

National Institute for Health and Clinical Excellence

Low Back Pain Stakeholder Comments

1. Please put each new comment in a new row.
2. Please do not paste other tables into this table, as your comments could get lost – type directly into this table.
3. Please fill in the document you are commenting on in the first column, for example, the **Full version**, or the **Appendices to full version**
4. Please insert the **Page number (given at the bottom of the page)** in the 2nd column and the **Line Number** (given at the far left of the document). If your comment relates to the document as a whole, please put **'general'** in this column. **Please refer page numbers not section numbers.**

Name:		John Goddard		
Organisation:		British Pain Society		
Order Number	Document.	Page Number	Line Number	Comments
Please number your comments if making more than one	Please indicate which version you are referring to: Full/NICE/Appendices.	Indicate Page number or 'general' if your comment relates to the whole document. Please do not include any non-numerical text (eg the word 'page') in these boxes unless comment is general.	When commenting on the full version Indicate the line number . Please do not include any non-numerical text (eg the word 'line') in these boxes	Please insert each new comment in a new row.
1	Both	General		Comments are addressed to the Full guideline, but are applicable to the NICE guideline where relevant.
2	Both	General		The title of the guideline is confusing. It uses terminology which is not well defined and identifies only part of the scope. The use of the term "acute" is particularly confusing in this context. The 12 month cut-off, acknowledged in the guideline, should be apparent in the title, along with the 6 week start. A suggested title is "Low back pain: the management of patients with non-specific low back pain of 6 weeks to 12 months duration".
3	Full	14	17	We acknowledge the difficulty in accurately defining cohorts of patients. This problem is also acknowledged in the guideline; page 15, line 9. Nonetheless, a more precise explanation should be given as to which groups of patients are included in the guideline. Is the guideline applicable to a first episode of low back pain only? We suspect it is intended to

				include recurrent episodes of low back pain lasting longer than six weeks. We understand that it does not cover exacerbations of low back pain in patients with long-term severe disabling low back pain.
4	Full	General		<p>Overall, we welcome this guideline and agree with the underlying principles of encouraging activity, exercise and self-management in a context of appropriately prescribed analgesia. We support early interventions at a six week timeline, although we consider the evidence for manipulation to be weak. We also strongly support the early consideration of combined physical and psychological interventions: we would call these pain management programmes and have published guidelines, which include recommendations on the personnel required to deliver these programmes (1).</p> <p>Our main concerns are with regard to the pathway of care in the sub-group of individuals who do not respond well to these measures.</p> <p>We wish to provide comment in this area, raise concerns with the methodology, and highlight other points where we believe the draft recommendations should be amended.</p> <p>1. Recommended guidelines for pain management programmes for adults. British Pain Society 2006, London.</p>
5	Full	42 47	3 1	<p>We acknowledge the difficulties in producing evidence based guidelines when evidence is not of high quality. However, there are well accepted tools, one of which is included in the NICE guidelines manual; Table 1, page 46, line 1. Full use of this tool appears to have been disregarded by the guideline development group and only published randomised controlled trials (RCTs) or systematic reviews of RCTs have been used (a level 1 assessment in Table 1). Levels of evidence from case-control or cohort studies (level 2) or case series (level 3) were excluded and expert consensus (level 4) was used in the absence of RCTs. We are concerned that high quality case-control and cohort studies have been specifically excluded without rigorous assessment.</p>
6	Full	30	2	<p>Deciding to exclude all studies which were not exclusively of back pain is a real loss and produces a strong bias towards studies conducted using biomedical models, with the primary outcome of pain, some with disability, and very few with psychological outcomes. While there may be some practical and social implications of having pain in particular locations, it is largely psychologically irrelevant and grouping patients by pain location (qua diagnosis) can even perpetuate a biomedical perspective on what are often problems of adjustment and rehabilitation, with clear and consistent psychological predictors emerging</p>

				from large scale epidemiological studies and systematic reviews. Most people with persistent pain have multiple pains, and the largest proportion of these is always low back pain, hence findings in low back pain are entirely consistent with those in mixed chronic pain groups. It is a great pity that NICE decided to take a traditional viewpoint which narrowed its scope and makes conclusions less useful to the large majority of people with persistent pains.
7	Full	7	7	Although psychological outcomes are highlighted as important and feature strongly in outcomes of many key clinical questions (Appendix B), they're largely absent from reviews of effectiveness; for instance of exercise in chapter 6, manual therapies in chapter 7, invasive treatments in chapter 11. This is largely for the reasons suggested in comment 6 (above), and entirely foreseeable. What is of concern is the fact that there is no comment on the gap in desired outcomes in summaries of effectiveness. This is just repeating the long term inadequacies of drug studies on chronic pain, using only pain as an outcome and belatedly realising that it doesn't predict function or mood – or continued health care use, sickness or absence from work.
8	Full	42	15	We note the statement that studies including patients with low back pain for longer than a year were only included if information in the paper suggested recurrent, rather than continuous, pain. However we are aware that most of the papers in the radiofrequency and spinal fusion sections contain a high proportion of patients whose pain is explicitly described as continuous.
9	Full	General		<p>We have some concerns with the consistency of the recommendations and their reflection of the presented evidence.</p> <p>For example, a very high quality systematic review of laser therapy found consistent benefit in RCTs, but is not recommended, nor even identified as an area for targeted research. Conversely, a meta-analysis and systematic review of spinal fusion (using predominantly the same 3 RCTs containing patients with low back pain of more than 12 months duration) were unclear of the benefit of spinal surgery, and yet referral for a surgical opinion is recommended before 12 months has elapsed.</p> <p>Similarly, high quality studies show improvements in pain, disability and patient reassurance after MRI, which is not recommended. No evidence for the benefit of patient information was found, nonetheless it is recommended.</p> <p>We do not necessarily agree or disagree with the recommendations of the guideline development group on these examples, but wish to highlight that this lack</p>

				of consistency leads us to challenge other recommendations that have been made.
10	Full	100	10	<p style="text-align: center;">Manipulation – Adverse events</p> <p>A systematic review (2) of 5 prospective studies shows that ~ 50% of patients experience mild to moderate, transient adverse effects after spinal manipulation. Several hundred cases of severe adverse effects are also on record (3). These relate mostly to upper spinal manipulations, but many chiropractors would manipulate the upper spine even if the patient suffers from low back pain. Estimates of incidence of these severe adverse events vary hugely and are problematic as under-reporting has been shown to be close to 100% (4,5,6). Prominently citing Cassidy et al (7), which has not been included in the evidence to recommendation assessment, neglects much of the previous evidence and is therefore selective and misleading.</p> <p>2. Ernst E. Prospective investigations into the safety of spinal manipulation. <i>J Pain Sympmt Managem</i> 2001; 21: 238-42.</p> <p>3. Ernst E. Adverse effects of spinal manipulation: a systematic review. <i>J R Soc Med</i> 2007;100:330-8.</p> <p>4. Lee KP, Carlini WG, McCormick GF, Albers GW. Neurologic complications following chiropractic manipulation: A survey of Californian neurologists. <i>Neurology</i> 1995; 45:1213-5.</p> <p>5. Dupeyron A, Vautravers P, Lecocq J, Isner-Horobeti ME. Complications following vertebral manipulation - a survey of a French region physicians. <i>Annales de readaptation et de medicine physique</i> 2002; 46: 33-40.</p> <p>6. Egizii G, Dupeyron A, Vautravers P. Spinal manipulation: a survey of French medical physicians who graduated with the national diploma of osteopathy from Strasburg University. <i>Ann Readapt Med Phy</i> 2005; 48: 623-31. doi:10.1016/j.anmmp.2005.04.013.</p> <p>7. Cassidy JD et al. <i>Spine</i> 2008; 33 (Suppl): S1860-1866.</p>
11	Full	101	7	<p style="text-align: center;">Manipulation</p> <p>It is unclear why the Cochrane review (8) was excluded. This review addresses in some detail the problems of heterogeneity that were said to be the reason for exclusion. The draft guidelines state that 8 RCTs on manipulation/mobilisation were included. In fact, there are only 7 (The UKBEAM study (9) is analysed twice). All except two had a high risk of bias. Thus the recommendation mainly rests on the UKBEAM and Cherkin (10) studies. Only the former of these two generated a positive result. But this trial did not attempt to control for placebo-effects. According to a survey of “the leaders of the chiropractic profession”,</p>

				<p>placebo-effects are a major contributor to the perceived benefits of chiropractic treatment (11). Therefore, the positive evidence is far less compelling than presented in the guidelines and may turn out to depend on a placebo-effect. A positive recommendation does not seem to be warranted.</p> <p>8. Assendelft WJJ, Morton SC, Yu Emily I, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low-back pain. <i>The Cochrane Database of Systematic Reviews</i>. 2004; Issue 1. Art No.: CD000447.pub2. DOI: 10.1002/14651858.CD000447.pub2.</p> <p>9. UK back pain exercise and manipulation (UKBEAM) Trial Team. <i>BMJ</i> 2004; 329: 1381-1384.</p> <p>10. Cherkin DC et al. <i>N Engl J Med</i> 1988; 339: 1021-1029.</p> <p>11. Jamison JR. Chiropractic holism: accessing the placebo effect. <i>J Manip and Physiol Ther</i> 1994; 17:339-46.</p>
12	Full	23	13	<p style="text-align: center;">Manipulation</p> <p>The guidelines assess 9 large groups of interventions of which manual therapies are only one part. The full GDG members panel of 13 individuals included two proponents of spinal manipulation/mobilisation (P Dixon and S Vogel). In addition, the chair of the panel (M Underwood) is the lead author of the UKBEAM trial on which the positive recommendation for manipulation/mobilisation seems to predominately rest. Proponents of spinal manipulation/mobilisation were therefore over-represented in the generation of these guidelines, which, in turn could have generated the over-optimistic conclusion regarding this intervention.</p>
13	Full	141	8	<p style="text-align: center;">Psychological interventions</p> <p>A better question would have been whether psychosocial screening tools can identify who may fail to benefit from treatments otherwise recommended, as that's what studies have addressed rather than selection of who will do best, which makes poor psychological sense.</p>
14	Full	164	24	<p style="text-align: center;">NSAIDs</p> <p>This recommendation is acknowledged to be from the NICE Osteoarthritis guideline and includes regular prescription of proton pump inhibitors with NSAIDs. It is included despite the narrative on pharmacological therapies (page 164, line 10) recognising that co-prescription of proton pump inhibitors may not be necessary in the low back pain population.</p>
15	Full	165	5,6,8	<p style="text-align: center;">Strong Opioids</p> <p>We acknowledge the dilemma of strong opioid prescription. Short term use does alleviate pain, but the studies on oxymorphone (12) and oxycodone (13) cited in the guideline show incidences of physical</p>

				<p>dependence and increased adverse events on withdrawal. In clinical practice there is reluctance on the part of prescriber and patient to stop strong opioids once started, for fear of pain getting worse. There is a risk that this will lead to dependency and problem drug use - approx 17% users (14). We are concerned that the prescription, and consequent problems, of strong opioids are likely to increase substantially in response to this guideline.</p> <p>We do not support this recommendation. Furthermore, if it remains extant we strongly encourage you to put it in the context of psychological and social assessment with multidisciplinary support and long-term supervision as recommended in the British Pain Society guidance (15), and the associated information for patients (16).</p> <p>12. Katz et al. <i>Curr Med Res Opin.</i> 2007; 23: 117-128.</p> <p>13. Webster LR et al. <i>J Pain</i> 2006; 7: 937-946.</p> <p>14. Ballantyne J, LaForge KS. <i>Pain</i> 2007; 129: 235-255.</p> <p>15. Recommendations for the appropriate use of opioids for persistent non-cancer pain. British Pain Society 2004, London.</p> <p>16. Opioid medicines for persistent pain: information for patients. British Pain Society 2004, London.</p>
16	Full	180	6	<p style="text-align: center;">Injections</p> <p>We are concerned at the blanket prohibition of the injection of therapeutic substances. All injections are not the same. No distinction is made in the guideline between diagnostic and therapeutic injections. It is our experience that there is considerable consensus between physiotherapists and pain specialists that certain patients benefit from facet joint injections temporarily, thus enabling them to participate actively in an exercise programme. We are also of the opinion, shared by many Orthopaedic surgeons, that diagnostic and therapeutic injections are indicated in the care pathway before consideration is given to spinal fusion.</p>
17	Full	14	21	<p style="text-align: center;">Diagnosis of non-specific low back pain</p> <p>The guideline describes non-specific low back pain as a diagnosis of exclusion when there is not a recognised patho-anatomic cause. We would agree with the exclusions listed in table 1. We also feel that there is an evolving literature supporting specific pathologies within the umbrella of non-specific low back pain; facetogenic, discogenic and sacroiliac mediated pain. These distinctions are important as they are amenable to diagnosis by specific injection procedures and may explain relatively poor results from spinal fusion.</p>

				<p>Rubenstein and van Tulder (17), in a recent evidence-based review of diagnostic procedures that is not included in the guideline conclude that <i>“There is strong evidence for the diagnostic accuracy of facet joint blocks in evaluating spinal pain, and moderate evidence for transforaminal epidural injections, as well as sacroiliac joint injections for diagnostic purposes.”</i></p> <p>Dreyfuss et al (18) showed that lumbar medial branch blocks were target specific, provided that precise target points were accurately used, and that needles were introduced in a particular direction. Structures other than the target nerves were not anaesthetized by lumbar medial branch blocks. Kaplan et al (19) showed that normal volunteers were protected from experimentally induced lumbar facet joint pain if the appropriate medial branches were anaesthetized. Together, these studies showed that lumbar medial branch blocks were target-specific and were a valid test of facet joint pain.</p> <p>Maigne (20) reports that <i>“Low back pain persisting or appearing after a technically successful lumbar fusion challenges clinicians. In this context, the sacroiliac joint could be a possible source of pain, but the frequency of its responsibility is not really known. We used sacroiliac anesthetic blocks, the gold standard for diagnosis, to determine this frequency. Our prospective series consisted of 40 patients with persistent low back pain after a technically successful fusion who received a sacroiliac anesthetic block under fluoroscopic control. The diagnostic criterion was a relief of more than 75% of the pain on a visual analog scale. We found a 35% rate of positive blocks.”</i></p> <p>We recommend that diagnostic injection procedures are undertaken before referral for spinal fusion.</p> <p>17. Rubinstein SM, van Tulder M. A best-evidence review of diagnostic procedures for neck and low-back pain. <i>Best Pract Res Clin Rheumatol.</i> 2008 Jun; 22(3): 471-82.</p> <p>18. Dreyfuss P, Schwarzer AC, Lau P, Bogduk N. Specificity of lumbar medial branch and L5 dorsal ramus blocks: a computed tomographic study. <i>Spine</i> 1997; 22: 895-902.</p> <p>19. Kaplan M, Dreyfuss P, Halbrook B, Bogduk N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. <i>Spine</i> 1998; 23:1847-1852.</p> <p>20. Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. <i>Eur Spine J.</i> 2005 Sep; 14(7): 654-8.</p>
18	Full	200	2	<p>Radiofrequency facet joint denervation Radiofrequency facet joint denervation is not a</p>

				<p>'surgical procedure' and should be included under the heading 'Injections'. Radiofrequency denervation is a percutaneous injection procedure performed in the main by pain medicine physicians. To our knowledge there are no surgeons performing this procedure in the UK.</p>
19	Full	200	2	<p>Radiofrequency facet joint denervation</p> <p>This guideline considered only 3 randomised controlled clinical trials (RCTs) of facet joint radiofrequency denervation versus placebo/sham – Leclaire (21), Van Wijk (22), and Nath (23).</p> <p>The Leclaire study (21) is assessed as a well conducted RCT with a low risk of bias. However, the two most recent systematic reviews which include lumbar facet joint radiofrequency denervation disagree. Manchikanti (24) concludes <i>“the study by Leclaire et al failed to meet one of the key criteria, namely study population with descriptions of specific inclusion and exclusion criteria, as well as appropriate diagnostic evaluation and criteria for inclusion in the study. Even though this randomized evaluation met six of the seven key domains, it failed to meet one of the three criteria for inclusion, thus creating a fatal deficiency resulting in non-inclusion in this analysis”</i>. Boswell (25) concluded <i>“the Leclaire study failed to define the study population using appropriate diagnostic criteria – this was a major error”</i>. Perhaps most damning is the comment by Leclaire himself in the discussion section of his paper (page 1414): <i>“When this study was initiated in 1991 the literature contained no clear criteria for identifying patients who would respond to this therapeutic approach. The inclusion criteria used by the authors proved to be insufficiently sensitive for determining the predominant facet origin of the subjects pain because the study population was made up of patients in whom other factors (eg. disc, myofascial, ligament) probably played a major role as the source of pain. The population whose low back pain was truly of facet origin could be identified more effectively by using selective facet blocks with lidocaine, bupivacaine and saline”</i>.</p> <p>Van Wijk (22) concluded that the combined outcome measure and VAS showed no difference between radiofrequency and sham, though in both groups the global perceived effect was significantly in favour of radiofrequency. However, in the intervention group, 61.5% of patients reported greater than 50% reduction in pain at 3 months. They also concluded that in selected patients radiofrequency denervation is more effective than sham treatment. This study, however, also has a number of deficiencies, such as the use of single intra-articular blocks and only 50% relief on VAS from this diagnostic block. There has also been</p>

criticism of the technical aspects of the procedure (26).

Considering the Nath study (23), it is important to note that this high quality and very recent trial relied on strict inclusion criteria utilising controlled medial branch blocks and correct technique. It is quite apparent from this well designed study that, provided patient selection is rigorous, radiofrequency denervation of the lumbar facet joints is not a placebo and results in significant improvements in back pain, leg pain and quality of life. It is also important to note the complication rate in the study was zero.

In a non-randomised study, widely recognised as the most meticulously performed study of radiofrequency denervation to date, Dreyfuss et al (27) selected patients on the basis of controlled diagnostic blocks and used a procedure technique which is anatomically and technically accurate. They also showed accurate and adequate coagulation of the target nerve by objective means (EMG). The results show that some 60% of patients obtained at least 90% relief of pain at 12 months and 87% of patients obtained at least 60% relief of pain at 12 months.

It is also worth considering the 10 year prospective audit of facet joint denervation for chronic back pain of 6 months duration by Gofeld et al (28). This group used double diagnostic blocks and correct technique. One hundred and nineteen patients (68.4%) had good (> 50%) to excellent (> 80%) pain relief when followed up for 24 months.

We believe it is clear that where studies are meticulous in performing controlled diagnostic blocks and correct technique the results of radiofrequency denervation for lumbar facet joint pain are very good. Only the Nath RCT could be considered as a 'meticulous' study in this regard and the results are positive. Unfortunately this guideline has chosen to include 2 other RCTs where the diagnostic criteria and technique were flawed. Furthermore, two recent systematic reviews (24, 25) both concluded that there was moderate to strong evidence that radiofrequency denervation is more effective than placebo.

Within the context of a multidisciplinary pain clinic, radiofrequency denervation is a valuable part of the pain physician's armamentarium. It is a simple injection procedure with a minor complication rate of 1% and provided the patient selection process is rigorous we feel that to suggest that radiofrequency denervation for chronic low back pain is ineffective is not justified.

We feel that radiofrequency denervation should be

				<p>recommended by the Guideline with the provision that it is performed within the context of a pain clinic setting allowing access to multidisciplinary therapy and only following an adequate diagnostic process where careful patient selection is paramount.</p> <p>21. Leclaire R, Fortin L, Lambert R et al. Radiofrequency facet joint denervation in the treatment of low back pain: a placebo controlled clinical trial to assess efficacy. <i>Spine</i> 2001; 26: 1411-1416</p> <p>22. van Wijk RMAW, Geurts JWM, Wynne HJ, Hammink E, Buskens E, Lousberg R, Knape JTA, Groen GJ. Radiofrequency denervation of lumbar facet joints in the treatment of chronic back pain. A Randomized, double-blind, sham lesion-controlled trial. <i>Clin J Pain</i> 2005; 21: 335-344.</p> <p>23. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (Facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. <i>Spine</i>. 2008 May 20; 33(12): 1291-7.</p> <p>24. Manchikanti L, Singh V, Vilims BD, Hansen HC, Schultz DM, Kloth DS. Medial branch neurotomy in management of chronic spinal pain: Systematic review of the evidence. <i>Pain Physician</i> 2002; 5: 405-418.</p> <p>25. Boswell M et al. A Systematic Review of Therapeutic Facet Joint Interventions in Chronic Spinal Pain. <i>Pain Physician</i> 2007; 10: 229-253.</p> <p>26. Bogduk J. Lumbar radiofrequency neurotomy (Commentary.) <i>Clin J Pain</i> 2005; 21: 335-344.</p> <p>27. 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</i> 2000; 25: 1270-1277.</p> <p>28. Gofeld M et al. Radiofrequency Denervation of the Lumbar Zygapophysial Joints:10-Year Prospective Clinical Audit. <i>Pain Physician</i> 2007; 10: 291-300.</p>
20	Full	28	1	<p>Radiofrequency facet joint denervation</p> <p>The guideline does not include radiofrequency facet joint denervation as a research recommendation, even though further research is felt to be necessary (page 206). If radiofrequency denervation is not recommended in the guideline, we believe further research on this technique should be included in the recommendations.</p>
21	Full	191	10	<p>Facet Joint Injections</p> <p>Lumbar facet joint and lumbar facet nerve injections have diagnostic utility but can also be therapeutic as evidenced by published studies and have become common practice in many western countries. In accordance with the criteria established by the</p>

International Association for the Study of Pain (29), the facet joints have been shown to be the source of chronic pain in 15% to 45% of patients with chronic low back pain (30,31).

Boswell's systematic review on therapeutic facet joint interventions included in the guideline (25) concluded that there is "*moderate evidence for short and long-term improvement in low back pain.*" However, the GDG chose to include only one RCT from this review (32). The methodology and conclusions of this study remain controversial. Boswell comments "*Carette et al failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain. They showed a prevalence of lumbar facet joint pain of 58% in patients with spinal pain, based on inclusion criteria in Phase 1 of the study. Failure to exclude placebo responders may have diluted the findings of true responders, making detection of differences between the study and control groups difficult. Further even though the results were judged to be positive at 6 months in the methylprednisolone group, they performed various types of analyses and finally concluded that there were no significant differences between groups.*"

More recent high quality observational studies and controlled trials have shown clinically important responses after facet joint injection (33) and medial branch block (34). Using medial branch blocks, a significant improvement was noted in overall health status with improvement not only in pain relief, but also with physical function and psychological status, as well as return to work (35). Furthermore, the duration of >50% pain relief was 10.7 + 0.58 weeks (mean + SEM) with each injection. The cost for 1 week improvement of quality of life was estimated to be \$67.

These studies show that facet joint injections and medial branch blocks have the potential, at least in the short to medium term, to provide excellent pain relief in nearly half of our patients. Within the context of multidisciplinary pain management this option for patients should remain available.

To abandon a potentially useful, inexpensive and low risk procedure on the strength of a single RCT published nearly 20 years ago and whose findings remain controversial needs to be more carefully considered.

29. Merskey H, Bogduk N. Classification of chronic pain: Descriptions of chronic pain syndromes and definitions of pain terms. Second Edition. IASP Press, Seattle, 1994.

30. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming

				<p>from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? <i>Spine</i> 1994; 19:1132-1137.</p> <p>31. Schwarzer AC, Wang S, 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. <i>Ann Rheum Dis</i> 1995; 54:100-106.</p> <p>32. Carette S, et al. A controlled trial of corticosteroid injections into facet joints for chronic low back pain. <i>NEJM</i> 1991; 325: 1002-1007.</p> <p>33. Shih C, et al. Lumbar Zygapophyseal joint injections in patients with chronic lower back pain. <i>J Chin Med Assoc</i> 2005;68:59-6.</p> <p>34. Manchikanti L, et al. Lumbar Facet Joint Nerve Blocks in managing chronic facet joint pain: One-year follow-up of a Randomised, Double-Blind Controlled Trial. <i>Pain Physician</i> 2008; 11: 121-132.</p> <p>35. Manchikanthi L, et al. Effectiveness of Lumbar Facet Joint Nerve Blocks in Chronic Low Back Pain: A Randomised Clinical Trial. <i>Pain Physician</i> 2001; 4: 101-117.</p>
22	Full	198	24	<p style="text-align: center;">Spinal fusion</p> <p>We are most concerned that that a recommendation is being made based on an unpublished reworking of a meta-analysis. The meta-analysis (see comment 23) is assessed as well conducted with a low risk of bias and yet an inconsistency has been spotted. The erratum, when published, is unlikely to have undergone peer review. The two meta-analyses included in the guideline do not show any significant benefit from spinal fusion surgery; we strongly believe this evidence should underpin any recommendation in the guideline, rather than an unpublished erratum.</p>
23	Full	198	30	<p>This should read “well conducted meta-analysis”, not “RCT”.</p>
24	Full	196	10	<p style="text-align: center;">Spinal fusion</p> <p>Spinal fusion surgery has an associated mortality and a significant morbidity. Facet joint injections and radiofrequency facet joint denervation have no reported mortality and minimal morbidity. We strongly believe that these percutaneous interventions should be undertaken before consideration of spinal fusion. Furthermore, it is our observation from current clinical practice that most Orthopaedic surgeons share a similar opinion.</p>
25	Full	26	1	<p style="text-align: center;">Care pathway</p> <p>Firstly, we would point out that the management of some patients with non-specific low back pain is complex and that an overly simplistic model will not</p>

				<p>suit all patients.</p> <p>We have two main concerns with the suggested pathway. It is not made clear where responsibility lies for the identification of red flags and serious pathology. We also believe that assessment by a pain specialist should be undertaken before spinal fusion is considered.</p>
26	Full	27	1	<p style="text-align: center;">Algorithm</p> <p>We believe this algorithm should be amended and could be improved. The core therapies box should lead to “improved” and “not improved” routes. The not improved box should contain the consideration of a combined physical and psychological (CPP) intervention. Four possible outcomes would then occur; Pain > 12 months; improved with CPP intervention; not improved with CPP intervention; did not undergo CPP intervention.</p> <p>We also strongly believe that the “not improved with CPP intervention” route and the “did not undergo CPP intervention” route should both lead to a “Referral to pain specialist box” before the patient is led out of the pathway. Diagnostic injection of therapeutic substances, radiofrequency facet joint denervation and use of alternative drugs for both nociceptive and neuropathic pain should be considered for difficult to manage patients if improvement is not occurring. Referral for assessment for spinal fusion should occur after the pain specialist box.</p>
27	Full	18	22	<p>Pain management programmes should be an added example. This would be consistent with the statement on page 140, line 13, where the British Pain Society Recommended guidelines for pain management programmes for adults (1) are acknowledged to be a standard for combined physical and psychological interventions.</p>
28	Full	140	14	<p>Combined should be substituted for Complex.</p>
29	Full	165 174 27	11 Column 2 Drug therapies box	<p>Weak opioid is the standard term, not Mild.</p>

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Closing date: 26 November 2008

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opinion or the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.