; 88 (2): 367-72. 2. Bartynski WS, Grahovac SZ, Rothfus WE. Incorrect needle position during lumbar epidural steroid administration: inaccuracy of loss of air pressure resistance and requirement of fluoroscopy and epidurography during needle insertion. <i>AJNR Am J Neuroradiol</i> 2005; 26 (3): 502-5. 3. Botwin KP, Natalicchio J, Hanna A. Fluoroscopic guided lumbar interlaminar epidural injections: a prospective evaluation of epidurography contrast patterns and anatomical review of the epidural space. <i>Pain Physician</i> 2004; 7 (1): 77-80. 4. Weil L, Frauwirth NH, Amirdelfan K, Grant D, Rosenberg JA. Fluoroscopic analysis of lumbar epidural contrast spread after lumbar interlaminar injection. <i>Arch Phys Med Rehabil</i> 2008; 89 (3): 413-6.

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				<p>Data from explanatory trials of non-image guided injections yields a number needed to treat (NNT) greater than 90. (5-9) In contrast, a high quality explanatory trial of image-guided transforaminal injection of steroids yields a NNT of 3. (10)</p> <ol style="list-style-type: none"> 5. Dilke TF, Burry HC, Grahame R. Extradural corticosteroid injection in management of lumbar nerve root compression. Br Med J. 1973 Jun 16;2(5867):635-7. 6. Carette S, Leclaire R, Marcoux S, et al. Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus. N Engl J Med. 1997 Jun 5;336(23):1634-40. 7. Breivik H, Helsa PE, Mohar I, Lind B. Treatment of chronic low back pain and sciatica: comparison of caudal epidural injections of bupivacaine and methylprednisolone with bupivacaine followed by saline. In: Bonica JJ, Albe-Fessard D, editors Advances in pain research and therapy. New York: Raven press; 1976.pp. 927-932. 8. Bush K, Hillier S. A controlled study of caudal epidural injections of triamcinolone plus procaine for the management of intractable sciatica. Spine (Phila Pa 1976). 1991 May;16(5):572-5. 9. Valat JP, Giraudeau B, Rozenberg S, et al. Epidural corticosteroid injections for sciatica: a randomised, double blind, controlled clinical trial. Ann Rheum Dis. 2003 Jul;62(7):639-43. 10. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. Pain Med 2010; 11 (8): 1149-68. <p>It is the position of the Spine Intervention Society that image guidance is absolutely essential for the safe and efficacious performance of epidural procedures, based on a large body of non-RCT evidence.</p>
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