National Institute for Health and Clinical Excellence

Low Back Pain

Guideline Consultation Comments Table

1 October 2008 – 26 November 2008

Status	Organisation	Order no.	Version	Page no	Line no/section no	Comment	**Response**
SH	Addensbrook Addenbrookes Hospital	1	Full	General	General	We welcome the NICE report on the acute management of patients with chronic non specific low back pain. The terms of reference focus on patients with pain for greater than 6 weeks and less than one year. We are unaware of evidence that states that patients with pain for greater than one year should be treated any differently than those with pain for greater than 6 weeks. The European guidelines (your reference 1) do not make this distinction. The situation is complicated by the realisation that any episode of pain may be a first episode, a recurrent episode, or an acute exacerbation of chronic back pain. Thus in a hospital-based cohort study (with mostly chronic low back pain patients) the total duration of pain was 9.5 years whilst the episode duration was merely 2.5 years (Frank et al. 2000). We would advise that: The terms of reference be extended to the treatment of chronic low back pain (Back pain greater than 6 weeks) as the current title is obtuse and liable to misinterpretation	Thank you for your comment. The title of the guideline has been changed. The scope of the guideline specified both pain for more than 6 weeks and less than one year. This cannot be changed. Recurrent episodes of back pain apply if they fall within the 6 up to one year time frame

SH	Addensbrook Hospital	2	Full	15 49	Asse ssme nt Box 1 Box 1	We would strongly disagree that rheumatoid arthritis is a cause of low back pain. We would advise that: There is no evidence to support this statement – indeed a study of 667 consecutive referrals with low back pain to a district hospital rheumatology service did not report a single patient with rheumatoid arthritis (Frank, De Souza, McAuley, Sharma, & Main 2000)	Agree. The Box of specific causes of LBP has been modified and rheumatoid arthritis removed from it.
SH	Addensbrook Hospital	3	Full	15 49	Box 1 Box 1	The term other inflammatory disorders is vague. We would advise that: ankylosing and related Spondyloarthritides might be more concise	Noted. Box 1 has been revised.
SH	Addensbrook Hospital	4	Full	15 49	Box 1 Box 1	No mention is made of referred pain from retroperitoneal structures eg Leaking aortic aneurysm or lymphoma We would advise that: These are included in this box This section ignores the literature on 'red flags' which is widely used in the training of doctors in both primary and secondary care settings (Clinical Standards Advisory Group - Chairman Prof M Rosen. 1994). Your box also ignores the role of metabolic bone disease which may reflect Vitamin D deficiency. This was the commonest 'specific' cause of low back pain reported in a cohort of 667 patients presenting in north west London, where there are large immigrant populations with a range of risk factors for Vitamin D deficiency – vegetarians with dark skin, dress habits of covering the skin etc (Frank, De Souza, McAuley, Sharma, & Main 2000) No mention is made of prolapsed lumbar disc as a cause of low back pain. Not all disc prolapses are associated with radicular pain. We would advise that: This is included in this box	Noted. Thank you for your suggestion
SH	Addensbrook Hospital	5	Full	50	1 - 3	There is no guidance on a structured approach to the	Assessment for serious spinal pathology is included in the

						diagnosis of back pain before arriving at the diagnosis of non-specific back pain. We would advise that: Advice is given for the appropriate investigation of low back pain. This would make it clear that MRI may be indicated in the assessment of a patients with low back pain and that chronic conditions such as 'ankylosing spondylitis and chronic spinal tumours have been appropriately excluded before the patient is given the diagnosis of 'Non-specific back pain'.	guideline. Specific guidance on further assessment practices was outside the scope of the guideline
SH	Addensbrook Hospital	6	Full	57		We would agree that plain Lumbar X-ray for Non-specific back pain is usually not indicated but should be considered for the diagnosis of spondylolysis/spondylolisthesis. This is not mentioned as a cause of chronic low back pain Evidence; Evaluation of Specific Stabilizing Exercise in the Treatment of Chronic Low Back Pain With Radiological Diagnosis of Spondylolysis or Spondylolisthesis. Clinical Studies – Diagnosis Spine. 22(24):2959-2967, December 15, 1997. *O'Sullivan, PB; Twomey, LT; Allison, GT.*	Outside the scope of the guideline
SH	Addensbrook Hospital	7	Full	58		We would agree that MRI should only be performed to exclude underlying pathology and where surgery is thought to be indicated. MRI has also been shown to polarise a clinician's diagnosis thus facilitating management (Murray V and AK Dixon personal communication).	Personal communications are not an accepted type of evidence for guideline development and so cannot be used
SH	Addensbrook Hospital	8	Full	34	Chap 5	We feel that the recommendations are appropriate. Although the need for non anatomical advise could be stressed more.	Noted. The study by Moseley was excluded from the review because

						Evidence: A Randomized Controlled Trial of Intensive Neurophysiology Education in Chronic Low Back Pain. Clinical Journal of Pain. 20(5): 324-330. 2004. *Moseley, GL; Nicholas, MK; Hodges, PW.*	if compared two educational interventions.
SH	Addensbrook Hospital	9	Full	49	Chap 6	We agree that evidence suggests that exercise is important but that the type of exercise remains uncertain. The concept of 'reactivation' rather than any particular exercise or reconditioning regime is appealing. Evidence: The association of physical deconditioning and chronic low back pain: a hypothesis-oriented systematic review.Disabil Rehabil. 2006 Jun 15;28(11):673-93. Smeets RJ, Wade D, Hidding A, Van Leeuwen PJ, Vlaeyen JW, Knottnerus JA.	Maintaining a physically active lifestyle is also recommended. This paper was retrieved by our searches but was not included as it did not meet our inclusion criteria.
SH	Addensbrook Hospital	10	Full	71?	Chap 7	It should be noted that The BEAM study, The Andersson study, the Deyo study, all studies that this document rely on, recruited patients with acute back pain less than 3 months standing and not strictly relevant to the chosen patient group for this study. It is probable that manipulation has only a very limited part to play in chronic back pain and that the treatment effect is at its greatest in the first 3 weeks of an episode of acute low back pain. Evidence: Mathews, JA; Mills, SB; Jenkins, VM; Grimes, SM; Morkel, MJ; Mathews, W; Scott, CM; Sittampalam, Y. Back pain and sciatica: controlled trials of manipulation, traction, sclerosant and epidural injections. *Br J Rheumatol.* 1987 Dec;26(6):416–423.	Noted. The relevance of individual papers for the guideline was assessed in terms of whether the population included was representative of the target population. The GDG agreed that although the study may mention patients presenting with LBP of <6 weeks duration, these are in fact patients with recurring episodes of LBP and so are not really acute LBP patients.
SH	Addensbrook Hospital	11	Full	94?	Chap 8	We agree that there is no evidence to support routine use of electrical therapies, lumbar supports or traction in chronic low back pain. However, indications for the use of corsets have been suggested(Frank & Hills 1989), and	Noted. The systematic review included in the review of lumbar support (van Duijvenbode)did include RCTs

						should be considered for that group of patients for whom manual therapies and exercise have failed; and to facilitate early return to work for those particularly with heavy manual jobs.	that used corsets as the lumbar support intervention. There was no evidence that corsets were effective in treating low back pain. As per NICE methodology we are not accepting book chapters as evidence when trial evidence is available.
SH	Addensbrook Hospital	12	Full	110?	Chap 9	We agree that combined physical and psychological programmes for patients with intractable pain should be recommended. We would hope that the final draft of this document would make more specific recommendations concerning content and minimum time required, as intensive programmes may be needed for satisfactory outcomes. Evidence: J Guzmán R Esmail, K Karjalainen, A Malmivaara, E Irvin, C Bombardier, Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ* 2001;322:1511-1516. The ingredients of such programmes have been reviewed (Carter & Birrell 2000).	The recommendations have been modified to mention the intensity and some recommended content of the programmes
SH	Addensbrook Hospital	13	Full	133?	Chap 10	A mention that a dramatic response to non-steroidal anti-inflammatory medication should raise the possibility of previously unsuspected ankylosing spondylitis might be helpful. Evidence: clinical experience A more cautionary approach to the use of opiods in chronic low back pain would be appropriate. The papers quoted are short term and do not record the rate of long-term addiction. There are few trials looking at this problem and until there is a good body of evidence to support this approach considerable caution should be recommended. The review also failed to comment on the need for long-acting medication to be prescribed, particularly at night	The recommendations have been modified to raise the potential risks of side effects when offering NSAIDs and/or Opioids. A separate recommendation warns of possible risk of opioid dependence.

						time to facilitate a better night's sleep. The distressing effects of disturbed sleep in acute and chronic back pain have been described (De Souza & Frank 2007) and longer acting medications have been recommended as standard practice for many years (Frank & Hills 1989). Currently, long-acting preparations of Dihydrocodeine and Tramadol exist and are valuable for this purpose in severe pain disturbing sleep. It has been reported that pain played a smaller role in the prediction of daily functioning than sleep disturbance (McCracken & Iverson 2002).	
SH	Addensbrook Hospital	14	Full	149?	Chap 11	We would disagree that the quoted papers give strong enough evidence for acupuncture to be singled out for routine use.	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.
SH	Addensbrook Hospital	15	Full	164?	Chap 12	Spinal fusion for low back pain is probably no better than intensive rehabilitation (Fairbank et al). We would recommend that no-one is recommended for surgery unless they have exhausted all forms of conservative treatment including an intensive multidisciplinary combined physical and psychological	Yes agree. Referral for consideration of spinal fusion is only recommended for people who have continuing severe problems following an intensive course of

						programme.. For an example of disappointing surgical outcomes see: Long-Term Functional Outcome of Pedicle Screw Instrumentation as a Support for Posterolateral Spinal Fusion: Randomized Clinical Study With a 5-Year Follow-up. Randomized Trial. Spine. 27(12):1269-1277, June 15, 2002. *Bjarke CF; Stender HE; Laursen, M; Thomsen, K; Bunger, CE.*	combined physical and psychological treatment and who have had optimal treatment for any psychological distress.
SH	Addenbrookes Hospital	16	Full	General		I am concerned that the economics is discussed purely in relation to the cost of the therapy provided. There is good evidence that indirect costs account for 90% of the total costs of back pain to society (Norlund & Waddell 2000). If the evidence is lacking about the true costs of treatment because sickness absence is not recorded adequately, then it should be noted that further research is needed.	NICE advises that economic analyses used to inform its guidance should be conducted from the perspective of the NHS and personal social service system, which excludes monetary estimates of productivity costs. The reason for this explained on page 32 of the NICE technology appraisals methods guide (http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)
SH	Addenbrookes Hospital	17	Full	General		This review should not encourage use of the term 'sciatica', even though it will have been used in some of the studies. Leg pain or radicular pain are both valuable terms whilst 'sciatica' implies radicular pain when it may be referred e.g. from a facet joint (Frank 1993).	Noted. We will review where we have used this term
SH	Addenbrookes Hospital	18	Full	General		The guidelines appreciate the importance of psychological factors in management whether practiced by psychologists or other health professionals. The key	Thank you for your comment. Following consultation the GDG modified the guideline and

						psychological obstacles to successfully overcoming an attack of back pain (yellow flags) have been formulated and widely agreed (Kendall, Linton, & Main 1997) and emphasize 'an expectation that passive treatments rather than active participation will help'. Both manipulation and acupuncture are 'passive' treatments, whilst exercise is 'active' and requires the patient to change their lifestyle as a form of secondary prevention of further back pain. The evidence-based cognitive behavioral principles (Linton 2000;Norlund & Waddell 2000) endorsed by the guidelines discourage passivity and encourage increasing activity. Greater weight should be given to active rather than passive treatments; and this should be reflected in the guidelines with exercise given more weight than acupuncture or manipulation alone.	recommendation to emphasise the key message of emphasising active rather than passive treatment and to promote self-management.
SH	Addenbrookes Hospital	19	Full	General		Rehabilitation physicians embrace all elements in assisting those with back pain back to return to normal lives, and thus it is the combination of modalities that are used (medical, physical, environmental and psychological (British Society of Rehabilitation Medicine 2004)). Analgesia is not an end in itself. It is the means to enable individuals to become active and regain normal activities, including work. Professor Black has recently emphasized the need for a return to work to become an endpoint in medical research (Black 2008). Thus analgesia needs to be linked to active treatments and is not an end in itself. Effective analgesia from medication or injections provide a window of opportunity in which to re-educate lifestyles. Both NSAIDs and opioids have a limited lifespan, with lessened efficacy and increased risk of side effects with prolonged use. The guidelines need to emphasize this in their commentary about the evidence reviewed.	Noted. Return to work was not one of our outcomes. Another guideline under development focuses on long term sickness absence and incapacity for work. Opioids and NSAIDs are recommended for short term use, and attention is drawn to the risk of side-effects.
SH	Addenbrookes	20	Full	Gene		The introduction should avoid suggesting that the only	Thank you for your comment.

	Hospital			ral		sources for back pain are pathological. Invasive procedures fnd the precise anatomical cause for back pain in over 60% of patients (Bogduk N personal communication). However, the risks and costs of such invasive investigations do not justify their use. The guidelines should refer to pathological processes producing low back pain or use ‘red flag’ terminology. Black, C. 2008, *Working for a healthier tomorrow: Dame Carol Black's review of the health of Britain's working age population.* TSO, London. British Society of Rehabilitation Medicine 2004, *Musculoskeletal rehabilitation: report of a working party (Chair Neumann V.).*, First edn, British Society of Rehabilitation Medicine, London. Carter, JT. & Birrell, LN. 2000, *Occupational Health Guidelines for the management of low back pain at work: evidence review and recommendations*, Faculty of Occupational Medicine, London. Clinical Standards Advisory Group - Chairman Prof M Rosen. 1994, *Back Pain*, HMSO, London. De Souza, LH. & Frank, AO. 2007, "Experiences of living with chronic back pain: the physical disabilities", *Disabil Rehabil*, vol. 29, no. 7, pp. 587-596. Frank, AO. 1993, "Low back pain - Regular Review", *BMJ*, vol. 306, pp. 901-909. Frank, AO., De Souza, LH., McAuley, JH., Sharma, V., & Main, CJ. 2000, "A cross-sectional survey of the clinical and psychological features of low back pain and	The scope of this guideline is for non specific low back pain for which there is not a well defined patho-anatomical cause. Specific causes are described.If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect.

						consequent work handicap: use of the Quebec Task Force Classification", *Int J Clin Pract*, vol. 54, no. 10, pp. 639-644. Frank, AO. & Hills, JE. 1989, "Spinal pain.," in *Disabling Diseases. Physical, Environmental and Psychosocial Management.*, First edn, AO. Frank & GP. Maguire, eds., Heinemann Medical Books., Oxford, pp. 41-78. Kendall, N., Linton, SJ., & Main, CJ. 1997, *Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss.*, First edn, Accident Rehabilitation and Compensation Insurance Corporation of NZ and the National Health Committee, Wellington, New Zealand. Linton, SJ. 2000, "Utility of cognitive behavioural treatments," in *Neck and back pain: the scientific evidence of causes, diagnosis and treatment*, First edn, vol. 1 AL. Nachemson & E. Jonsson, eds., Lippincott, Williams & Wilkins, Philadelphia, pp. 361-381. McCracken, LM. & Iverson, G. L. 2002, "Disrupted sleep patterns and daily functioning in patients with chronic pain", *Pain Research & Management.*, vol. 7, no. 2, pp. 75-79. Norlund, AI. & Waddell, G. 2000, "Cost of back pain in some OECD countries," in *Neck and back pain: the scientific evidence of causes, diagnosis and treatment*, First edn, vol. 1 AL. Nachemson & E. Jonsson, eds., Lippincott, Williams & Wilkins, Philadelphia, pp. 421-425.	

SH	BackCare	1	NICE	general		Many people find that their back pain is recurrent, and therefore clarification is needed on how the 6 weeks and 1 year time limits are defined. The distinction between acute, sub-acute and chronic is artificial and in many cases not appropriate. We suggest to make it clear that this GL is for people who are experiencing an episode of back pain that has lasted longer than 6 weeks but shorter than 1 year.	This will be made clear in the introduction
SH	BackCare	2	NICE	general		While we welcome the focus on treatments and not professionals, users of the GL will need a clue to think wider than the traditional providers for back pain treatments. One of the big changes will be availability of treatments such as manual therapy and acupuncture provided by osteopaths, chiropractors and acupuncturists. We suggest to make this clear in the GL since it is a major shift from current practice.	It is outside of our remit to say who should deliver interventions, beyond that health professionals should have the necessary qualifications and competencies to treat people.
SH	BackCare	3	NICE	general		Back pain is often of a recurrent nature. The current GL provides useful treatments when a patient has experienced back pain for 6 weeks, but no attention is being paid to prevention of new episodes of back pain. Many people find that they have to exercise regularly to prevent flare ups. It is therefore important that patients are taught how to care for their back when they have had their treatment and have controlled their current episode of back pain. This would be very useful for for example the exercise recommendation.	Agreed. The guideline is intended for those with new episodes or recurring episodes of back pain. Advice to maintain a physically active lifestyle is given. Advice on the prevention of recurrent back pain is outside the scope of this guideline
SH	BackCare	4	NICE	general		Effective management of back pain needs commitment from patients and healthcare providers. While some of the recommendations require action and commitment from the individual patient, we would suggest to make this more	This is given prominence in the core therapies box in the algorithm .

						explicit. Healthcare providers can play a very important role in helping patients to take control of their back pain and treatments may assist in this. This fits in with the biopsychosocial approach that is recommended.	
SH	BackCare	5	NICE	3	14	We agree that this GL may result in fewer people experiencing back pain, but it may be more realistic to expect fewer people being affected by their back pain, not necessarily a reduction in the prevalence.	Thank you. We have edited the text.
SH	BackCare	6	NICE	3	18	This is a very biomedical explanation of back pain and is a step away from the biopsychosocial model that is now generally accepted.	Noted. Thank you
SH	BackCare	7	NICE	7		This GL is only for people with non-specific low back pain and the recommendations under 'Assessment' state that X-ray should not be used and MRI only in certain cases. There are however no (positive) recommendations on how non-specific low back pain should be diagnosed and assessed. How do professionals and patients know that this GL applies without having an evidence based assessment?	The starting point of this guideline is the management of people who have had low back pain for more than six weeks when specific causes would normally have been excluded
SH	BackCare	8	NICE	7		Alexander Technique is not listed in the recommended treatments, although the full GL does include a reference to the A-TEAM trial. The Alexander Technique is an unique combination of exercise and education and while these two elements are listed, it would be a lost opportunity not to specify what combination of exercise and education is most beneficial. The Alexander Technique is the only education/exercise programme that has a solid evidence base, but at the moment anyone can offer a combined education and exercise programme and say it is NICE recommended. We would suggest to include the Alexander Technique in the list of	The ATEAM trial was included in the review for advice to exercise, exercise programmes and massage. Although there is a recommendation for exercise programmes, specific types of exercises cannot be recommended. An additional recommendation suggests possible contents of such programmes. .

						recommended treatments.	
SH	BackCare	9	NICE	7	13	Good communication between healthcare providers and patients is crucial in providing good care. Healthcare providers can use very different words and phrases to describe non-specific back pain and the choice of wording is very important in ensuring that the patient is re-assured. While information and education are listed as 'treatments', we would suggest to highlight the importance of communication. At the moment BackCare is involved in a large research project around the difficulties of implementing evidence based recommendations for the management of back pain in primary care. In this project we are working with 9 GP practices, 2 PCTS and 9 patient representatives in identifying barriers to effective implementation of evidence based recommendations. While this is work in progress (due for completion in early 2010) one of the key findings is the importance of good communication between healthcare providers and patients. None of the GLs touch on this, but it seems a key player in implementation. Linking in with this is also communication with other stakeholders such as employers and occupational health. A link with the review by XXXX seems logical but is currently missing in this GL.	We agree good communication between health professionals and patients is important. This is stated in the patient centred care section of the guideline
SH	BackCare	10	NICE	8	6	The evidence for manual therapy comes primarily from UK BEAM which found evidence for the use of manual therapy that may include spinal manipulation. The recommendation states that spinal manipulation has to be included.	The recommendation comes the evidence from BEAM which included a package of manual therapy which included manipulation
SH	BackCare	11	NICE	8	15	'Do not use TENS' is a very strong negative recommendation for an intervention that is still be	Not enough evidence of clinical benefit was found to recommend

						researched. The methods of TENS RCTs have been criticised and the TENS programmes used in these trails may not reflect daily practice. We know of many people using TENS successfully. We suggest to reflect this in the recommendation and include a research question on TENS?	this intervention for use within the NHS. A research recommendation has been included in the full guideline
SH	BackCare	12	NICE	10	20	The recommendation on referral for spinal fusion only applies to people who have not improved from at least 2 other options (at least 1 'simple' treatment and the combined physical and psychological programme). From a patient point of view this seems a very long time to wait before you can even get an opinion on spinal fusion. We would like to have access to an opinion on spinal fusion widened to people who feel unable to cope with their back pain. This is supported by the evidence that states that surgery gives in the short-term more relief than non-invasive options.	The recommendation made is based on the clinical and cost effectiveness evidence found for those who had had non specific low back pain for more than one year. No evidence was found to support having surgery at an earlier stage.
SH	BackCare	13	NICE	11		Only referring patients for an opinion on spinal fusion and not on the interventions listed under 1.9.5 is very artificial. The professional referring a patient for surgery is unlikely to be able to say what surgical technique is best for this patient. It would therefore be better to refer patients for an opinion on spinal surgery and not list specific interventions.	The evidence reviewed did not identify any evidence for the effectiveness of other surgical procedures for people with non specific low back pain. The GDG felt it was not possible to recommend referral for an opinion on these
SH	BackCare	14	NICE	12	16	The recommendation on TENS implies some uncertainties around the use of TENS for non-specific low back pain. It would therefore be useful to specify what these uncertainties are and to make a research recommendation around this.	A research recommendation has been added to the full guideline, however we are limited to five key research recommendations that appear in the NICE guideline and the GDG gave a higher to priority

							to other areas.
SH	BackCare	15	NICE	13	3	Since this refers to one specific RCT, it would be useful to include a reference to this study.	Added
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	1	Full	42	6	During identification of evidence only RCTs and systematic reviews (of RCTs) were considered for selection. Sir, Micheal Rawlins, National Institute for Health and Clinical Excellence Chair Professor has said " RCTSs have been put on undeserved pedestal. A diversity of approaches, involving analysis of all aspects of evidence base, should be used to inform decisions about whether drugs or treatments are effective". BMA news Saturday October 25, 2008 pg 3.	Most of the clinical questions addressed the effectiveness of interventions therefore systematic reviews or RCT's were considered by the GDG to provide the most robust evidence on which to base recommendations. For other questions other study designs were considered.
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	2	Full	42	9	During development of this guideline, Expert consensus was used when RCTs were not available. No merit seems to have been given to intermediary levels of evidence as suggested by table 1 before using expert opinion.	Most of the clinical questions addressed the effectiveness of interventions therefore systematic reviews or RCT's were considered by the GDG to provide the most robust evidence on which to base recommendations. For other questions other study designs were considered.
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	3	Full	49	7	This guideline says that diagnosis of non – specific back pain is dependent on clinician being satisfied that there is no specific cause for their patient's pain and has gone ahead and listed the causes of back pain that needs to be ruled out in box 1. Our point of contention is that several causes of specific back pain have been missed including Mechanical Back Pain due to facet joint arthropathy and originating from sacroiliac joints[1] , discogenic back pain [2], back pain of musculoskeletal origin [3]	The GDG reviewed the data appertaining to the management of low back pain where specific causes of low back pain given in box 1 were excluded. Studies which fulfilled this inclusion criteria were reviewed and the evidence is based on those studies which included all other

						The failure to recognise these causes would either lead to lack of specific treatments or worse inappropriate treatments as revealed by Maigne et al[4]. Injections procedures not only have diagnostic value but also serve as therapeutic procedures to reveal the specific causes. It would not be appropriate to subject the patients to surgery without prior ruling out the causes of back pain which are not amenable to surgery. In failure of this approach it will lead to failure of the surgery to ameliorate pain condition. Hence generalised recommendation against injection therapy needs to be reconsidered and appropriately phrased. The guidelines goes on to say that diagnosis of specific causes of low back pain is beyond the remit and yet has not refrained from enlisting an incomplete list of causes of specific back pain. Our suggestion would be to include the above mentioned causes in the list of specific back pain to correctly define the scope of this guideline i.e non –specific back pain. 1. Bogduk N. The zygapophysial joints. In *Clinical Anatomy of the Lumbar Spine and Sacrum*, 3rd ed. Churchill Livingstone, New York, 2005, pp 29-38. 2. Heikki Hurri, Jaro Karppinen. Discogenic pain. Pain 2004;112: 225–228. 3. N. Ann Scott, PhD, Bing Guo, MD, Pamela M. Barton, MD, and Robert D. Gerwin, MD. Trigger Point Injections for Chronic Non-Malignant Musculoskeletal Pain: A Systematic Review. Pain medicine 2008 Nov 5. [Epub ahead of print]	studies of low back pain. In doing so the GDG adhered to the recommended practice of separating low back pain into serious spinal pathology (, nerve root pain and other back pain or non—specific back pain.

						4. Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. Eur Spine J. 2005 Sep;14(7):654-8.)	
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	4	Full	132	4	In the evidence statements for TENS, the decision of GDC seems to be based on mainly on one RCT (Deyo et al 1990, NEJM)[1] and yet this study does have certain flaws. 1) Deyo et al have studied patients with back pain of average duration of 4 years. Hence this study automatically falls outside the scope of these guidelines. 2) Deyo et al have included patients with nerve root irritation and neurologic deficits which again renders it outside the scope of this guideline. 3) They have added heat treatment to the treatment groups. Heat is known to work reasonably well for some patients and not for other patients. This has introduced an irrefutable bias in the study. 4) Their treatment group seem to have received treatment using frequency and setting adjusted by therapist rather than in consultation with the patient and yet it is well known that theoretical relationship between pulse frequency, duration and pattern may break down as currents follow the path of least resistance through the underlying tissue. So in clinical practise a trial and error approach is used whereby patients titrate current amplitude, frequency and duration to produce the appropriate outcome. The patient's report of the sensation produced by TENS is the easiest means of assessing the type of fibre active [2]. The statement in the study that 100% patients in the TENS group identified that they received TENS treatment is not a justification enough that the patients received adequate treatment i.e they	This was taken back to the GDG. The Group agreed with their previous decision to use this evidence and agreed a research recommendation should be made. Thank you for recommending these papers; these had been identified during the reviewing process but had subsequently been excluded on the basis of their size (Marchand and Topuz), because no relevant studies were included in the systematic review (Poitras) and non relevant outcomes (Deyo 1990)Following NICE methodology we would not include secondary sources such as chapters from books when we have trial evidence (Johnson 2008, McQuay 1998).

						perceived paraesthesia associated with adequate treatment. This is evident from the fact that 84% patients from SHAM group with non functioning device guessed they had functioning unit and received right treatment. Hence this study does not only fall out of the scope for the guidelines but also has bias and there are serious concerns whether the treatment group received adequate treatment. Also GDC seems to have ignored well documented fact that it is very difficult to blind TENS intervention[3,4] Also GDC seems to have ignored article by Stephane Poitras et al [5] 'Evidence – informed management of chronic low back pain with TENS as well conducted RCTS by Marchand et al [6] and Topuz et al [7]. We suggest that though TENS in itself may not be adequate for complete pain relief it is an important, safe, and cost effective adjunct to various strategies which can be used by this cohort of patients for self-initiation of pain management. We suggest GDC needs to review the evidence for TENS and withdraw the didactic statement TENS not recommended for low back pain and suggest a possible role of TENS for low back ache. 1. Deyo R, Walsh N, Martin D, Schoenfeld L, Ramamurthy S. A controlled trial of transcutaneous electrical nerve stimulation and exercise for chronic low back pain. N Engl J Med 1990;322:1627-34. 2. Johnson, MI (2008) Transcutaneous Electrical	

						Nerve Stimlation. In: Kitchen SM (ed) Electrotherapy: Evidence based practice, Churchill Livingstone, pg 259-286. 3. Deyo RA, Walsh NE, Scoefeld LS, Ramamurthy S. Can trials of physical treatments be blinded? The example of TENS for chronic pain. American Journal of Physical Medicine and Rehabilitation. 4. Evidence – based resource for pain relief. Henry McQuay and Andrew Moore. 5. Stephane Poitras, Lucie Brosseau. Evidence – informed management of chronic low back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound and thermography. The Spine Journal 2008;8:226-233. 6. Marchand S, Charest J, LI J, Chenard JR, Lavignollle B, Laurencelle L. Is TENS purely a placebo effect? A controlled study on chronic low back pain Pain 1993;54:99-106. 7. Topuz O, Ozfiden E, Ozgen M, Ardic FO. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskeletal Rehabil 2004;17:127-33.	
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	5	FULL	165	11	Recommendation for starting mild opiods with paracetamol surely comes before starting stronger opiods - WHO pain ladder.	The sequence in which drugs can be prescribed has been clarified in the recommedations and care pathway. Strong opioids are an option after paracetamol and weak opioids.

SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	6	FULL	191	3	We do believe that this question is well beyond the remit of this guideline. Injections of any therapeutic substances in the back are used for specific purposes i.e as a part of a **diagnostic work up** or for treatment of **specific cause of back pain** (back pain arising from facet joints, SI Joints, discogenic back pain) As these guidelines only address non specific back pain and does admit that diagnosis of specific causes of back pain are well beyond the remit, our suggestion would be to drop this question as it is beyond the scope of this guideline.	The GDG addressed the use of therapeutic injections into the low back for NSLBP. This included papers which performed an initial injection to evaluate the patient response. These papers formed part of the submission and the decision. Inclusion of these papers did not change the recommendation on injection therapies
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	7	FULL	194	4	Even if this guidelines did try and answer the question regarding the injection therapy, to refute a treatment on basis of a single RCT is unsafe and inappropriate. The various characteristics of single RCT [1] quoted by the guidelines stand out: 1) The patients included in this RCT(Carette et al) had back pain duration of 18 months in methylprednisolone group and 24 months in placebo group. This should automatically renders this RCT outside the scope of the guidelines and it should not be considered. 2) Carette et al showed statistically significant response in the methylprednisolone group at 6 months. Due to increased interventions in methylprednislone group, the exact nature of which is not revealed apart from repeat facet joint injections, the authors went to do further statistical analysis to come to conclusion that injection therapy is not useful. This statistical manoeuvre casts a shadow on the reliability of the results of this RCT. 3) We also argue that saline injection is not completely without any beneficial effects and hence not an appropriate placebo group.	It was not within the guideline scope to investigate diagnostic classification. However, as part of the analysis of the trials all papers where a previous positive response to an initial injection were included. The GDG were not able to consider the possibility of placebo responders in this or any other therapy other than through the medium of a well conducted RCT. The GDG requested that RCTs form the basis of the recommendations to provide consistency with other therapies evaluated in the development of these guidelines. Data from cohort studies was not considered in the presence of well conducted RCTs. Although the GDG felt the

						There are more recent systematic reviews as well RCTs available which need to be analysed and considered before any question regarding injection procedures for either diagnostic or therapeutic purposes can be answered [2,3,4]. 1. Carette S, Marcoux S, Truchon R, Grondin C et al . A controlled trial of corticosteroid injections into facet joints for chronic low back pain. The New England Journal of Medicine 1991;325(14):1002-1007. 2. Sehgal N, Elmer E Dunbar, Rinoo V Shah, James Colson. Systematic Review Of Diagnostic Utility Of Facet (Zygapophysial) Joint Injections In Chronic Spinal Pain: An Update. Pain Physician 2007;10:213-228. 3. Mark V Boswell, James Colson, Nalini Sehgal, Elmer E Dunbar, Richard Epter. A Systematic Review of Therapeutic Facet Joint Interventions in Chronic Spinal Pain. Pain Physician 2007;10:229-253. 4. Laxmaiah Manchikanti, Vijay Singh, Frank J.E. Falco, Kimberly A.Cash, Vidyasagar Pampati. Lumbar Facet Joint Nerve Blocks in Managing Chronic Facet Joint Pain: One-Year Follow-up of a Randomized, Double-Blind Controlled Trial. Pain Physician 2008, 11:121-132.	evidence did not support the use of such therapies it felt that there was a need to research these treatments and has made a research recommendation that appropriate studies are a research priority.
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	8	Full	200	2	Radiofrequency denervation of facet joints is not performed for non-specific back pain. It is carried out for back pain due to specific cause i.e proven to be originating from the facet joints. Hence it is outside the	In the context of this guideline non-specific pain is that for which there is not a serious cause (tumour sepsis, fracture)

						scope of this guideline and guideline should not make an attempt to answer this question. Radiofrequency denervation of facet joint is not a surgical procedure. Three RCTs have been included while considering the role of radiofrequency neurotomy. One RCT considered by the guidelines (Leclaire et al) did not show functional improvement after radiofrequency neurotomy. Before including this RCT in any kind of analysis, guidelines must consider a very important factor regarding inclusion criteria in this RCT. In their own discussion, Leclaire at el have admitted "When this study was initiated in 1991, the literature contained no clear criteria for identifying patients who would respond to this therapeutic approach. Therefore, one inclusion criterion used by the authors in their clinical practice for several years was significant relief of low back pain for more than 24 hours after facet injections under fluoroscopy, as determined by the attending physician. In the current study, this essential criterion also was validated by one of the researchers (L.F.). However, this criterion proved to be insufficiently sensitive for determining the predominant facet origin of the subject's pain because the study population was made up of patients in whom other factors (*e.g.,* disc, myofascial, ligament) probably played a major role as the source of the pain". This is the very reason this particular RCT has been excluded in recent systematic reviews and should also be excluded from present porposed guidelines. Various other articles other than those mentioned in the guidelines need to be considered before any conclusions to efficacy of radiofrequency can be ascertained [2,3,4,5].	In the absence of evidence that any specific interventional techniques are effective, even on carefully selected subjects then there is no necessity to consider these as a different sub-group.

						1. 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 effi cacy. *Spine* 2001 26:1411-1416 2. Geurts JW, van Wijk RM, Stolker RJ, Groen GJ. Efficacy of radiofrequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials. *Reg Anesth Pain Med* 2001; 26:394-400. 3. 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. *Pain Physician* 2002; 5:405-418. 4. Boswell M et al. A Systematic Review of Therapeutic Facet Joint Interventions in Chronic Spinal Pain. Pain Physician 2007; 10:229-253 5. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. *Spine* 2000; 25:1270-1277.	
SH	Blackpool, Flyde and Wyre Hospitals NHS Foundation	9	Appendix A	7	g	'Consideration of indications for referral for surgery'. We are intrigued how this has been included in the final scope of the guidelines. Throughout the scope consultation with the various stakeholders published on 9th May 2007, it has been	The recommendation is to refer people for an opinion by a specialist spinal surgical service This is specifically for people with non-specific low back pain – not

						continuously mentioned that surgery is beyond the remit of this guideline. Many stakeholders including Chartered Society of Physiotherapy (pg 18 no 8), Nuffiled Orthopaedic Centre NHS Trust (pg 39 no 6), Pain Concern (pg 41 no 3),Royal College of Anaesthetist (pg 48 no 2), Sedgefield PCT (pg 55 no 1), South Devon Healthcare Foundation Trust (pg 60 no 4), the College of Chiropractors (pg 64 no2), Wyeth Pharmaceuticals (pg 70 no 13) have raised the issue of including the patients with radiculopathy pain syndrome within the scope of the guideline. The standard response has been "the decision has been made to exclude patients with radicular signs as this will inevitably lead us to make recommendation about surgery and when surgery should be contemplated in patients with radicular signs. Surgery is beyond the remit of this guideline." This gave the impression that GDC did not want to include radicular pain syndrome within the scope as they felt that the surgery which probably would be inevitable response of this pain syndrome fell beyond the scope of this guideline. Also South Devon Healthcare Foundation Trust (pg 61 no 5 of scope consultation) raised the point that surgery needs to be appraised as this informs the decision making process and is crucial in enabling patients to move on rather than hoping that they will be cured by surgery at later stage. To this response was "surgery is beyond the the scope of this guideline" 1.1.1 In spite of this, the question regarding the referral for surgery seems to be included in the final scope and recommendation has been made regarding	for people with radicular pain. In the light of there being some evidence for the effectiveness of spinal fusion the GDG considered that for selected patients who had failed to benefit from maximal conservative treatment then referral for a specialist spinal surgical opinion was appropriate. It is anticipated that this recommendation will reduce number of patients referred for a surgical opinion for NSLBP

						spinal fusion surgery in the draft guideline. We believe GDC made it abundantly clear that surgery was beyond the scope of the guideline during the initial consultation and hence should refrain now from including this question in the scope and making any recommendation regarding it.	
SH	Boston Scientific	1	NICE	General		NICE is publishing in October its Guidance on Spinal Cord Stimulators for chronic neuropathic pain. The Clinical Guideline on low back pain should consider advising on indications for referral to SCS, as it is giving advice for indications for referral to surgery.	Neuropathic pain is outside of the remit of this guideline
SH	Boston Scientific	2	Appendix C	21		The algorithm should be more detailed and clearly specify the steps for patients. Reading the guideline, I was not sure what a patient suffering from low back pain should do first, when treatments should be stopped to go to next level, when drugs should be started, etc.	Thank you for your comment. The algorithm has been amended to make the pathway clearer.
SH	Brain and Spine Foundation	1	Full	General		This guideline is a significant change from current practise for patients who have low back pain longer than six weeks in duration. The creation of specific information for patients who fall into this category would clearly support the implementation and also support the clinicians. Clear guidance on self help and the availability of 'manual therapists'.	Thank you for your comment. NICE produce a document - Understanding NICE Guidance specifically for patients and carers, which will outline the recommendations made within this document. In addition the development of a patient information leaflet is being considered.
SH	British Association of Spinal Surgeons	1	Full	General	General	The overwhelming concern of our Society is how the target population for these guidelines is identified. It has to be made absolutely clear that potentially treatable causes of back pain have been excluded by an appropriate spinal service. We consider the diagnosis of "non-specific low back" pain	Thank you for your comment. We have revised the introduction and assessment chapters of the guideline to ensure the target population for this guideline is clear. The GDG have also

						to be one of exclusion. This means that no patho-anatomic cause has been identified, (not that there in no patho-anatomic cause).Thus, it needs to be made very clear that patients are only managed in accordance with these guidelines when other diagnoses have been excluded. The most important source of information in determining the potential diagnosis is the patient's history. In order that an appropriately detailed history can be taken and considered it essential that any patient with persistent and disabling symptoms of back pain should be assessed by a specialist in spinal pathology or specialist triage service. Part of such an assessment would include further evaluation with whatever imaging that service deems appropriate. Following such an assessment we would be more confident that the definition of “non-specific low back pain” could be fulfilled. However, red flags may not be present at a first assessment. Failure to improve with time in the presence of a non variable pain is a definite red flag. Repeat clinical reassessment needs to be stressed with this in mind. Reassessment must be carried out by someone suitably skilled to recognise serious spine pathology.	recommended that the diagnosis be kept under review when treating people with NSLBP. If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect.
SH	British Association of Spinal Surgeons	2	Full	General		There is no real mention in the guideline that the patient should take responsibility for their own management of their back pain and the fact that back pain is a normal symptom to be managed by the patient. The emphasis here is of a passive menu of treatment modalities. For example, it should be emphasised that explanation of the problem without active intervention of the types recommended in the guidance is a legitimate approach to back pain and should probably be top of the list.	Noted. Advice and information to promote self management is at the top of the core therapies box in the algorithm.

SH	British Association of Spinal Surgeons	3	Full	7 - 12	1 to 13	We suggest it would be very useful to have a measure of the size of the treatment effect attributed to each of the interventions mentioned. This will provide some guidance for the purchasing authorities in terms of cost utility.	Have provided cost effectiveness rather than effect size
SH	British Association of Spinal Surgeons	4	Full	7 - 12	14 to 17.	We consider appropriate imaging should be an essential part of the diagnostic process. It is therefore an essential tool in determining whether the patient fulfils the criteria for non-specific low back pain and in excluding causes of pain for which there may be a specific intervention available.	Thank you The recommendation is that imaging should only be performed if there is a clinical indication. An additional recommendation has been made to keep diagnosis under review.
SH	British Association of Spinal Surgeons	5	Full	21	Section 4.0	Given that ”non-specific low back pain” is a diagnosis of exclusion there is probably a multitude of underlying causes. A priority for research should be investigating identifiable causes of back pain. This should lead to specific treatments which are likely to be much more effective.	This was taken back to the GDG who felt there were other research areas of higher priority.
SH	British Association of Spinal Surgeons	6	Full	22	Section 4.2 of the FULL GUIDELINE – recommendations for asse	Standard practice for our members is to request an MRI when they believe that a structural and possibly reversible cause of the patient’s pain is potentially identifiable. Many of our members consider that pain in the region of the sacroiliac joint or buttock (and therefore within the anatomical region described as the,”back”) can result from lumbosacral nerve root compression and thus may be amenable to surgery. Therefore, an MRI should be requested when there is a suspicion of lumbosacral nerve root compression in addition to the other indications listed. This also needs to be amended in the algorithm shown in appendix C of the summary document.	lumbosacral nerve root compression is not included within this guideline, this will be made clear in the guideline

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SH	British Association of Spinal Surgeons	7	Full	7	12	This defines a key priority for implementation as promoting patient choice. This is in conflict with the very recommendations embodied in the full guidelines. These restrict patient choice. This should read “promote patient information regarding choices”.	Noted.
SH	British Association of Spinal Surgeons	8	Full	8	4	A statement should be included indicating that referral for spinal fusion should only be considered for symptoms that are making life unacceptable in terms of disruption of social fabric and employment. Spinal fusion is not a natural consequence of the failure of a range of other approaches but should be regarded as a new decision.	This was taken back to the GDG who amended the recommendation to clarify circumstances in which a recommendation would be made
SH	British Association of Spinal Surgeons	9	Full	8	5	To avoid the statement “do not offer injections of therapeutic substances into the back” being misinterpreted as a blanket ban on injections for all conditions this statement should include a caveat, for example, “for the specific back pain situation which is the subject of this guidance”.	Thank you for your suggestion. This was taken back to the GDG who amended the recommendation.
SH	British Association of Spinal Surgeons	10	Full	14	23	Non specific low back pain should not be defined as symptoms for which there is no recognised patho-anatomic cause. What is really meant in the context of this document, is that there is no important or specific cause for the back pain which require alternative treatment to the management strategies recommended in the guidance. The same comment applies to page 15 line 3.	Noted. This has been clarified in the text
SH	British Association of Spinal Surgeons	11	Full	100	17	It should be pointed out that while nine may constitute a course of manual therapy if there is no improvement after six sessions there will be no benefit.	Noted. The recommendation mentions that up to a maximum of 9 sessions of manual therapy may be prescribed.
SH	British Association	12	Full	180 -		The RCT’s of highest quality (three) show no benefit when	One paper (Thomas) consisted of

	of Spinal Surgeons			191		acupuncture is compared to sham. Why is the recommendation giving such importance for up to 10 treatments when there is no effect when taking the best level 1 evidence. The recent systematic review of acupuncture was not available at the time of draft. It is now available and should be included. Effectiveness of Acupuncture for Low Back Pain: A Systematic Review Yaun et al . Spine: Volume 33(23), 1 November 2008, pp E887-E900	population of interest, all the other papers included a population with LBP over longer duration than 12 months. The GDG agreed that it was appropriate to include those with recurring episodes of LBP which could include those whose last episode was longer than 12 months previously. Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However, acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore this should be considered as a possible treatment. Three of the five studies describe duration of treatment as up to 10 sessions so this was used to base the recommendation. Thank you for mentioning the recent review.. We obtained a copy and found that the included studies were either already included in the guideline (through inclusion in the Cochrane review or separate inclusion) or they were excluded because of sample size or design. Moreover the conclusions are consistent with

							the recommendations from this guideline.
SH	British Association of Spinal Surgeons XXXX	1	Full	general		I have run a one-stop spinal service involving physiotherapy, radiology and orthopaedic spinal surgery with input into a chronic pain service and psychology services (limited) for some 15 years, and established appropriate guidelines for our services. We have carried out a number of audits of the service. The facts are that 80 – 85% of patients referred to the service have non-specific LBP. The others have significant pathologies. Surely this must be stressed as this is likely to be the case for patients presenting to any practitioner or healthcare professional. The documents seem to assume that the reader knows how to differentiate between the presentation of non-specific LBP and specific pathological conditions eg acute and subacute disc herniations, spinal infections, tumours (primary, metastatic and neurological) , fractures and spinal stenosis, to name some of them. Surely the document must stress that first of all that a clear history must be undertaken including general enquiry and past history to first of all exclude life threatening pathologies (as in RED FLAGS), and patients with neurological symptoms, and that if any of these are missed and go on to have any of the recommended treatments in the "guidelines" such as a twelve session course of manipulation or acupuncture for any of these conditions, then they may not only cause harm, but at the very least will delay appropriate treatment.	Thank you for your comment. The guideline does not cover the acute phase. Our population are those who have had back pain for at least 6 weeks. However following comments received we have recommended that the diagnosis be kept under review when treating people with NSLBP.If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect.
SH	British Association of Spinal Surgeons XXXX	2	Full	General		The guide lines again talk about the use of X-rays in the context of only LBP. I would point out that in practice, X-rays are much more readily available (immediately) and much cheaper than an MRI scan. Also the clinical value of an x-ray varies according to the patient's age. It may well be of value in children and teenagers (scoliosis and spondylolysthesis) or in the older age group (fragility	We found no evidence of clinical benefit in having an x-ray in people with non specific low back pain, but there was some evidence of harm. Other conditions are outside of our remit.

						fractures and degenerative spondylolysthesis). Simply saying that x-rays are not recommended is misleading and dangerous and may lead to treatment being delayed or the wrong treatment prescribed, as in the RED FLAG situation. I think the relative value of x-rays and MRI in the guidelines should be changed accordingly.	
SH	British Association of Spinal Surgeons XXXX	3	Full	General		Taking into account the fact that the guidelines should discuss the general presentation spinal conditions, MRI should be recommended immediately if neurological symptoms are present, eg radicular leg pain, weakness or sensory disturbance, particularly in the presence of bladder or bowel, and neurogenic claudication. Only then can the appropriate treatment be offered.	The scope states that neurological disorders are excluded from this guideline.
SH	British Chiropractic Association	1	FULL	100	3	Should read low amplitude as opposed to small. This is the commonly used term in the scientific literature.	changed
SH	British Chiropractic Association	2	FULL	100	5	Should read normal range of motion, not available range of motion.	changed
SH	British Chiropractic Association	3	FULL	14	22	“Non specific low back pain is pain muscle tension…” In addition to the slightly confusing language used in this sentence, the fact remains that there is currently no evidence suggesting that the lumbar muscles are the primary source of lower back pain or indeed the accompanying stiffness. According to the renowned anatomist/pain specialist Nicolai Bogduk, “There are no scientific data, however, that sustain the belief that muscles may be a source of chronic pain” (1). Lesions of the discs, facet joints sacroiliac joints have been shown to be the most frequent primary sources of pain in provocative diagnostic studies involving chronic low back patients and will as a rule result in secondary muscle tension as well as stiffness (2,3,4). This is true even though we cannot identify the tissues in question with a standard clinical examination or even with diagnostic imaging (1). From a biomechanical perspective it is most likely that pain/stiffness in the lower back region involves	Thank you for this suggestion, the introduction has been amended.

						several of the structures mentioned above. . It is suggested that the sentence be reworded such that symptoms as opposed to anatomical structures are emphasised. *Non-specific low back pain will usually be experienced as tension, soreness and stiffness affecting the lower back region for which there is not a well defined patho-anatomical cause. Several structures including the joints, discs and connective tissues likely contribute to symptoms.* 1.Bogduk N. The anatomical basis for spinal pain syndromes. J Manipulative Physiol Ther. 1995 Nov-Dec;18(9):603-5. 2.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. 3.Bogduk N. Pain provocation tests for the assessment of sacroiliac joint dysfunction. J Spinal Disord. 1999 Aug;12(4):357-8. 4.Schwarzer AC, 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.	
SH	British Chiropractic Association	4	FULL	79	5	In the section dealing with exercise, “Advise all patients with low back pain to exercise”. This sentence strikes me as being too strong in as much as there are patients	Advice to exercise and offering a structured exercise programmes were reviewed separately. A key

						whose symptoms worsen with exercise and others who experience no clinical benefit (5). A more appropriate phrasing would be for patients to *"consider undergoing a supervised exercise programme"*. 5. Manniche C, Østergaard K, Jordan A.Training of back and neck in the year of 2002. Ugeskr Laeger. 2002 Apr 1;164(14):1910-3.	message of the guideline is to promote physical activity hence the advice to exercise.
SH	British Chiropractic Association	5	FULL	79	6	On page 79 line 6, it states that "Consider offering a structured exercise programme tailored to the individual". Due the fact that no commonly studied exercise programmes have been shown to be clinically more effective than others (5,6) and that group classes have been shown to be as clinically efficacious and more cost effective than one to one based exercise that this sentence should be changed to *"Consider offering a supervised programme under the guidance of a health professional."* We are still unable to identify which patients will benefit from exercise and furthermore, what exactly the mechanism by which exercise is effective – when it is (5). Lastly, the dose-response relationship of exercise has not been addressed in this review. It would be helpful for both clinicians as well as patients if guidance was provided relating to the duration and intensity of exercise programmes (7). This seems odd given that the document explicitly states that clinicians/patients may consider up to 9 manipulations over a 3 month period or 10 acupuncture treatments. *5.* Manniche C, Østergaard K, Jordan A.Training of back	The GDG concluded that there was evidence that exercise specifically designed for the individual were more effective than routine exercises. The GDG recommends that these should be delivered in a class setting. Information on the duration and intensity of exercise programmes are given in the narratives wherever given by the paper. The number of sessions are now specified in the recommendation, and are based on the large and well conducted RCT BEAM trial

						and neck in the year of 2002. Ugeskr Laeger. 2002 Apr 1;164(14):1910-3. 6. Mannion AF, Muntener M, Taimela S, Dvorak J. Comparison of three active therapies for chronic low back pain: results of a randomised clinical trial with one-year follow-up. Rheumatology. 2001;40 (7): 772-778. 7. Manniche C, Jordan A. The Value of Exercise Therapy. Spine, Editorial. 1995 Jun 1;20(11):1221-2.	
SH	British Chiropractic Association	6	FULL	43	1	Side-effects, although rare, have not been mentioned in the recommendations section even though it has been stated In Choice of Outcomes page 43 line 1 “”Secondary outcomes were safety and adverse events” will be addressed. Since an entire section has been devoted to Adverse Events and Manual Therapies even though it was concluded that “No evidence was found to show any increase in serious events in people with non-specific low back pain”, Page 122, 7.4.2, it seems reasonable that side-effects and exercise should be addressed specifically, if only to say that they are rare. They do though take place.	The GDG asked for a specific question on adverse events of manual therapy to be reviewed. Side-effects from other therapies would have been reported if mentioned in the studies.
SH	British Chiropractic Association	7	FULL	122	1	It seems reasonable that side-effects and exercise should be addressed specifically, if only to say that they are rare	Noted. Thank you
SH	British Chiropractic Association	8	FULL	100	11 - 14	The agreed upon remit of the GDG was particularly specific regarding the definition of the patient population that this document addresses, i.e. “chronic non-specific low back pain”. Literature relating to patients with signs of nerve root compression/irritation leading to sciatica or referred pain to the lower extremities was not included in this document. Furthermore, on page 122, 7.4.2. it is clearly stated that “Manipulation other than for the lumbo-pelvic region is excluded from this review”. Why then have possible risks associated with neck	Thank you. Table 7.4.2 mentions that upper spine manipulation is excluded from the evidence review and the paper by Cassidy (2008) has been removed from the introduction. Only evidence on thoraco-lumbar manipulation is included.

						manipulations been included in the introductory section dealing with Manual therapies (page 100, lines 11-14)? The neck has no anatomical, functional or neurological relationship to non-specific lower back pain. It makes no sense therefore to include possible adverse effects of neck manipulations (even if as has been stated that risks are similar to those associated with GP consultations (8,9)). I strongly suggest that this be removed from the introduction as it only serves to confuse both clinicians and patients in what is otherwise a very clearly delineated subject matter. It also detracts from the quality of the document as a whole. 8.Thiel HW, Bolton JE, Docherty S, Portlock JC. Safety of chiropractic manipulation of the cervical spine: a prospective national survey. Spine. 2007 Oct 1;32(21):2375-8; discussion 2379. 9.Cassidy JD, Boyle E, Côté P, He Y, Hogg-Johnson S, Silver FL, Bondy SJ. Risk of vertebrobasilar stroke and chiropractic care: results of a population-based case-control and case-crossover study. Spine. 2008 Feb 15;33(4 Suppl):S176-83.	
SH	British Chiropractic Association	9	FULL	118	1	Manual Therapies – adverse events: The BCA would respectfully recommend that this section be deleted in its entirety. The text repeatedly states that most data relates to patients suffering from neck and shoulder area pain – which is not within the remit of this document and furthermore, newer, larger, and higher quality prospective studies conclude that risks from cervical manipulation are indeed “low, to very low” (8). A systematic review involving patients with confirmed lumbar disc herniations undergoing spinal manipulative treatment concluded that the risk of “causing a clinically worsened disc herniation or	The statement has been added to Table 7.4.2 in the evidence to recommendation column

						cauda equine syndrome" was less than 1 in 3.7 million! (10). Due to the fact that the patients involved in this review were suffering with more serious and unstable conditions than those involved in the current guideline development the likelihood of a serious adverse event would be expectedly lower. A single statement similar to that provided on page 100, line 10 would suffice. If the GDG is to base its conclusions on the studies included in the review dealing with non-specific lower back pain only, the sentence could read: *There is an extremely low risk of serioius adverse events when receiving spinal manipulation for non-specific low back pain.* Bearing in mind that NSAIDs have a hugely higher incidence of adverse events (10) ranging from gastrointestinal bleeding (which may result in death), liver damage (which may also be fatal), renal failure and bone marrow depression and that the section on Pharmacological therapies has not warranted a specific sub-section which addresses with potential adverse events renders a specific section dealing with adverse events relating to lower back manipulations preposterous. This is further underscored by the fact that sections dealing with invasive procedures such as acupuncture; injections and spinal surgery (with serious adverse events found between 1-2% of patients) have also not included specific sub-sections relating to adverse events. 10. Oliphant D. Safety of spinal manipulation in the treatment of lumbar disk herniations: a systematic review and risk assessment. J Manipulative Physiol Ther. 2004	

						Mar-Apr;27(3):197-210.	
SH	British Chiropractic Association	10	FULL	100	17	9 sessions of manipulation? The dose-response of spinal manipulation and chronic low back pain has not been firmly determined. The GDG have apparently agreed upon the number 9, which indeed reflects the studies included in this review. I feel certain that this number is overly restrictive and suggest that 8-12 sessions would be more reflective of the clinical reality when treating chronic lower back pain patients. Furthermore, I would add that clinicians should consider altering their treatment strategy if patients have not experienced "meaningful" clinical benefit after 3-4 sessions as the likelihood of achieving a good clinical result diminishes significantly if no improvement has been attained by this time (11). 11. Axén I, Jones JJ, Rosenbaum A, Lövgren PW, Halasz L, Larsen K, Leboeuf-Yde C. The Nordic Back Pain Subpopulation Program: validation and improvement of a predictive model for treatment outcome in patients with low back pain receiving chiropractic treatment. J Manipulative Physiol Ther. 2005 Jul-Aug;28(6):381-5.	The decision on the maximum number of sessions to recommend was based on evidence for which health economic data was available. This was the UKBEAM trial.
SH	British Chiropractic Association	11	FULL	45	1	Should read 'were selected'.	Corrected.
SH	British Chiropractic Association	12	FULL	68	20	Should read 8-12	Change made
SH	British Chiropractic Association	13	FULL	192	28	Should read RCT as opposed to systematic review	This has been rectified in the guideline.
SH	British Chiropractic Association	14	FULL	31	4	The definition of chiropractic should make it clear that chiropractic is a profession and not a type of treatment. It should emphasise the package of care offered by	The definition has been amended.

						chiropractors, including biopsychosocial assessment, diagnostic skills and the contribution that chiropractors make in determining the health status of our patients. Treatments used should include mention of manipulation, other manual therapies, structured rehabilitation programmes, medical acupuncture/dry needling, electrical modalities, etc.	
SH	British Chiropractic Association	15	FULL	GENERAL		There is a need to define providers of SMT – i.e. chiropractors, osteopaths and manipulative physiotherapists.	It is outside of our remit to say who should deliver interventions, beyond that health professionals should have the necessary qualifications and competencies to treat people.
SH	British Chiropractic Association	16	FULL	100	8	There are relatively few physiotherapists who are fully qualified to undertake spinal manipulation (grade 5 manipulation). Clarification on the Grade of manipulation being recommended should be included.	Noted. The chapter introduction mentions the requirement of specialist post-graduate training to carry out manipulation.
SH	British Chiropractic Association	17	FULL	6	18	To read: “Consider referral for an opinion on spinal stabilisation surgery for people who have completed an optimal and comprehensive package of care including a combined physical and psychological treatment programme and who have persistent severe non-specific low back pain for which the patient would consider surgery.” *(and replace all future references to spinal fusion)*	Thank you for your suggestion. This was taken back to the GDG who modified the recommendation. However spinal fusion is the only intervention for which there is evidence so it cannot be replaced by another term.
SH	British Chiropractic Association	18	FULL	7	6	Simply repeating P6 line 14 in the context of assessment will cause confusion if the word. ‘management’ is used. X-rays are also a cheap and effective alternative to MRI if hip disease or previous trauma are issues and these situations are not uncommon	X-rays for hip disease or trauma is outside this guideline
SH	British Chiropractic Association	19	FULL	12	23	Screening protocols should not be fixated on psychological factors, when high pain at onset, social factors such as poor housing, social isolation, poor access to transport and co-morbidities have considerable effects	Noted

						on outcomes.	
SH	British Chiropractic Association	20	FULL	14	15	It is agreed that the effects of therapies on subgroups are important to research but could not some indication of where to look for these subgroups be offered? I am thinking particularly of mechanical subgroups since the interventions of manipulation, exercises and spinal stabilisation surgery that are recommended frequently target mechanical factors.	It was not within the scope to investigate sub-grouping of patient. The GDG felt there was insufficient evidence and this should be a research recommendation
SH	British Institute of Musculoskeletal Medicine	1	Full	General		While the reason for it is understood, the use of the term, "Non-specific low back pain", has problems as the definition is merely by exclusion of those conditions for which a definite diagnosis has been made. Some groups of clinicians, using their distinctive explanatory models and diagnostic methods, may make specific diagnoses within this area that others would not distinguish from the non-specific category. If such diagnoses have been used to define the entry criteria for trials then those data may not be found when searching "non-specific back pain". On the other hand trials of treatments that do not differentiate responsive groups may suffer from Type II errors. Examples of this situation are: [1] back pain without radiation to the leg(s) but positive signs of dural irritation or tension as elicited by procedures such as the "slump test". Use of this test varies widely between different clinicians. Hence a finding by neurosurgeons, who seldom use the slump test, that discectomy is not effective in back pain must be judged in the light of their reliance on MRI appearances as distinct from clinical tests that may more clearly indicate when inflamed dura is the pain generating structure.	Thank you for your comment. Searches conducted were for low back pain and the associated synonyms. We did not specify non specific within the search strategies used. We have revised both the introduction and assessment chapters to make the population clearer . .The scope of this guideline is the treatment and management of NSLPB. If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations

						[2] a specific diagnosis of ligamentous insufficiency in the lumbar region or pelvis may be seen by some clinicians to be an indication for prolotherapy [hypertonic dextrose] injections. Recent published RCTs of such injections in non-specific low back pain may have less power than studies in which more specific diagnoses are made in line with the practice of many clinicians using this treatment.	
SH	British Institute of Musculoskeletal Medicine	2	Full	7		Emphasis on passive interventions : On page 7 concerning key priorities, three passive treatments are specifically mentioned viz manipulation; acupuncture and spinal fusion. This will inevitably focus the attention of patients and commissioners on securing these services. While there is evidence that these procedures are cost-effective, the patients' oft repeated plea to be given understanding of their condition and how they can manage it themselves is somewhat side-lined by an inevitable emphasis on these provisions. Only in research recommendations [2.7 p 28] is it mentioned that patients' perception of "self efficacy" should be assessed. We would suggest that this should be given higher priority in research and service delivery. A further concern was the mention of upto nine sessions of manipulation being provided. Among those using manipulation in their management we have been unable to find anyone agreeing with this figure. Consensus was around a usual number of sessions being three to six with nine being a definite outlier	Noted. This was taken back to the GDG who agreed the message of promoting patient involvement and understanding of their care would be clear enough through the care pathway and associated material with this guideline (eg UNG) The recommendation for manual therapy was modified to "up to a maximum" of 9 sessions. That figure was based on data for which health economics were available (the UK BEAM trial)
SH	British Institute of Musculoskeletal Medicine	3	Full	?		Alexander Technique : In keeping with the aim of increasing self-efficacy, the recent MRC trial of Alexander technique demonstrates a benefit greater than either acupuncture or manipulation has achieved in the studies quoted in the guideline draft. Further the effect is shown to increase at one year over that at three months. Clearly an evidence-based guideline must respond to this work. We	This was taken back to the GDG. The trial and accompanying health economic analyses have now been included in the guideline.

						would recommend that fastidious trials are commissioned to attempt to identify the key components of this technique and its optimum delivery to patients.	
SH	British Institute of Musculoskeletal Medicine	4	Full	29		**Research** : Many of the conclusions come with the admission that the evidence for them is not strong and there is need for further research. The identification of research questions within the guideline [2.7] is to be applauded and many others could be added but there is no recommendation on how such research should be brought about. Wholesale rejection of treatments trusted by clinical teams because of a lack of data risks demotivating staff and losing effective methods, while it is clearly unacceptable for practices to persist by little more than tradition. Experience shows that the present system for initiating and funding each individual research project is ponderous and is not delivering the numerous answers that are needed for a truly "learning service" to exist. Neither providers nor commissioners are likely to see research as their primary responsibility so that it will always be an add-on organisationally and financially. However the first national health service Director of Research, Prof Peckham, while emphasizing the need to increase NHS research stated that this would not come from increased central funding but that local health services should be prepared to fund the research they needed from their budgets. We suggest that the guidelines recommend that clinical care and evaluation could be commissioned and funded simultaneously. Providers would then contract to deliver defined care services and answer specific research questions. A limited number with academic links should be commissioned as "Clinical Research Centres [CRCs]" to provide the longitudinal, population-based research to which the NHS is ideally suited. The documentation and data collection currently being instituted in these services for monitoring	Thank you for your comment. We are asked by NICE to identify high priority research recommendations. They will go through a prioritisation process within NICE that considers all research recommendations generated from NICE guidance. What is funded and how the research is commissioned is outside of the developers brief, but we shall pass this comment onto NICE

						and audit purposes is such that relatively small additional resources would be required for evaluation if the procedures and personnel were put in place as new services are set up. Realistically research questions, such as : "**What is the effectiveness and cost effectiveness of sequential interventions (manual therapy, exercise and acupuncture) compared with single interventions on pain, functional disability and psychological distress, in people with chronic non-specific back pain of between six weeks and one year?" [2.7 p 29 lines 5-9],** can probably only be answered by such a designated centre where the required multidisciplinary teams are assembled. As important as trials of individual treatments are, the context in which they are given may be as important – co-interventions, selection, sequence etc. CRCs would provide the milieu in which case selection, and differing patient pathways could be evaluated to determine not only whether a treatment is capable of effect but also the optimum delivery to identified responsive patients.	
SH	British Institute of Musculoskeletal Medicine	5	Full	159?		Injections : Both zygo-apophyseal and sacro-iliac joint steroid injections, and prolotherapy injections have strong support from the clinicians using them and patients who feel that longstanding impairment has been thereby alleviated. In practice prolotherapy is used in accord with a clinical algorithm whereby only those patients who have failed to respond to postural and ergonomic interventions and manipulation, have long stable histories of activity limitation and are positive for clinical tests of ligamentous pain are offered the treatment. In practice consecutive series of such patients show high levels of satisfaction whereas RCTs have generally not confirmed effectiveness. It could well be that failure to use the	Noted. Although the GDG felt the evidence did not support the use of such therapies it felt that there was a need to research these treatments and has made a research recommendation that appropriate studies are a research priority.

						algorithm above would result in considerable statistical noise from unresolved factors other than those to which the injection is targeted. We would suggest that these injections should remain within the range that can be commissioned particularly if controlled evaluation of their effectiveness is included in the contract.	
SH	British Institute of Musculoskeletal Medicine	6	Full	General		In Summary: BIMM Council and members were generally positive concerning the draft recommendations. Reservations identified were of the emphasis given to passive treatments compared with empowerment, the number of manipulation sessions suggested and the exclusion of some treatments particularly prolotherapy which is valued in situations where little else is at present offered. An addition to the suggested provisions were the recognition that local commissioners should address the many gaps in the evidence in this area by looking to contract evaluation along with service provision to bring about a truly "learning service".	Thank you for your comments. Providing information and advice for people to manage their back pain has a central position in the care pathway. The manual therapy recommendations have been revised and clarified. The evidence found for prolotherapy showed no effect on pain or disability for this population and therefore the GDG could not recommend it
SH	British Nuclear Medicine Society	1	Full	General		There appears to be no mention positive or negative for the role of the isotope bone scan in such patients. I suspect from having read the document they would conclude there is no role but it is a fair question to ask if they have considered it in their literature search as some centres would see it of value to exclude or diagnose significant pathology especially facet arthropathy, spondylolysis, and sacroiliitis.	This was not considered to be in the remit of this guideline. If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect.
SH	British Society for Rehabilitation medicine	1	Full	General		We welcome the NICE report on the acute management of patients with chronic non specific low back pain. The terms of reference focus on patients with pain for greater than 6 weeks and less than one year. We are unaware of evidence that states that patients with pain for greater than one year should be treated any differently	Thank you for your comment. The duration of low back pain was specified in the remit given to us by NICE This was included in the scope and reviewed during the consultation period.

						than those with pain for greater than 6 weeks. The European guidelines (your reference 1) do not make this distinction. The situation is complicated by the realisation that any episode of pain may be a first episode, a recurrent episode, or an acute exacerbation of chronic back pain. Thus in a hospital-based cohort study (with mostly chronic low back pain patients) the total duration of pain was 9.5 years whilst the episode duration was merely 2.5 years (Frank et al. 2000). We would advise that: The terms of reference be extended to the treatment of chronic low back pain (Back pain greater than 6 weeks) as the current title is obtuse and liable to misinterpretation.	
SH	British Society for Rehabilitation medicine	2	Full	15 and 49	Box 1 and Box 1	We would strongly disagree that rheumatoid arthritis is a cause of low back pain. We would advise that: There is no evidence to support this statement – indeed a study of 667 consecutive referrals with low back pain to a district hospital rheumatology service did not report a single patient with rheumatoid arthritis (Frank, De Souza, McAuley, Sharma, & Main 2000). The term other inflammatory disorders is vague. We would advise that: ankylosing and related Spondyloarthritides might be more concise No mention is made of referred pain from retroperitoneal structures eg Leaking aortic aneurysm or lymphoma We would advise that: These are included in this box This section ignores the literature on 'red flags' which is widely used in the training of doctors in both primary and secondary care settings (Clinical Standards Advisory Group - Chairman Prof M Rosen. 1994). Your box also	This was taken back to the GDG. Box 1 was amended.

						ignores the role of metabolic bone disease which may reflect Vitamin D deficiency. This was the commonest 'specific' cause of low back pain reported in a cohort of 667 patients presenting in north west London, where there are large immigrant populations with a range of risk factors for Vitamin D deficiency – vegetarians with dark skin, dress habits of covering the skin etc (Frank, De Souza, McAuley, Sharma, & Main 2000).	
SH	British Society for Rehabilitation medicine	3	Full	50	1 2 3	There is no guidance on a structured approach to the diagnosis of back pain before arriving at the diagnosis of non-specific back pain. We would advise that: Advice is given for the appropriate investigation of low back pain. This would make it clear that MRI may be indicated in the assessment of a patients with low back pain and that chronic conditions such as 'ankylosing spondylitis and chronic spinal tumours have been appropriately excluded before the patient is given the diagnosis of 'Non-specific back pain'.	Assessment for serious spinal pathology is included in the guideline. Specific guidance on further assessment practices was outside the scope of the guideline
SH	British Society for Rehabilitation medicine	4	Full	57		We would agree that plain Lumbar X-ray for Non-specific back pain is usually not indicated but should be considered for the diagnosis of spondylolysis/spondylolisthesis. This is not mentioned as a cause of chronic low back pain Evidence; Evaluation of Specific Stabilizing Exercise in the Treatment of Chronic Low Back Pain With Radiological Diagnosis of Spondylolysis or Spondylolisthesis. Clinical Studies – Diagnosis Spine. 22(24):2959-2967, December 15, 1997. *O'Sullivan, PB; Twomey, LT; Allison, GT.*	Outside the scope of the guideline

SH	British Society for Rehabilitation medicine	5	Full	58		We would agree that MRI should only be performed to exclude underlying pathology and where surgery is thought to be indicated. MRI has also been shown to polarise a clinician's diagnosis thus facilitating management (Murray V and AK Dixon personal communication).	Thank you for your comment. Personal communications are not an accepted type of evidence for guideline development and so cannot be used
SH	British Society for Rehabilitation medicine	6	Full	34		Chapter 5 Information education and patient treatment preferences. We feel that the recommendations are appropriate. Although the need for non anatomical advise could be stressed more. Evidence: A Randomized Controlled Trial of Intensive Neurophysiology Education in Chronic Low Back Pain. Clinical Journal of Pain. 20(5): 324-330. 2004. *Moseley, GL; Nicholas, MK; Hodges, PW.*	Noted. That reference was excluded because of inappropriate comparator; it compared 2 educational interventions.
SH	British Society for Rehabilitation medicine	7	Full	49		Chapter 6 Exercises We agree that evidence suggests that exercise is important but that the type of exercise remains uncertain. The concept of 'reactivation' rather than any particular exercise or reconditioning regime is appealing. Evidence: The association of physical deconditioning and chronic low back pain: a hypothesis-oriented systematic review.Disabil Rehabil. 2006 Jun 15;28(11):673-93. Smeets RJ, Wade D, Hidding A, Van Leeuwen PJ, Vlaeyen JW, Knottnerus JA.	Maintaining a physically active lifestyle is also recommended. This paper was retrieved by our searches but was not included as it did not meet our inclusion criteria.
SH	British Society for Rehabilitation medicine	8	Full	71		Chapter 7 Manual Therapies It should be noted that The BEAM study, The Andersson study, the Deyo study, all studies that this document rely on, recruited patients with acute back pain less than 3 months standing and not strictly relevant to the chosen patient group for this study. It is probable that	Noted. The relevance of individual papers for the guideline was assessed in terms of whether the population included was representative of the target population. The GDG agreed that

						manipulation has only a very limited part to play in chronic back pain and that the treatment effect is at its greatest in the first 3 weeks of an episode of acute low back pain. Evidence: Mathews, JA; Mills, SB; Jenkins, VM; Grimes, SM; Morkel, MJ; Mathews, W; Scott, CM; Sittampalam, Y. Back pain and sciatica: controlled trials of manipulation, traction, sclerosant and epidural injections. *Br J Rheumatol.* 1987 Dec;26(6):416–423.	although the study may mention patients presenting with LBP of <6 weeks duration, these are in fact patients with recurring episodes of LBP and so are not really acute LBP patients.
SH	British Society for Rehabilitation medicine	9	Full	94?		Chapter 8 Non-pharmacological therapies We agree that there is no evidence to support routine use of electrical therapies, lumbar supports or traction in chronic low back pain. However, indications for the use of corsets have been suggested(Frank & Hills 1989), and should be considered for that group of patients for whom manual therapies and exercise have failed; and to facilitate early return to work for those particularly with heavy manual jobs.	Noted. The systematic review included in the review of lumbar support (van Duijvenbode)did include RCTs that used corsets as the lumbar support intervention. There was no evidence that corsets were effective in treating low back pain. As per NICE methodology we are not accepting book chapters as evidence when trial evidence is available.
SH	British Society for Rehabilitation medicine	10	Full	110		Chapter 9 Psychological interventions and combined physical and psychological interventions. We agree that combined physical and psychological programmes for patients with intractable pain should be recommended. We would hope that the final draft of this document would make more specific recommendations concerning content and minimum time required, as intensive programmes may be needed for satisfactory outcomes. Evidence: J Guzmán R Esmail, K Karjalainen, A Malmivaara, E Irvin, C Bombardier, Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ* 2001;322:1511-1516. The	The recommendations have been modified to mention the intensity and some recommended content of the programmes

						ingredients of such programmes have been reviewed (Carter & Birrell 2000).	
SH	British Society for Rehabilitation medicine	11	Full	133		Chapter 10 Pharmacological therapies A mention that a dramatic response to non-steroidal anti-inflammatory medication should raise the possibility of previously unsuspected ankylosing spondylitis might be helpful. Evidence: clinical experience A more cautionary approach to the use of opiods in chronic low back pain would be appropriate. The papers quoted are short term and do not record the rate of long-term addiction. There are few trials looking at this problem and until there is a good body of evidence to support this approach considerable caution should be recommended. The review also failed to comment on the need for long-acting medication to be prescribed, particularly at night time to facilitate a better night's sleep. The distressing effects of disturbed sleep in acute and chronic back pain have been described (De Souza & Frank 2007) and longer acting medications have been recommended as standard practice for many years (Frank & Hills 1989). Currently, long-acting preparations of Dihydrocodeine and Tramadol exist and are valuable for this purpose in severe pain disturbing sleep. It has been reported that pain played a smaller role in the prediction of daily functioning than sleep disturbance (McCracken & Iverson 2002).	Noted. Thank you for your suggestion Noted. The recommendations have been reordered and the risk associated with opioids is made in a recommendation.
SH	British Society for Rehabilitation medicine	12	Full	149?		Chapter 11 Invasive procedures We would disagree that the quoted papers give strong enough evidence for acupuncture to be singled out for routine use.	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However, acupuncture needling not based on

							acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.
SH	British Society for Rehabilitation medicine	13	Full	164		Chapter 12 Surgery Spinal fusion for low back pain is probably no better than intensive rehabilitation (Fairbank et al). We would recommend that no-one is recommended for surgery unless they have exhausted all forms of conservative treatment including an intensive multidisciplinary combined physical and psychological programme.. For an example of disappointing surgical outcomes see: Long-Term Functional Outcome of Pedicle Screw Instrumentation as a Support for Posterolateral Spinal Fusion: Randomized Clinical Study With a 5-Year Follow-up. Randomized Trial. Spine. 27(12):1269-1277, June 15, 2002. *Bjarke CF; Stender HE; Laursen, M; Thomsen, K; Bunger, CE.*	Yes agree. Referral for consideration of spinal fusion is only recommended for people who have continuing severe problems following an intensive course of combined physical and psychological treatment and who have had optimal treatment for any psychological distress.
SH	British Society for Rehabilitation medicine	14	Full	General		I am concerned that the economics is discussed purely in relation to the cost of the therapy provided. There is good evidence that indirect costs account for 90% of the total	NICE advises that economic analyses used to inform its guidance should be conducted

						costs of back pain to society (Norlund & Waddell 2000). If the evidence is lacking about the true costs of treatment because sickness absence is not recorded adequately, then it should be noted that further research is needed. This review should not encourage use of the term 'sciatica', even though it will have been used in some of the studies. Leg pain or radicular pain are both valuable terms whilst 'sciatica' implies radicular pain when it may be referred e.g. from a facet joint (Frank 1993). The guidelines appreciate the importance of psychological factors in management whether practiced by psychologists or other health professionals. The key psychological obstacles to successfully overcoming an attack of back pain (yellow flags) have been formulated and widely agreed (Kendall, Linton, & Main 1997) and emphasize 'an expectation that passive treatments rather than active participation will help'. Both manipulation and acupuncture are 'passive' treatments, whilst exercise is 'active' and requires the patient to change their lifestyle as a form of secondary prevention of further back pain. The evidence-based cognitive behavioral principles (Linton 2000;Norlund & Waddell 2000) endorsed by the guidelines discourage passivity and encourage increasing activity. Greater weight should be given to active rather than passive treatments; and this should be reflected in the guidelines with exercise given more weight than acupuncture or manipulation alone. Rehabilitation physicians embrace all elements in assisting those with back pain back to return to normal lives, and thus it is the combination of modalities that are used (medical, physical, environmental and psychological (British Society of Rehabilitation Medicine 2004)).	from the perspective of the NHS and personal social service system, which excludes monetary estimates of productivity costs. The reason for this explained on page 32 of the NICE technology appraisals methods guide (http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf) Noted. We will review where we have used this term Thank you for your comment. Following consultation the GDG modified the guideline and recommendation to emphasise the key message of emphasising active rather than passive treatment and to promote self-management Noted. Return to work was not one of our outcomes. Another guideline under development focuses on long term sickness absence and incapacity for work. Opioids and NSAIDs are recommended for short term use, and attention is drawn to the risk of side-effects. The scope of this guideline is for non specific low back pain for which there is not a well defined

						Analgesia is not an end in itself. It is the means to enable individuals to become active and regain normal activities, including work. Professor Black has recently emphasized the need for a return to work to become an endpoint in medical research (Black 2008). Thus analgesia needs to be linked to active treatments and is not an end in itself. Effective analgesia from medication or injections provide a window of opportunity in which to re-educate lifestyles. Both NSAIDs and opioids have a limited lifespan, with lessened efficacy and increased risk of side effects with prolonged use. The guidelines need to emphasize this in their commentary about the evidence reviewed. The introduction should avoid suggesting that the only sources for back pain are pathological. Invasive procedures fnd the precise anatomical cause for back pain in over 60% of patients (Bogduk N personal communication). However, the risks and costs of such invasive investigations do not justify their use. The guidelines should refer to pathological processes producing low back pain or use 'red flag' terminology. References Black, C. 2008, *Working for a healthier tomorrow: Dame Carol Black's review of the health of Britain's working age population.* TSO, London. British Society of Rehabilitation Medicine 2004, *Musculoskeletal rehabilitation: report of a working party (Chair Neumann V.).*, First edn, British Society of Rehabilitation Medicine, London. Carter, JT. & Birrell, LN. 2000, *Occupational Health Guidelines for the management of low back pain at work: evidence review and recommendations*, Faculty of	patho-anatomical cause. Specific causes are described.If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect

						Occupational Medicine, London. Clinical Standards Advisory Group - Chairman Prof M Rosen. 1994, *Back Pain*, HMSO, London. De Souza, LH. & Frank, AO. 2007, "Experiences of living with chronic back pain: the physical disabilities", *Disabil Rehabil*, vol. 29, no. 7, pp. 587-596. Frank, AO. 1993, "Low back pain - Regular Review", *BMJ*, vol. 306, pp. 901-909. Frank, AO., De Souza, LH., McAuley, JH., Sharma, V., & Main, CJ. 2000, "A cross-sectional survey of the clinical and psychological features of low back pain and consequent work handicap: use of the Quebec Task Force Classification", *Int J Clin Pract*, vol. 54, no. 10, pp. 639-644. Frank, AO. & Hills, JE. 1989, "Spinal pain.," in *Disabling Diseases. Physical, Environmental and Psychosocial Management.*, First edn, AO. Frank & GP. Maguire, eds., Heinemann Medical Books., Oxford, pp. 41-78. Kendall, N., Linton, SJ., & Main, CJ. 1997, *Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss.*, First edn, Accident Rehabilitation and Compensation Insurance Corporation of NZ and the National Health Committee, Wellington, New Zealand. Linton, SJ. 2000, "Utility of cognitive behavioural treatments," in *Neck and back pain: the scientific evidence of causes, diagnosis and treatment*, First edn, vol. 1 AL. Nachemson & E. Jonsson, eds., Lippincott, Williams &	

						Wilkins, Philadelphia, pp. 361-381. McCracken, LM. & Iverson, G. L. 2002, "Disrupted sleep patterns and daily functioning in patients with chronic pain", *Pain Research & Management.*, vol. 7, no. 2, pp. 75-79. Norlund, AI. & Waddell, G. 2000, "Cost of back pain in some OECD countries," in *Neck and back pain: the scientific evidence of causes, diagnosis and treatment*, First edn, vol. 1 AL. Nachemson & E. Jonsson, eds., Lippincott, Williams & Wilkins, Philadelphia, pp. 421-425.	
SH	British Society of Skeletal Radiologists	1	Full	15	7	Patients with non specific low back pain are apparently identified by a process that has no evidence to support it. There is no analysis of the error rates of clinical judgement alone. The whole guideline therefore fails as it does not address a coherent group. It is not acceptable to dismiss this selection process as being outside the guideline remit.	The commission from NICE was to produce a guideline on non-specific low back pain.
SH	British Society of Skeletal Radiologists	2	Full	20	21 to 30	As comment 1but to add the question – how can these conditions be excluded? Clinical judgement alone is flawed. These uncommon but important conditions are best excluded by MR imaging. Therefore MR has a role in the patient who has low back pain but does not respond to several weeks of conservative management. This is the current Royal College of Radiologists and European Guidance on the topic. The draft NICE guidance contradicts these documents. Making the best use of clinical radiology services, 6th edition (2007) http://www.rcr.ac.uk/content.aspx?PageID=995	The exclusion of these conditions were specified in the scope which was consulted on. The GDG recommended that if any of these conditions were suspected an MRI should be considered.
SH	British Society of	3	Full	50	15	This is not the only question that should be covered with	The recommendation is based on

	Skeletal Radiologists					regard to MR imaging of those who have failed conservative management. Most of the evidence considered uses imaging in all cases of low back pain. We addressed a different question. Namely "How many patients with ongoing low back pain have a significantly abnormal MR study". This evidence is UK based and has been used to support the current Royal College of Radiologists guidelines. Clinical Radiology Volume 56, Issue 11, November 2001, Pages 922-925 Limited Magnetic Resonance Imaging in Low Back Pain Instead of Plain Radiographs: Experience with First 1000 Cases Eugene G. McNally[f1], David J. Wilson and Simon J. Ostlere Department of Radiology, Nuffield Orthopaedic Centre, Oxford, U.K. Received 20 March 2000; revised 23 November 2000; accepted 27 December 2000. ; Available online 12 March 2002. Abstract 2 AIM: We report our experience with the first 1000 patients with non-traumatic low back pain (LBP) without radiculopathy undergoing limited sequence magnetic resonance imaging (MRI) instead of plain radiography.	high quality RCT's found. Only evidence from RCTs was considered. Case series and other study designs were not reviewed. Economic analysis also showed that this was not cost effective for our population

						METHODS: Between January 1996 and December 1998, 1042 patients with low back pain unresponsive to conservative treatment were examined using a limited MR protocol comprising sagittal T1-weighted and STIR imaging. Plain radiographs were not performed. RESULTS: Malignancy, infection, vertebral fracture, spondylitis, pars defects and cord tumours were detected in 20%. Of the 82 osteoporotic vertebral fractures detected, 51 (62%) were recent and 31 had normal marrow signal indicating that they were old. Eighty pars defects were identified, 45(56%) had spondylolisthesis, 29(37%) were undisplaced and 6 (7%) had pars oedema only. Neoplastic disease was found in 17(8%) of which none was suspected before imaging. Benign neoplastic diseases such as vertebral AVM/haemangiomata were excluded. Twenty-one patients had a variety of disorders including ankylosing spondylitis (7), large vessel aneurysm (3), discitis (2), ovarian cyst (2), sequestered disc (2), sacral insufficiency fracture (2) and one patient each with burst fracture, retroperitoneal haematoma and a previously unsuspected horseshoe kidney. CONCLUSION: The majority of patients with LBP are best assessed clinically and imaging is usually not required. In patients with worrying symptoms, MRI with a limited protocol detects a greater number of abnormalities than previously reported studies using plain radiographs and has replaced plain radiography in our hospital. We report our experience with the first 1000 patients and highlight issues such	

						as protocols, detection rates and communication issues. *McNally E. G.et al*. (2001). *Clinical Radiology*56, 922–925.	
SH	Department of Health	1	Full	General		Thank you for the opportunity to comment on the draft for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation	Thank you
SH	General Osteopathic Council	1	Full	General		Overall the guideline is to be applauded for its patient centredness. The Group is to be congratulated on a clear and well-documented summary of the scope, protocol and reviews of evidence. It would be a welcome development if the publication of the guideline brought about greater cooperation and integration between all of the professional groups involved in the management of patients with chronic non-specific low back pain. It would have been a helpful addition to the scope of the guideline if service provision and the practicalities of integrated care pathways had also been considered. Overall, the guideline has merit in that it is reasonably non-controversial. The central issue concerns whether the publication of the guideline will advance the treatment for non-specific low back pain to the benefit of patients: the emphasis on separate treatment modalities probably won't achieve this result. More appreciation should be given to the fact that patients can require various different interventions during the management of a single episode of non-specific low back pain in order to promote their rehabilitation. This can require a distinct set of skills among various healthcare professionals and a sufficient	Thank you for your comment. Service delivery is not within the remit of this guideline, however implementation of the guideline across the NHS will be within the remit of NICE.

						degree of technical experience to ensure effective delivery. More guidance is needed on how multi-disciplinary care pathways should be managed, and how such multidisciplinary models dovetail with other current NHS initiatives. No recommendations have yet been made concerning acceptable outcome measures to be used to assess patients' progress while receiving any of the recommended treatment modalities. This would represent a practical benefit and prevent patients having unnecessarily extended programmes of treatment that could increase the chronic nature of their back pain.	
SH	General Osteopathic Council	2	Full	General		The title of the guideline is surprising and perhaps less confusing terminology would be more appropriate? The merging of "acute management" and "chronic non-specific low back pain" does at first seem contradictory, since the report appears to be about the management of up to 12 months of low back pain episodes lasting longer than 6 weeks. The use of the term "sub-acute" rather than "chronic" to describe back pain at six weeks could be considered. The guideline is unclear on whether patients will be receiving management for recurrences of episodes that have failed to respond to acute management, or ongoing management of patients who have failed to respond to initial measures. A clearer definition of "acute management" in the glossary or guideline booklet would be helpful in order to avoid confusion.	The title is under consideration and we have requested that it be changed to make it clearer Noted. The guideline does include management of recurring back pain and this will be made clearer.
SH	General Osteopathic	3	NICE	3	18 – 20	The introduction to the guidance discusses "non patho-anatomic" causes of non-specific low back pain, but this is confusing and contradictory in the light of later discussion	Thank you . we have clarified this in the text

	Council					of facet joint pain (Page 191, line 16) and discogenic back pain (Page 193, line 14) in the full guideline.	
SH	General Osteopathic Council	4	Full	8	1 – 23	It is interesting that key priorities for implementation include reference to individual treatment modalities rather than multi-modal packages of care. It is not clear what the relationship between the key priorities for implementation has with the guidance. To tackle chronic low back pain across England, a wide range of suitably skilled health professionals will need to be integrated into care pathways. Many osteopaths, chiropractors and acupuncturists have the clinical skills, capability and motivation, but lack knowledge about the NHS and about working within it. It would be helpful to see the inclusion of some specimen multidisciplinary pathways (there are successful models of good practice in Plymouth PCT and Dorset PCT), or some guidance concerning implementing multidisciplinary care to facilitate the greatest benefit for patients. We would strongly advocate consistency between this guideline and other national service delivery guidance, for example the Department of Health's Musculoskeletal Services Framework.	Combined physical and psychological treatment programme is a key priority. Noted Noted. This is beyond the guideline's remit. Noted Thank you..
SH	General Osteopathic Council	5	Full	8	5	A small number of patients do benefit from steroid injections where NSAIDs have not been successful. Steroid injections can also be a safer treatment option than NSAIDs and should only be delivered as part of a package of care, not in isolation.	The evidence does not support steroid injections for the target population

SH	General Osteopathic Council	6	Full	11	5	A small number of patients do benefit from steroid injections where NSAIDs have not been successful. Steroid injections can also be a safer treatment option than NSAIDs and should only be delivered as part of a package of care, not in isolation.	The evidence does not support steroid injections for the target population
SH	General Osteopathic Council	7	Full	37		Due to revisions to the Osteopaths Act 1993, the General Osteopathic Council no longer has a duty to promote. Instead reference to its statutory duty should read: "to regulate and develop the practice of osteopathy in the UK".	The definition in the glossary has been amended.
SH	General Osteopathic Council	8	Full	49	3 -6	It seems an optimistic assumption that specific causes of low back pain will have been excluded early in an episode of low back pain. Should not persistent low back pain be investigated by imaging at an earlier point, and within primary care, prior to referral to secondary management? For example, a recommendation to screen patients for an aortic aneurysm.	The review found no evidence that early imaging would identify serious pathology provided that the clinician ensures that serious causes of low back pain(presented in box 1) are excluded
SH	General Osteopathic Council	9	Full	49	12 - 13	The box describing specific causes of low back pain should be moved to a place much earlier in the text. It should be made more explicit that these are causes of low back pain that are not being considered in the guideline.	The box is in the introduction to the guideline as well as the assessment chapter
SH	General Osteopathic Council	10	Full	50	12 - 14	The recommendation that "patients should only be referred for MRI within the context of a referral for spinal fusion" should perhaps be amended to include "an opinion on surgical intervention", instead of focusing specifically on spinal fusion.	Thank you for your suggestion
SH	General Osteopathic	11	Full	60	4.3.3 .2	This study does not appreciate that some centres are using triage/intermediate orthopaedic services of this	Service provision is out side of the remit for this guideline

	Council					nature; this represents an increased cost of care compared with early manual treatment. This is an instance where the guideline is weak on service provision and the integration of modalities.	
SH	General Osteopathic Council	12	Full	63 – 78		The section on information, education and patient treatment preferences does not appear to get to the nub of the issues surrounding patient education and its role in effective ongoing patient self-management. Self-management is not adequately addressed in the guideline, apart from the recommendation that patients will be encouraged to maintain a physically active lifestyle, and exercise appropriate to their circumstances. No guidance has been given concerning how to improve self-efficacy and this is a major deficiency in the guideline. It would be helpful to state that the recommendations for patient preference and expectations of treatments is based on group consensus and generic NICE guidelines for patient-centred care, as no specific evidence was found, as stated on page 78 of the full report. The guidance does not explain what educational materials have worked well when subjected to trials and how these have been most effectively communicated. Should on-going developments such as the Expert Patient Programme be commented upon? Information must be accurate, up-to-date and accessible to be of value to patients and healthcare professionals. The low level of understanding that exists about many manual therapies amongst primary care professionals/commissioners following the publication of previous guidelines would suggest that this area should	A key message of the guideline is to promote self-management, and to this end the GDG have reworded the recommendations to give more information on the content of recommended educational advice. The evidence to rec table (section 5.4.3) clearly states the recommendation for patient preference is based on group consensus and generic NICE guidance on patient-centred care

						be given significant attention.	
SH	General Osteopathic Council	13	Full	79 - 98		The exercise statements are too broad and vague. What does advising patients to exercise mean specifically? Patients vary widely in what they consider to be exercise, from walking a short distance to intensive sport. More detail is needed to make this guidance clinically meaningful. The recommendations about exercise and exercise training do not give an indication of what types of exercise have been shown to be effective, although the data are in the full version. There is no interpretation of that evidence to guide its implementation in practice. It has not been stated whether any evidence was sought or identified concerning adverse events associated with exercise programmes. Some forms of exercise would be ill-advised for certain patients. It is important for key competencies to be identified in all providers with respect to education, training and regulation (if available). Specific knowledge of the spinal anatomy and the causes of back pain must be implicit within these competencies. While it should be recognized that there are no single exercises that will help all patients and tailor-made programme should capitalise on this detail, all patients should be encouraged to stay active and increase their aerobic exercise. Communication should be made to all healthcare professionals involved in the management of non-specific low back pain to ensure they are aware of the recommended key competencies required to carry out	This was taken back to the GDG. Group size information was rarely supplied by the authors. An additional recommendation now gives examples of types of exercise programmes and content.

						programmes of this nature. Some patients prefer group programmes to one-to-one sessions. Ensuring clear communication appropriate to all levels of knowledge and understanding of the causes of back pain could be challenging. It will be important to set a limit on group sizes to ensure that patients gain sufficient benefit from programmes of this nature.	
SH	General Osteopathic Council	14	Full	100 - 123		The number of recommended treatments for manual therapy should be rephrased in order to emphasise that nine treatments is <u>the maximum</u> and that the number of treatments to be delivered is based on the judgment of the clinician and measured patient outcomes. The potential cost implication for this recommendation is of considerable concern, and average numbers of treatment cited in research studies may be more helpful. Consideration should be given to the capacity of the manual therapy professions to deliver treatment of this nature. Greater clarity could be given to professional groups who could be described as providing "manual therapy". This should be accompanied by information concerning the standards of training and registration required of professionals who deliver this intervention. It would be more accurate to add that "manual therapists" deliver a package of high quality care, not only 'manipulation' in isolation.	The recommendation has been modified to state up to a maximum of nine sessions
SH	General Osteopathic Council	15	Full	141	3 -5	It would be helpful to provide recommendations for adequately assessing levels of disability or psychological distress, in order to implement this recommendation.	No studies were identified for our population on psychosocial screening, therefore the GDG felt unable to make a

						No information has been provided concerning how long a patient with severe non-specific low back pain would have to persist with a physical and psychological treatment programme before other options were considered.	recommendation, but a recommendation for further research on screening protocols has been made . The recommendation has been modified to include information on intensity/duration of the programme.
SH	General Osteopathic Council	16	Full	164	19 - 25	It would be helpful to state the indications for recommending COX2 inhibitors, which are prescription only, rather than NSAIDs, which can be purchased over the counter.	Only some NSAIDs are available over the counter. There is no reason to anticipate that over the counter preparations and prescription items will be different in effectiveness when used in equivalent doses. Thus any decision on choice of NSAID / COX-2 inhibitor needs to be informed by their comparative adverse effect profiles, and acquisition costs. This will involve a discussion between the patient and their pharmacist or doctor.
SH	General Osteopathic Council	17	Full	180 – 191		Although electro-acupuncture is mentioned in the full text of the guideline, no mention has been made of the use of accompanying techniques including moxibustion and cupping. This should be clarified for implementation. Key competencies for acupuncturists should be identified. Acupuncture is currently unregulated but presently undergoing review and moving towards regulation; a small number of acupuncturists, however, do not belong to any	We did not identify any papers or reviews which used acupuncture in association with moxibustion or cupping. The question addressed acupuncture needling as a treatment. Training and competencies required for delivering interventions are a matter for the

						(voluntary) registering body. There are also a large number of short (one-day) dry needling courses – clarification is needed regarding the minimum training requirements to safely and effectively deliver the treatment envisaged by the guideline.	relevant professional bodies and are outside of the remit for this guideline
SH	General Osteopathic Council	18	Full	191 – 195		Clarification is needed concerning whether this treatment is being given in isolation or whether it is part of a package of pain management measures. A package of care that has been shown to be successful when including injection therapy should continue. The scope of the guideline should be made explicit in any form of disseminated material, to ensure it is clear that the treatment of radiculopathy/nerve root pain is not included within this recommendation.	Packages were not considered This is excluded from the guideline and this is stated in the introduction.
SH	General Osteopathic Council	19	Full	196 – 207		The comments concerning referral for surgery are perplexing, given that non-specific low back pain is being considered. This classification has, by definition, not recognised patho-anatomic causes and it is hard to see why spinal fusion would be considered. It might make more sense to describe in greater detail the circumstances in which spinal fusion should be considered and to emphasise that spinal fusion should only be considered when all other avenues for treatment and management of symptoms have been fully explored.	The recommendation is for referral for an opinion on this treatment after people have failed to respond to other courses of treatment have had a combined physical and psychological treatment programme and have severe disability. Making recommendations for type of fusion procedure used is beyond the scope of this guideline
SH	General Osteopathic Council	20	Appendix B	1 - 7		It is surprising that the Low Back Pain questions include reference to adverse events related to manual therapies, but do not address to the same extent adverse events related to other interventions. Substantial evidence exists regarding adverse events of pharmacological	The GDG asked for a specific question on adverse events of manual therapy to be reviewed. Side-effects from other therapies would have been mentioned and

						interventions, and possibly some evidence relating to the other categories. This would provide a more balanced set of information on which healthcare professionals and other key staff could base their decisions.	reported if mentioned in the studies.
SH	Hove Poly Clinic	1	Full	General		I believe that the authors of the draft guidelines have been very selective in the evidence that they have chosen to back up the statements that they make. I would like to draw their attention to the response, to NICE of these proposed guidelines by XXXX of the British Pain Society. He presents a fully researched and balanced document. I would like you to note that I fully support XXXX's comments and hope that the authors take notice of his document and revise their proposed guidelines.	We searched and reviewed evidence for the population within the remit for the guideline following the NICE systematic methodology that is available from their website. This was presented and considered by the GDG who used this along with their clinical experience to base their recommendations. The Group will consider all the comments received when revising the guideline
SH	Interactive Teaching Method [Alexander Technique]	1	NICE	General		A study published in the BMJ in August 2008 (BMJ 2008;337:a884) concluded that lessons in the Alexander Technique were very effective in the long-term management of chronic back-pain. We suggest that lessons in the AT be added to the guidelines, and make specific suggestions in rows 2-10 below for changes to the NICE and Full guidelines. In this row are two paragraphs explaining further why the AT is an appropriate intervention. The Alexander Technique is an education in self-management of movement. It teaches people to notice and prevent poor movement strategies that can lead to the perpetuation of symptoms long beyond the recovery	The ATEAM trial (and accompanying economic analysis) has been included in the reviews for advice to exercise, exercise programmes and massage. Although we are recommending patients self management, and exercise programmes we do not recommend specific types of exercise programmes. Instead an additional recommendation gives suggestions of content for those programmes

						time one would associate with an injury or condition. For example, people habitually use inappropriate muscle groups - they stiffen the muscles of the neck in order to walk, they stiffen the muscles of the back to give themselves a sense of security while sitting. This inappropriate use of muscle groups is frequently done with great force, and often constitutes a source of self-generated pain and discomfort. The AT combats this self-generated pain and discomfort with lessons involving mixture of verbal interaction and gentle manual techniques. The AT alerts people to the fact that they can make better movement choices as they engage in their daily activities. These improved choices involve less inappropriate use of muscle groups (stopping using the neck muscles to walk, stopping stiffening the back muscles to give a sense of security) and using less force. Lessons promote flexibility and ease of movement, and can prevent the pain and discomfort caused by the person's habitual movement strategies.	
SH	Interactive Teaching Method [Alexander Technique]	2	NICE	6		Add bullet point after line 7 to read 'Consider offering a course of lessons in the Alexander Technique, plus exercise'. [renumbering required here, and in later sections]	Thank you for your suggestion
SH	Interactive Teaching Method [Alexander Technique]	3	NICE	6		[Clarity] Footnote 1: the referents of 'these therapies' are unclear.	This will be clarified in the final version
SH	Interactive Teaching Method	4	NICE	7		Heading 1.3 Exercise - add the words 'and self-	Thank you for the suggestion

	[Alexander Technique]					management in movement'	
SH	Interactive Teaching Method [Alexander Technique]	5	NICE	8		Add new 1.3.4 and renumber the following points - 'Consider offering lessons in self-management in the Alexander Technique'.	Thank you for your suggestion this will be considered by the GDG
SH	Interactive Teaching Method [Alexander Technique]	6	NICE	21		Courses of Therapies box. Add below heading 'Exercise' and after the words 'A structured .... to the individual' the following words 'Lessons in the Alexander Technique plus exercise'	Thank you for your suggestion
SH	Interactive Teaching Method [Alexander Technique]	7	NICE	21		Core Therapies box. Below the second 'AND' add the words 'lessons in the Alexander Technique' after 'exercise therapy'	Thank you for your suggestion
SH	Interactive Teaching Method [Alexander Technique]	8	FULL	7	18	Add bullet point after line 7 to read 'Consider offering a course of lessons in the Alexander Technique, plus exercise'. [renumbering required here, and in later sections]	Exercise programmes are already a key priority. Specific types of exercises cannot be recommended. In the exercise chapter suggested content of exercise programmes are given.
SH	Interactive Teaching Method [Alexander Technique]	9	FULL	9	6	Heading 1.3 Exercise - add the words 'and self-management in movement'	This was taken back to the GDG who amended the exercise recommendation to include suggestions of content of exercise programmes
SH	Interactive Teaching Method [Alexander Technique]	10	FULL	9	13	Add new 1.3.4 and renumber the following points - 'Consider offering lessons in self-management in the Alexander Technique'.	Specific types of exercises cannot be recommended. In the exercise chapter suggested content of exercise programmes are given
SH	Medtronic Ltd	1	Nice	10	20	Section 1.9 is entitled 'referral for surgery' and sub-section 1.9.1 states "Consider referral for an opinion on spinal	

						fusion for people who have completed a comprehensive package of care including a combined physical and psychological treatment programme and who have persistent severe non-specific low back pain for which the patient would consider surgery". Other types of surgery are suitable for these patients and have been considered by the interventional procedures programme (lumbar discs) and the technology appraisals programme (spinal cord stimulation). IPG 100 on prosthetic lumbar intervertebral disc insertion looked at artificial intervertebral discs which have been developed to act as a functional prosthetic replacement unit for intervertebral units in much the same way as prostheses have been developed for a variety of joints such as the hip or knee. The procedure is used to treat: • Patients with low back pain refractory to conservative treatment for more than six months • Patients currently considered suitable for spinal fusion surgery The IPG states: "Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure. However, there is little	The searches for this guideline did not find any RCTs demonstrating that the effectiveness of disc replacement was either superior to conservative treatment or of equivalent effectiveness to spinal fusion. In the absence of such evidence the GDG did not consier thre was a justification for referring for consideration of disc replacement surgery .

						evidence on outcomes beyond 2–3 years and collection of long-term data is therefore particularly important." This guidance was published in November 2004 and also states that "Prostheses vary considerably and newer ones may have different outcomes to those previously reported". We strongly believe that intervertebral disc replacement should be included in the guideline as a surgical treatment option for patients with low back pain. There have been a number of studies published since the issue of IPG 100 and these have been provided to the institute for further consideration. Spinal Cord Stimulation has recently been approved for use in neuropathic pain (TA 159). We believe that the institute should consider 'nesting' this guidance within the low back pain guideline for those patients with low back pain of neuropathic origin.	Neuropathic pain is not within the scope of this guideline.
SH	Merck Sharp & Dohme Limited	1	NICE and Full	General		Merck Sharp & Dohme Limited ("we") welcome the opportunity to comment on the draft guideline for low back pain. We believe NICE clinical guidelines should reflect clinical practice and set the standard both nationally and	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there

						internationally in a particular therapy area. We therefore fundamentally disagree with the draft guideline for the following principal reasons:- 1. The Guideline Development Group (GDG) seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE guideline on the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis*) and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis, appendices*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain? Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to	is unlikely to be a difference in therapeutic effectiveness of NSAIDs/COX-2 between the OA and LBP populations and that cost effectiveness was driven by the side effects profile and the GDG felt that the side effects would be similar between the osteoarthritis and LBP populations

						have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendations from the osteoarthritis guidelines in such a way. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages applied in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain,	Cross referring to other guidelines recommendations where appropriate is standard practice

						using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline. 2. We are not aware of NICE taking clinical guideline recommendations on treatments from one therapy area and applying them to another (without adjustment) in the past. We fundamentally disagree with the application of such methodology without providing transparent and explicit justification, and would wish to express our concern about this becoming a precedent for the future. Given NICE's aim for providing robust and transparent recommendations to ensure optimal patient care, we question the application of this methodology. 3. Whilst recommendations on NSAIDs and the COX-2 inhibitors seem to have been imported from CG59 (and so based on the economic model in that guideline), the economic model developed for CG59 received criticism from numerous stakeholders during the guideline consultation phase. Not all of these points were addressed in the final version of the guideline. Furthermore, the model remains unpublished and	

						unavailable (in either a read-only or executable form). Given the implicit central importance of this model in the recommendations made by the GDG, this seems a questionable approach. 4. Neither of the COX-2 inhibitors which are available in the UK (celecoxib and etoricoxib) are indicated for the treatment of chronic low back pain. Although the scope stated that unlicensed medications may be included in the guideline, we feel that this compounds the other issues we raise in this response. 5. The Clinical Guidelines on osteoarthritis were not listed in the set of "related guidance", as described in the final scope. Whilst CG59 was not published at the time, the publication was expected and listed on the NICE website, with work on-going. We would, therefore, seek to understand the GDG's justification for including the COX-2 inhibitor recommendations from CG59. 6. There appear to be numerous inconsistencies in the guideline relating to the discussion of NSAIDs and COX-2 inhibitors. For example, on page 19, the guideline states that NSAIDs are included in the assessed therapies. However, whilst included in the guideline, COX-2 inhibitors are not listed; this is also true of the algorithm on page 27.	This was added when the systematic review included in the review of the literature reported the use of cox-2 as well as NSAIDS. The wording of the recommendations have been revised to make this clearer

						Elsewhere in the guideline (e.g. page 168), NSAIDs and COX-2 inhibitors are listed as separate agents. We believe that this interchanging of terminology could be confusing to the reader, particularly as neither of the COX-2 inhibitors are licensed for low back pain. We request the GDG review the guideline and accurately specify when they refer to (traditional) NSAIDs alone, COX-2 inhibitors alone, or NSAIDs *and* COX-2 inhibitors. In summary, unless the guideline was to take into consideration the points raised above (and adjusted appropriately), we strongly feel the COX-2 inhibitors should be excluded from the low back pain guideline.	
SH	Merck Sharp & Dohme Limited	2	NICE	9	15 - 19	The GDG seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE guideline on the management of osteoarthritis (*NICE Clinical Guideline CG59 on osteoarthritis*) and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis *(NICE Clinical Guideline CG59 on osteoarthritis*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain?	In the full guideline the evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that

						Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendation in such a way. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages	the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. .

						applied in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we would ask the GDG to remove the COX-2 inhibitors from this guideline.	
SH	Merck Sharp & Dohme Limited	3	NICE	21	Algorithm	With reference to the "algorithm" presented in the guideline, we would like to draw the GDG's attention to numerous inconsistencies relating to the discussion of NSAIDs and COX-2 inhibitors. For example, on page 19 of the full guideline, it states that NSAIDs are included in the assessed therapies. However, whilst included in the guideline, COX-2 inhibitors are not listed; this is also true of the algorithm on page 21 in the NICE guideline and page 27 in the full guideline. Elsewhere in the full guideline (e.g. page 168), NSAIDs and COX-2 inhibitors are listed as separate agents. We believe this interchanging of terminology could be confusing to the reader, particularly as neither of the COX-2 inhibitors are licensed for low back pain. We request the GDG review the guideline and accurately specify when they refer to (traditional) NSAIDs alone, COX-2 inhibitors alone, or NSAIDs *and* COX-2 inhibitors.	The terminology has been clarified in the guideline. The evidence review was for NSAIDs or COX-2, and this has been clarified in the text.
SH	Merck Sharp &	4	NICE	21	Algor	Under "core therapies" we believe the guideline should not be recommending exercise for all patients, as it may	Exercise is one of the treatment options. If the health professional

	Dohme Limited				ithm	not be appropriate for certain patients with low back pain. Standard medical practice would be to advise the patient to remain mobile, but not to engage in active exercises, unless this is appropriate for the specific condition.	felt it was not advisable for an individual to exercise they could recommend one of the other treatments. Advice to remain active has been added to the core therapies box.
SH	Merck Sharp & Dohme Limited	5	Full	11	9 -12	The GDG seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE guideline on the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis*), and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis, appendices*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain? Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation.

						unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendation in such a way. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages applied in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline.	
SH	Merck Sharp & Dohme Limited	6	Full	14	17 - 20	We note that this guideline considers treatment for chronic low-back pain, where symptoms are present for a period of between six weeks and one year. Assuming that the GDG have imported the recommendations on COX-2 inhibitors from CG59, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a 6 week to one year treatment duration for low back pain? We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions, and it is not clear if any has been performed.	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of

							adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation
SH	Merck Sharp & Dohme Limited	7	Full	19	8 -10	With reference to the "Pharmacological interventions" listed, we would like to draw the GDG's attention to numerous inconsistencies in the guideline relating to the discussion of NSAIDs and COX-2 inhibitors. For example, on page 19, the guideline states that NSAIDs are included in the assessed therapies. However, whilst included in the guideline, COX-2 inhibitors are not listed. This is also true of the algorithm on page 27. Elsewhere in the guideline (e.g. page 168), NSAIDs and COX-2 inhibitors are listed as separate agents. We believe this interchanging of terminology could be confusing to the reader, particularly as neither of the COX-2 inhibitors are licensed for low back pain. We request the GDG review the guideline and accurately specify when they refer to (traditional) NSAIDs alone, COX-2 inhibitors alone, or NSAIDs *and* COX-2 inhibitors.	The terminology has been clarified in the guideline. The evidence review was for NSAIDs or COX-2, and this has been clarified in the text.
SH	Merck Sharp & Dohme Limited	8	Full	27	Algor ithm	With reference to the "algorithm" presented in the guideline, we would like to draw the GDG's attention to numerous inconsistencies relating to the discussion of NSAIDs and COX-2 inhibitors. For example, on page 19, the guideline states that NSAIDs are included in the	Thank you for your comment It is not listed on page 19 because we did not review the evidence but cross referred to a recommendation made in the

						assessed therapies. However, whilst included in the guideline, COX-2 inhibitors are not listed; this is also true of the algorithm on page 27. Elsewhere in the guideline (e.g. page 168), NSAIDs and COX-2 inhibitors are listed as separate agents. We believe this interchanging of terminology could be confusing to the reader, particularly as neither of the COX-2 inhibitors are licensed for low back pain. We request the GDG review the guideline and accurately specify when they refer to (traditional) NSAIDs alone, COX-2 inhibitors alone, or NSAIDs *and* COX-2 inhibitors.	Osteoarthritis guideline. We have clarified within the pharmacological chapter that although NSAIDS and COX-2 may be regarded as a single drug class the use of the two terms is for clarity and differences in side effects.
SH	Merck Sharp & Dohme Limited	9	Full	27	Algorithm	Under "core therapies" we believe the guideline should not be recommending exercise for all patients, as it may not be appropriate for certain patients with low back pain. Standard medical practice would be to advise the patient to remain mobile, but not to engage in active exercises, unless this is appropriate for the specific condition.	Advice to exercise and offering a structured exercise programmes were reviewed separately. A key message of the guideline is to promote physical activity hence the advice to exercise. The algorithm has been modified following consultation to make this clearer.
SH	Merck Sharp & Dohme Limited	10	Full	42	3 -21	The guideline does not list information from other therapy areas (such as osteoarthritis) as a source for evidence. Given the differing aetiologies, it would not seem appropriate to do so. It is therefore confusing for the GDG to consider an economic model designed for osteoarthritis when making recommendations on treatments within this guideline.	Related NICE Guidance, including a reference to the osteoarthritis guideline, is mentioned in section 3.11
SH	Merck Sharp & Dohme Limited	11	Full	44	6 -15	Whilst the economic model produced for CG59 used a QALY outcome and NHS perspective, it is unclear how the osteoarthritis study population could be considered to meet the inclusion criteria for the review of clinical evidence (lines 7-8).	The cost effectiveness model used in CG59 was largely driven by the comparative adverse effect profiles of the different compounds. The GDG felt that

							the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation
SH	Merck Sharp & Dohme Limited	12	Full	44	1 -25	Whilst the criteria is set out for evidence to be included in the health economic review, it seems that the recommendations on NSAIDs and the COX-2 inhibitors have been imported from CG59 (and so based on the economic model in that guideline). This would seem to be inconsistent with the stated criteria. The economic model developed for CG59 received criticism from numerous stakeholders during the guideline consultation phase. Not all of these points were addressed in the final version of the guideline. Furthermore, the model remains unpublished and unavailable (in either a read-only or executable form). Given the implicit central importance of this model in the recommendations made by the GDG, this seems a questionable approach.	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for

							low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation
SH	Merck Sharp & Dohme Limited	13	Full	47	20 - 26	The GDG seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE guideline on the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis*), and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis, appendices*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain? Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing,	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation

						- treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendation in such a way. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline.	
SH	Merck Sharp & Dohme Limited	14	Full	47	20 - 26	The Clinical Guidelines on osteoarthritis were not listed in the set of "related guidance", as described in the final scope. Whilst CG59 was not published at the time, the publication was expected and listed. We are therefore surprised by, and disagree with the inclusion of CG59 as a set of related guidance. We would also seek to understand the GDG's justification for inclusion of the COX-2 recommendations from CG59.	The cost effectiveness model used in CG59 was largely driven by the comparative adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation

SH	Merck Sharp & Dohme Limited	15	Full	51	18 - 19	We acknowledge that patients randomised to radiography were more satisfied than those in the usual care group. This is a very good patient-centred observation and acknowledges the role of radiography in reassuring patients that they do not have a sinister cause for low back pain.	Noted
SH	Merck Sharp & Dohme Limited	16	Full	164	1 -14	There appear to be numerous inconsistencies in the guideline relating to the discussion of NSAIDs and COX-2 inhibitors. In this section, for example, COX-2 inhibitors are not listed as a pharmacological therapy. Elsewhere in the guideline (e.g. page 168), NSAIDs and COX-2 inhibitors are listed as separate agents. We believe this interchanging of terminology could be confusing to the reader, particularly as neither of the COX-2 inhibitors are licensed for low back pain. We request the GDG review the guideline and accurately specify when they refer to (traditional) NSAIDs alone, COX-2 inhibitors alone, or NSAIDs *and* COX-2 inhibitors.	The terminology has been clarified in the guideline. The evidence review was for NSAIDs or COX-2, and this has been clarified in the text.
SH	Merck Sharp & Dohme Limited	17	Full	164	10 - 14	It is stated that CG59 applied "specifically to adults aged 45 years or over who had osteoarthritis". Whilst it is also stated that the balance of risks and benefits may be different in people with low back pain, with specific reference to potential younger age, there is no discussion on the appropriateness, applicability or validity of importing an entire recommendation (on the COX-2 inhibitors). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain?	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that

						We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages applied in the two guidelines (page 164, lines 12-14). The economic model developed for CG59 received criticism from numerous stakeholders during the guideline consultation phase. Not all of these points were addressed in the final version of the guideline. Furthermore, the model remains unpublished and unavailable (in either a read-only or executable form). Given the implicit central importance of this model in the recommendations made by the GDG, this seems a questionable approach. Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline.	the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation

SH	Merck Sharp & Dohme Limited	18	Full	164	10 - 14	The guideline states:- "*The balance of risks and benefits may be different in people with low back pain, many of whom are aged less than 45. In particular, co-prescribing a proton pump inhibitor to reduce upper gastro-intestinal side-effects (PPI) may not always be necessary in younger people.*" This statement is then contradicted on the following page (165 lines 1&2) where the guideline states:- "*In either case, these* (NSAID/COX-2) *should be co-prescribed with a PPI, choosing the one with the lowest acquisition cost*." We would ask the GDG to correct this to avoid confusion.	The recommendation has been clarified to specify prescribing a PPI only in those over 45 years of age
SH	Merck Sharp & Dohme Limited	19	Full	164	12 - 14	The GDG acknowledge that, due to differences in the ages of populations assessed (all ages in this guideline vs. >45 years in CG59), it may be necessary for there to be adjustments in the recommendations taken from CG59. We fully support this acknowledgement. However, this acknowledgement seems to be made without any formal cost-effectiveness modelling. For the GDG to acknowledge this difference is tantamount to acknowledging differences between the two guidelines. We would argue strongly that, if this were to be taken to the next logical stage, it clearly leads to queries on the strength and validity of the entire recommendations in CG59 and their applicability to the low back pain guideline.	Table 10.3.4 (Evidence statements table) explains that the cost effectiveness modelling for the OA guideline was driven by side effects of COX-2. The GDG felt those would be similar in the LBP population than in the OA population and so thought it appropriate and applicable to this guideline's population
SH	Merck Sharp & Dohme Limited	20	Full	164 - 5	24 , 1-2	The GDG seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE	The evidence to recommendations column in the

						guideline on the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis*), and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis, appendices*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain? Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas, - licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendation in such a way. The GDG themselves question the validity of using the	Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their recommendation

						recommendations from CG59, due to the differing ages applied in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline.	
SH	Merck Sharp & Dohme Limited	21	Full	167	20 - 22	The GDG seems to have imported the recommendations on the COX-2 inhibitors from the recently published NICE guideline on the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis*), and it is unclear what validity checks have been performed. Given the lack of explanation regarding the rationale for this incorporation, we can only presume the recommendation stems from the economic model which was developed to assess a variety of treatments for the management of osteoarthritis (*NICE Clinical Guideline CG 59 on osteoarthritis, appendices*). For example, how has it been established that the treatment outcomes and costs associated with a two year duration of treatment for osteoarthritis, apply to a six week to one year treatment duration for low back pain? Whilst we accept that a degree of cross referencing to other guidelines is necessary to achieve consistency and avoid confusion, we do not feel that importing recommendations from the osteoarthritis guideline is warranted here. We would have expected the GDG to have exercised a degree of rigour to ensure that it is appropriate to make such significant assumptions. Specific areas of uncertainty include (but are not limited to) the: - significantly different therapy areas,	The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived from an OA population could usefully inform their

						- licensed indications (COX-2 inhibitors are unlicensed in low back pain), - scale of clinical data available on agents in low back pain vs. other therapeutic areas, - therapeutic dosing, - treatment duration, and - underlying patient populations. We would strongly question the validity of importing the recommendation in such a way. The GDG themselves question the validity of using the recommendations from CG59, due to the differing ages applied in the two guidelines (page 164, lines 12-14). Therefore, unless a revised economic model (assessing the cost-effectiveness of treatments in low back pain, using data from trials in low back pain) were to be developed, and/or a full justification of incorporating recommendations from a different therapy area were to be given, we ask the GDG to remove the COX-2 inhibitors from this guideline.	recommendation
SH	Merck Sharp & Dohme Limited	22	Full	168		We are pleased that in the section entitled "Evidence Statements for NSAIDs/ Cox-2s" that the GDG has identified:- "*Not all traditional NSAIDs or Cox-2 inhibitors are licensed for use for people with back pain.*" If the GDG wish to make recommendations on the COX-2 inhibitors (even though they are unlicensed in low back pain), we would request they adjust the statement to the more factually accurate:- *"At the time of guideline publication, not all traditional NSAIDs, and none of the COX-2 inhibitors, are licensed*	Thank you for your suggestion. Although not licensed specifically for low back pain BNF states that NSAIDS are used for short term treatment of mild to moderate pain including musculoskeletal pain and selective Cox-2 may be used in preference to NSAIDS for patients at high risk of developing gastro-intestinal side effects

						for use for people with back pain." Specifically, the only NSAIDs which are available in the UK and indicated for low back pain are: Emflex® (acemetacin), Diclomax Retard®, Diclomax SR®, Dyloject, Motifene, Voltarol Injection (all diclofenac).	
SH	Merck Sharp & Dohme Limited	23	Full	168		The GDG state that *"insufficient evidence was found concerning the long-term use of oral NSAIDs".* In line with other comments in this response, it is unclear as to whether this comment also relates to COX-2 inhibitors. We agree with the GDG that there is insufficient long-term evidence of COX-2 inhibitors in low back pain. As the only long-term evidence for the COX-2 inhibitors is in patients suffering from osteoarthritis and rheumatoid arthritis, it is inappropriate to assume these data also apply to patients with low back pain. Therefore, for the GDG to incorporate the recommendations of CG59, based on an economic model which used these same long-term trials as the primary input, seems paradoxical. In line with the GDG's statement in section 10.3.4, we believe it is wholly inappropriate to take evidence from other therapy areas and assume it applies to another.	Evidence to recommendations table has been amended to make this clearer The evidence to recommendations column in the Evidence statements table (10.3.4) explains that the justification concludes that there is unlikely to be a difference in therapeutic effectiveness of any NSAIDs/COX-2 inhibitors when used to treat LBP. The cost effectiveness model used in CG59 was largely driven by the comparative the adverse effect profiles of the different compounds. The GDG felt that the comparative incidence of adverse effects would be similar between the osteoarthritis and LBP populations of a similar age. In the absence of any large RCTs directly comparing different NSAIDs or COX-2 inhibitors for low back pain the GDG felt that the adverse effect data derived

							from an OA population could usefully inform their recommendation
SH	Merck Sharp & Dohme Limited	24	Full	168		The GDG states that *"modelling was carried out for over 45 age group"*. However, it is not explicitly stated that the modelling formed part of the osteoarthritis guideline. It is therefore open to interpretation and may mislead the reader. NICE Clinical Guideline (CG59), "*Osteoarthritis: the care and management of osteoarthritis in adults*", February 2008	This has been clarified in the text
SH	MHRA	1	Full Nice	11 164 9	5 &6 20 &21 10&11	The current guidance from the Commission on Human Medicines (CHM) states that the ***lowest effective*** dose of NSAIDs (traditional NSAIDs or COX-2 inhibitors) should be used for the shortest time necessary, and the need for long-term treatment periodically reviewed. Although short-term use has been discussed in the guidance, it would also be helpful to stress that treatment should be at the ***lowest effective*** dose. Furthermore, current guidance from CHM recommends that NSAIDs associated with the lowest cardiovascular? risk (e.g. low dose ibuprofen or naproxen) are *generally* the preferred treatment option.	Thank you for your comment. This was taken back to the GDG and the wording and order of the recommendations has been modified.
SH	MHRA	2	Full Nice	11 164 165 167 9	9 -12 24-25 1 15-18	Although it is acknowledged in the full guidance that "not all traditional NSAIDs or COX-2 inhibitors are licensed for use for people with back pain" neither of the currently authorised oral COX-2 inhibitors (etoricoxib and celecoxib) are specifically indicated in low back pain/ muscular pain. It may therefore be more appropriate to suggest the use of COX-2 inhibitors only in those patients who cannot tolerate traditional NSAIDs.	Thank you . We have amended wording to reflect the point that COX-2 inhibitors do not have licences for use in back pain.
SH	MHRA	3	Full	11	11	The SPCs (summary of product characteristics) for the	The recommendation was taken

			Nice	165 9	&12 1&2 18&19	traditional NSAIDs and the COX-2 inhibitors do not advise their routine co-prescription with proton pump inhibitors. Since the guideline refers to short-term use of NSAIDs, the advice to routinely co-prescribe proton pump inhibitors may not be appropriate.	from the osteoarthritis guideline and recommends co-prescribing PPIs only for those aged over 45.
SH	MHRA	4	Full Nice	11 164 9	7 -11 20-25 12-17	In the event that recommendations relating to COX-2 inhibitors are retained in the guidance, current CHM advice is that COX-2 inhibitors should not be used in preference to non-selective NSAIDs except when specifically indicated (for example high risk of duodenal ulcer) *and* after assessing cardiovascular risk. It may also be beneficial if the guideline includes advice relating to the need to exercise caution in patients at increased cardiovascular risk in relation to COX-2 inhibitors.	Thank you. The guideline has made link to advice in NICE OA guidance on the use of NSAIDs/COX-2s in those aged over 45 who are at most risk of adverse events
SH	MHRA	5	Full Nice	11 164 9	7 &8 22&23 12 &13	Although the absolute risk of side effects is higher in the elderly population and high risk patients, a lower level risk is also present in younger, healthier people. We suggest; *"Give due consideration to the risk of side effects from NSAIDs <u>particularly</u> in older people…."* *or similar.*	The recommendation includes oler people and others at high risks .
SH	NCCHTA referee 1	1	Full	196		Referral to surgery is stated to be out of scope but the GDG have examined it anyway –I am not sure how helpful GPs will find this recommendation – see comments in Section three	. The scope states that indications for referral for surgery would be included within this guideline. In order to recommend who should be referred for specialist assessment we needed to identify which surgical approaches had some evidence for effectiveness and then from these studies identify the characteristics of those recruited in order to make a recommendation .

SH	NCCHTA referee 1	2	Full	General		Generally methods seem sound - however there are a few queries which are due to not including detailed information on the methods.	Noted thank you
SH	NCCHTA referee 1	3	Full	41	4	Appendix G was not included (listed as "TO ADD") and therefore I could not evaluate details of the search criteria and other parts of the review methodology. Examples below.	This will be available on publication
SH	NCCHTA referee 1	4	Full	42	23	How many reviewers decided whether to include a study and how many reviewers extracted data? If only 1 as the methods suggest, this seems to go against normal review methodology – the process is not clear.	The review methodology followed the NICE Guidelines Manual. Only one reviewer worked on the guideline, however they consulted a senior reviewer and the clinical advisor when study selection and extraction were complicated. The reviews are also scrutinised by the GDG members.
SH	NCCHTA referee 1	5	Full	42		Were non-English language studies included? Or grey literature searched? This may have helped identify further studies for areas where there was little evidence,	Due to resources and time available only English language studies were included for review. Grey literature is not normally looked for unless relevant for a specific question. Most of the clinical questions addressed the effectiveness of interventions therefore systematic reviews or RCT's were considered by the GDG to provide the most robust evidence on which to base recommendations. For other questions other study designs were considered.
SH	NCCHTA referee 1	6	Full	52	5	The inclusion/exclusion criteria states that studies with patients with pain <6 weeks or >1 year are excluded. But many studies included these patients as well as those in the required range. For example the trial on p.52 listed	The remit of the guideline stated the target population was patients with pain between 6 weeks and 1 year, however when the GDG felt

						under MRI v. no MRI had almost a half of patients with duration over 12 months. Was it possible for a study to be included for which the majority of patients were outside the required duration?	that a population in a study matched the target population such as recurring episodes of back pain, they agreed to include that paper.
SH	NCCHTA referee 1	7	Full	General		When a systematic review was identified, often a number of the studies in the review were not identified separately which is fine as it avoids double counting. However the process is unclear. Were reviews identified first and primary studies included in these reviews excluded from further searches? Otherwise how did the search strategy fail to pick these studies up?	We searched for both systematic reviews and primary studies. if we found a good quality systematic reviews we would use this and not extract the studies within the review. However the search strategy would still have retrieved them.
SH	NCCHTA referee 1	8	Full	42	13	Studies with less than 20 per arm were excluded as they would have “insufficient power”. However, this is also likely to be true for some included studies which had more than 20 subjects per arm. A better rationale would be that these very small trials would contribute very little even to meta-analyses. I suspect that there would be few trials of such small size and these would be mainly pilot trials. Were pilot trials included in the review?	Pilot trials were not included in evidence reviews. They were excluded regardless of the sample sizes in each arm.
SH	NCCHTA referee 1	9	Full	42 78 81 & elsewhere	6	Only RCTS and SRs are included and not cohort/case-control studies. This may be appropriate but needs further justification as it does not fit into the levels of evidence (given in table 1) which puts observational studies before expert consensus. Observational studies can add useful evidence in certain cases, particularly as many interventions have few RCTs and recommendations are mainly based on the GDG views. For example, it appears from p.78 that cohort studies could usefully have contributed to evidence on patient preferences and treatment expectations.	Most of the clinical questions addressed the effectiveness of interventions therefore systematic reviews or RCT’s were considered by the GDG to provide the most robust evidence on which to base recommendations. For other questions other study designs were considered.
SH	NCCHTA referee 1	10	Full	General		Findings from studies are given based on statistical significance but there is no mention of clinical significance.	Noted. The statistical results provided by the studies are

						Readers and guideline groups should be interested not just on whether statistical significance has been achieved but whether the difference is an important change. How much did the GDG take into account the extent of change or difference between 2 groups? Descriptions in terms of effect sizes rather than mean differences may help assess the comparative extent of change, particularly as often the possible score range for an outcome is not given, or even the actual results are not given, and so it is difficult to evaluate the size of change. The details of trial results in the guidelines are also inconsistent – sometimes giving actual change scores and 95% CI's, other times just stating whether the trial showed statistical significance or not (eg x-ray section compared to information and education section)	reported in the extractions. The GDG were presented the results reported in the studies. The chapters were amended to improve consistency of results reporting.
SH	NCCHTA referee 1	11	Full	General		What was the primary time point for outcome that the group were looking at? Did the GDG concentrate on short term outcomes when change was likely to be greater or long term? This is not clear.	All followup periods given in the trials were reported in the review, however few studies report results longer than 12 months.
SH	NCCHTA referee 1	12	Full	79		6.1.2 advising all people to exercise is not the same as making it an option as stated on p.92	Advice to exercise was reviewed as a separate question to exercise programmes. The comment on p.92 referred to keeping exercise programmes a treatment option for patients and is separate from the general advice to exercise recommendation
SH	NCCHTA referee 1	13	Full	97		It is stated that there is no evidence that 1 to 1 based exercise is better than group – but the 1 review found with low bias and high quality did find that individual programmes were more effective.	The evidence refers to Individually designed exercise programmes (ie designed specifically for the patient), not exercise programmes carried out on a 1 to 1 basis
SH	NCCHTA referee 1	14	Full	179		"conflicting evidence" of antidepressants on pain – based	Despite conflicting evidence for antidepressants to reduce pain,

						on that provided, all the evidence suggests overall that there may be little effect of antidepressants with the only conflicting result being in 2 studies by same author. Was the size of difference between the 2 groups large in these 2 studies and were the studies generally of high quality? Given there is little evidence to suggest antidepressants improve pain, function or depression in LBP, I am not sure the guideline here is supported by the evidence.	the GDG agreed there was little risk and low cost associated with treatment so decided to recommend them
SH	NCCHTA referee 1	15	Full	204		The evidence on referral to surgery is limited, particularly for the population targeted in these guidelines, and essentially recommendations appear based on expert consensus. Whilst apparently sensible, the recommendations seem to be more external to the evidence than the other recommendations given. Given the GDG state this is out of scope, I wonder whether this topic should be dropped and kept for a wider more intensive investigation on effectiveness of surgery?	. The scope states that indications for referral for surgery would be included within this guideline. In order to recommend who should be referred for specialist assessment, we tried to identify those who benefited from surgical treatments rather than reviewing the surgical treatments themselves.
SH	NCCHTA referee 1	16	Full	Appendix B		This is confusing – I am not sure why "number of references" is repeated twice on each row and with different numbers.	Thank you. This will be corrected
SH	NCCHTA referee 1	17	Full	68 170 177	20 4 8	Occasional typos (examples given)	Corrections made in the chapters
SH	NCCHTA referee 1	18	Full	General		These seem generally clear and reasonable given the presented evidence.	Noted thank you
SH	NCCHTA referee 2	1	Full	General		The guideline reflects the scope document in terms of 'cost-effectiveness'.	Noted thank you
SH	NCCHTA referee 2	1	Full	General		The guideline appears to be valid in terms of the health economic components. I am happy with the logic of the model in Appendix E. These models are always an area of dispute between economists in terms of their features. However, the	Thank you for your comment. We will review and consider your suggestion. There is a glossary explaining the health economics acronyms and

						assumptions used are explicit. Presentation is an issue. Figures 2 and 3 are very unappealing and too small. Some in text references to the jargon buster would not go amiss. Many readers of the guideline will be terrified of economic ratios and curves. Table 12. Sensitivity Analysis – too many anacronyms and not writing words and headings in full. Think of the educated lay person, scared of economics.	terms used in the guideline.
SH	NCCHTA referee 2	2	Full	28	4	'Why is this important?' Check this	Noted
SH	NCCHTA referee 2	3	Full	45	9	The model produces a cost utility analysis, rather than the model is a cost-utility analysis.	Changed.
SH	NCCHTA referee 2	4	Full	45	5 -12	This explanation of the economic evaluation methods is not clear. Readers need to work hard to guess at the explanation of the method because it isn't detailed or specific enough.	Section 3.6.2 rewritten.
SH	NCCHTA referee 2	5	Full	45	12	I suggest you use 'model estimates' rather than model 'results'.	Changed.
SH	NCCHTA referee 2	6	Full	55	3	'perceived risk of radiation at £43'. The expression and presentation of this section needs to be carefully rethought. A non-economist might conclude that people are willing to pay for the risk of radiation. Suggest 'people would be willing to pay £43 on average to avoid the radiation incurred during an x-ray.	The summary of this study has been rewritten.
SH	NCCHTA referee 2	7	Full	55	57	Rapid MRI versus X-Ray. This section needs to be rewritten. The problem here is insufficient synthesis concerning the findings of the economic analysis for Hollingworth et al. (2003) and Jarvik et al. (2003). The present exposition jumps between the studies with a separate report on each. It isn't completely clear which study is the object of comments. More synthesis of the findings would eradicate this problem. What is the essence of the two papers? Write about that.	Section rewritten

SH	NCCHTA referee 2	8	Full	57	11	A cost effectiveness analysis was also done – grrrr- another example of poor expression.	Section rewritten.
SH	NCCHTA referee 2	9	Full	108	7	There is repetition in reporting the same study under another section. Why not just report on the additional material and tell the reader to refer to the earlier detail?	Thank you for your suggestion. However keeping the relevant information in the text saves the reader having to look up other sections of the guideline.
SH	NCCHTA referee 2	10	Full	143		Table Health Economics Analysis. This entry needs to be proof read and corrected.	Section rewritten
SH	NCCHTA referee 2	11	Full	158	19	Mentions assumptions and other data used. The assumptions need to be stated explicitly or refer the reader here to the full assumptions in Appendix E.	Agreed. It is not possible to list the assumptions in full in the main text, but we have added a cross-reference to the relevant parts of Appendix E
SH	NCCHTA referee 2	12	Full	162		Table right column…. Sentence beginning 'This strategy…' is very long and confusing.	amended
SH	NCCHTA referee 2	13	Full			Where economic evidence for treatments exists, the evidence to recommendations tables appear to me to be justified. It is conservative in the light of uncertainty and the way this is examined through the Cost-effectiveness Acceptability Curves (CEAC), but economic methodologies lead to a conservative framework for decision making. It is interesting that not all of the economic evidence has been translated into 'evidence into recommendations' in the tables. Perhaps this needs to be further looked at to see if more recommendations could be made. Before that is possible though there needs to be more synthesis of the evidence on cost-effectiveness where more than one study is available for a treatment. This is difficult, but is possible I think.	Have ensured that there is now a "evidence to recommendations" statement in the tables for each of the HE studies included, in all of the chapters.
SH	NCCHTA referee 2	14	Full	17	11	Full stop needed at the end of sentence.	changed

SH	NCCHTA referee 2	15	Full	17	12	There is a random word ‘management’ included.	Changed
SH	NCCHTA referee 2	16	Full	17	17 - 19	Sentence beginning with malignancy needs rewording.	Noted
SH	NCCHTA referee 2	17	Full	17	26	To stay active and avoid best rest – doesn’t make sense.	corrected
SH	NCCHTA referee 2	18	Full	17	30	Comma needed after pain.	corrected
SH	NCCHTA referee 2	19	Full	17	32	Need not needs	corrected
SH	NCCHTA referee 2	20	Full	18	5	Back pain related should be back pain-related	changed
SH	NCCHTA referee 2	21	Full	18	13	‘Are’ not ‘is’.	corrected
SH	NCCHTA referee 2	22	Full	18	14	Explicated? use explained	Thank you
SH	NCCHTA referee 2	23	Full	18 and 19	10-31 1-16	The presentation and punctuation of this whole section need attention	changed
SH	NCCHTA referee 2	24	Full	20	13	Change heading to ‘Audience for guideline’	Noted.
SH	NCCHTA referee 2	25	Full	27		Heading of diagram should include ‘clinical care pathway or ‘care pathway’.	Noted
SH	NCCHTA referee 2	26	Full	45	1	Were not was	Corrected.
SH	NCCHTA referee 2	27	Full	45	2	Analysis should be analyses, with a comma after it.	Corrected.
SH	NCCHTA referee 2	28	Full	45	6	Leave ‘when’ out of this sentence.	Corrected.
SH	NCCHTA referee 2	29	Full	45	6	Comma after monotherapy.	Corrected.
SH	NCCHTA referee 2	30	Full	45	16	Don’t use ‘done’ – this sounds awful read aloud – instead use ‘developed’ or ‘constructed’. In accordance with not in accordance to.	Changed.
SH	NCCHTA referee 2	31	Full	54	9 -12	This is a very long sentence which needs to be rewritten. The reference to Kendrick et al needs to come at the end	Section rewritten.

						of the sentence.	
SH	NCCHTA referee 2	32	Full	54	16	A full stop is needed after society.	Section rewritten.
SH	NCCHTA referee 2	33	Full	54	17	After the word separately change to 'and serve as an indicator of the service perspective'.	Section rewritten.
SH	NCCHTA referee 2	34	Full	54	29	Unit of not unit	Section rewritten.
SH	NCCHTA referee 2	35	Full	55	4	After'at' insert 'a'.	Section rewritten.
SH	NCCHTA referee 2	36	Full	55	5	Will should be would.	Section rewritten.
SH	NCCHTA referee 2	37	Full	55	6	'This intervention' confusing – name it	Section rewritten.
SH	NCCHTA referee 2	38	Full	55	26	After as, 'its' instead of 'the'.	Section rewritten.
SH	NCCHTA referee 2	39	Full	57	17 & 18	Tenses are mixed again.	Section rewritten.
SH	NCCHTA referee 2	40	Full	59	3	'Early imaging was found more costly and slightly more effective'. (Than what???? I wonder) Very poor sentence.	Section rewritten.
SH	NCCHTA referee 2	41	Full	66 74 77 80	30 2 12 5	These sentences should be rewritten so they don't begin with 'no'. This sentence is also used in other places and reads badly.	Your comment has been noted. Thank you
SH	NCCHTA referee 2	42	Full	89	10	presenting not consulting	Changed.
SH	NCCHTA referee 2	43	Full	89	7	Uppercase for Pain exercise and Manipulation	Changed.
SH	NCCHTA referee 2	44	Full	89	6-10	Look at sentence, very long and complicated.	Rewritten.
SH	NCCHTA referee 2	45	Full	89	10 - 13	Confusing sentence, structured poorly.	Rewritten.
SH	NCCHTA referee 2	46	Full	89	16	The Back Book should be in inverted commas	Corrected.

SH	NCCHTA referee 2	47	Full	89	22	Use ‘responses’ not ‘data’ in this sentence.	Changed.
SH	NCCHTA referee 2	48	Full	89	28	Use ‘because’ not ‘since’.	Changed.
SH	NCCHTA referee 2	49	Full	90	1-5	Constantly swapping tenses, poor expression.	Most rewritten.
SH	NCCHTA referee 2	50	Full	90	6-25	Expression, clarity and punctuation of sentences.	Most rewritten.
SH	NCCHTA referee 2	51	Full	94		Table contents are well written.	Thank you
SH	NCCHTA referee 2	52	Full	97	18 - 19	Rewrite sentence so it does not start with ‘no’.	Your comment has been noted. Thank you
SH	NCCHTA referee 2	53	Full	142	8	Was not were	Section rewritten
SH	NCCHTA referee 2	54	Full	144		Table – ‘group were those sick listed’ Not clear at all – what’s this about what group? Tense problems again.	Section rewritten
SH	NCCHTA referee 2	55	Full	156	14	Remove ‘were’ and place after 2004.	Changed in text
SH	NCCHTA referee 2	56	Full	General		The guideline needs to be thoroughly proof read and re-written in parts. Use of English, grammar, syntax, tense confusion and punctuation are all very big issues. A lot of work is needed on this, before it can go out.	Noted thank you
SH	NHS Direct	1	Full	General		NHS Direct have considered the content and make no comment.	Thank you
SH	NHS Quality Improvement Scotland	1	Full	General	General	The authors of the NICE low back pain (LBP) guideline should be congratulated on producing a logically laid out report that is easy to read and in particular sets out recommendations on the type of patient educational information that should be supplied.	Thank you.
SH	NHS Quality Improvement Scotland	2	Full	General	General	NHS Quality Improvement Scotland (NHS QIS) does have reservations about the continued production of clinical guidelines on low back pain (LBP) being produced. In particular the value of producing more guidelines that only relate to patients who do present with LBP and ignore the	Noted. Thank you for your comment.

						group of patients who have referred lower limb symptoms. This latter group are consistently more debilitated and often require more specialised care than those patients with LBP only.	
SH	NHS Quality Improvement Scotland	3	Full	General	General	The strongest message in the guidelines is lost at the bottom of the paragraph at the bottom of page 17/line 28: *'…very few patients presenting with back pain will need further investigation before making a diagnosis of acute non-specific low back pain. The general approach to the treatment for acute non-specific low back pain is advice to stay active and to avoid best rest, plus pain reliving medications such as NSAIDs.'*	Noted. The guideline has been amended to highlight the key message the GDG wanted to make, ie promote self-management
SH	NHS Quality Improvement Scotland	4	Full	General	General	It could be suggested that the initial objective in commissioning the guidelines was not met. The referral from the Department of Health and Welsh Assembly Government, asked the Institute: *…'to prepare a clinical guideline on the acute management of patients with chronic (longer than 6 weeks) low back pain. To include indications for referral and pathways of care.'* However the guidelines committee chose to include patients with pain up to one year. These parameters will produce widely differing groups of patients with differing demands and requirements; a patient with LBP for seven or eight weeks is a very different patient group than those at one year. This will make general recommendations on care difficult to implement and adhere to.	This is correct. The cut off period of 12 months is stated in the scope and this decision was made following stakeholder comments during the scope consultation period. In order to produce a guideline within the timeframe given with the resources available the guideline has focused on the management of people with non specific back pain who have failed to resolve from acute episodes, and to prevent them from developing chronic low back pain.
SH	NHS Quality Improvement Scotland	5	Full	General	General	There was no mention of the term 'Red Flags' This is the accepted worldwide generic term for indicators of possible serious spinal pathology. Although the guidelines refer to	Thank you for this suggestion. This will be considered.

						some individual factors that are seen as red flags it would seem inappropriate to not stick to a clear and consistent terminology in other similar guidelines.	
SH	NHS Quality Improvement Scotland	6	Full	General	General	The authors of the NICE LBP guidelines have been hampered by the varying parameters that have been consistently used in the research of LBP. This is especially evident in Section 7.1 Manual Therapies. The research in this area is difficult to compare as the justified parameters set out in the RCTs by the different authors vary. This has particular relevance to the NICE LBP guidelines as many of the studies used to support the recommendations for manual therapy do not separate between patients with LBP and referred leg pain.	The GDG is aware of the variability in reporting of the distribution of pain in included studies. The GDG has drawn a distinction between referred pain – typically felt above the knee and radicular pain typically felt below the knee. Refereed pain above the knee fits within the definition of NSLBP used for this guideline. Papers where the focus was clearly on radicular pain (sciatica) were excluded.
SH	NHS Quality Improvement Scotland	7	Full	14 16	3 9	There is an inconsistent message being given with regards the natural history of LBP. The guidelines state that most episodes of LBP are short lived. This is contradicted later on in the same section when research is quoted that suggests : *"One year after a first episode of back pain 62% of people still have pain and 16% of these initially unable to work are not working after one year."* This inconsistent message will not aid patients who know that symptoms of LBP are generally not as short lived as thought and are certainly recurrent.	The target population for this guideline is those people who have had NSLBP more than six weeks and up to a year. This includes those who have recurrent episodes. The introduction makes the point that there is little epidemiological data available for this population and that published data does not distinguish between back pain lasting longer or less than one year. However, the aim of the guideline is to prevent the condition becoming chronic.
SH	NHS Quality Improvement	8	Full	17	28	Non mechanical causes, which may indicate possible serious spinal pathology should be always be considered	Agreed. The GDG have recommended that diagnosis be

	Scotland					throughout an episode of care for LBP patients. Therefore caution is raised in respect to the following statement, which does not emphasise the importance of this sort of assessment much earlier in any LBP assessment *"…for those with pain that continues for longer than six weeks or who further deteriorate between six weeks and one year the possibility of a specific cause needs to re considered"*	kept under review.
SH	NHS Quality Improvement Scotland	9	Full	18	2	The guidance on maintaining normal activities is inaccurate. *"The overall objective of treatment of non-specific low back pain lasting six weeks to one year is to ensure that an episode of low back pan does not result in long term withdrawal from normal activities."* This time scale is too wide. By one year it will be too late in most cases to prevent this withdrawal from activities and work	Noted. The time-scale is specified in the scope of the guideline which was consulted on with stakeholders and then agreed with the commissioners.,
SH	NHS Quality Improvement Scotland	10	Full	31		The omission of physiotherapy in the glossary section is a major error. Physiotherapists are the single largest NHS profession who manage LBP. This should be addressed and accurately defined in the final version.	Physiotherapy has been added to the glossary
SH	NHS Quality Improvement Scotland	11	Full	35		The definition of 'McKenzie' is inaccurate and misleading. It requires careful revision. There is sufficient evidence available to support the inclusion of many of the aspects of Mechanical Diagnosis and Therapy, in line with its inclusion is some other recently produced LBP clinical guidelines. A much more accurate definition is : *'McKenzie Method of Mechanical Diagnosis and Therapy* *This is a system of assessment and management for all musculoskeletal problems that uses classification into*	The definition has been amended.

						non-specific mechanical syndromes. Assessment involves the monitoring of symptomatic and mechanical responses during the use of repeated movements and sustained postures. Management involves both direction specific exercises (for instance, extension or flexion) and mobilisation procedures if required. Direction specific exercises are clinically determined by abolition, centralisation or decrease in symptoms, increase in range of movement or other suitable responses.'	
SH	NHS Quality Improvement Scotland	12	Full	34		It is pleasing to see clearly defined the need form patients to be supplied with consistent and validated educational resources.	Thank you for your comment
SH	NHS Quality Improvement Scotland	13	Full	164		The recommendations for the use of anti-depressants in patients with LBP only are unique. Most pharmacological guidelines recommend this medication for neurogenic pain, which presents in referred symptoms	Noted
SH	NHS Quality Improvement Scotland	14	Full	180		The recommendation for the use of acupuncture goes against one of the key messages of these guidelines that *'…general approach to the treatment for acute non-specific low back pain is advice to stay active.'* Attention should be drawn to the key findings from the recently produced NHS QIS Evidence note on acupuncture, which concluded the follow: *- There is insufficient evidence to conclude whether acupuncture is effective or cost-effective for acute low back pain (LBP).* *-Acupuncture is more effective than no treatment and sham acupuncture in the short-term for pain relief in chronic LBP.* *-Adding acupuncture to usual care (or specific treatment) is more effective than usual care (or specific treatment)*	Noted Thank you for your comment.. Advice to stay active is one of the core recommendations of the guidelines and should be recommended to all people with LBP. Acupuncture and all other treatments are offered in addition to this advice. The emphasis on active lifestyle and self management has been made more prominent in the guideline and flow diagram Out of the evidence included, one well conducted large UK-based RCT with relevant population (LBP < 1year) found that acupuncture was associated with

						alone for chronic LBP. *-Two economic evaluations suggest adding acupuncture to usual care is cost-effective compared to usual care alone for subacute and chronic LBP.* *-Evidence directly comparing the effectiveness of acupuncture to other therapies in chronic LPB is limited and evidence for their relative cost-effectiveness is lacking.* http://www.nhshealthquality.org/nhsqis/files/EN24%20Acupuncture%20final.pdf Part of this conflicting message gain can be attributed to the wide variances in research parameters of the RCTs reviewed. Also the patient group covered by these guidelines six weeks to one year will again cloud the issue. Further research should be encouraged before such long passive courses of acupuncture are recommended.	an improvement in pain, at 24 months, compared to usual care. The GDG also considered that further research on the effects on prolonged treatment was required
SH	North West Pain Group	1	Full	general	Guideline development group members list and minutes of meetings of grou	The expertise and consitution of the Guidelines Development Group is an important factor in defining the usefulness of this document in setting standards of care for this difficult group of patients. We are concerned that the skills of the team are not representative of health care professionals currently involved in the NHS care of these patients. As a consequence the group may not be able to grasp some of the issues in the specialist literature. It is of interest that special expertise was recruited to the group when discussing acupuncture, but not when discussing spinal injections. There is ambiguity in your description of the professions represented in the team. Some are referred to by their registered profession eg 'occupational therapist'. Others are described in other ways - 'acupuncturist'. Acupuncture cannot be so identified : indeed the BMAS,	Recruitment to the Guideline Development Group was made following an open and transparent process. The group is made up of a range of health professionals and patient members with expertise in the different areas being considered by this guideline. The GDG are qualified to assess the evidence presented and consider the resulting recommendations. Registered stakeholders were notified of the expertise we required, one of which was an expert in non surgical

					p	the leading organization offering training in acupuncture, insists that its trainees are registered with a health profession. To be consistent, the 'acupuncturist' should be identified by his registered profession.	interventional procedures such as: a Radiologist, Rheumatologist or Anaesthetist with experience and working knowledge of non specific low back pain. All GDG members were selected based on the academic and clinical expertise they could bring to the group, We have edited the titles and professions of the GDG members cited in the guideline.
SH	North West Pain Group	2	Full	132		On *Transcutaneous Electrical Nerve Stimulation* the decision seems to be based on a single RCT (Deyo et al your ref 38). However, we note: 5) The average duration of 4 years means that many of the patients in the study fall outside the scope of this guideline. 6) Patients with nerve root irritation and neurologic deficits are outside the scope of this guideline. 7) Their treatment group received treatment using fixed setting. The use of TENS in a clinical setting involved altering frequency, duration and pattern is used. The statement in the study that 100% patients in the TENS group identified that they received TENS treatment is not a justification enough that the patients received adequate treatment i.e they perceived paraesthesia asscociated with adequate treatment. This is evident from the fact that 84% patients from the sham group with a non functioning device guessed they had a functioning unit and received	This was taken back to the GDG. The Group agreed with their previous decision to use this evidence and agreed a research recommendation should be made. Thank you for recommending these papers; these had been identified during the reviewing process but had subsequently been excluded on the basis of their size (Marchand and Topuz), because no relevant studies were included in the systematic review (Poitras), and because of non relevant outcomes (Deyo 1990)

						the right treatment. We thus have serious concerns as to whether the treatment group received adequate treatment, and whether it was administered in the way it would have been in routine clinical practice. The difficulty of blinding TENS for study purposes has been ignored in their search for relevant literature, despite this difficulty being well described [2,3] We do not understand why the articles by Poitras [4] and well conducted RCT by Marchand [5] and Topuz [6] have not been considered. In our practice we concede that though TENS in itself may not be fully effective as a monotherapy it is an important, safe, and cost effective adjunct to various strategies used in this cohort of patients who can then initiate self treatment. *We request a review of the evidence for TENS . The statement that TENS is 'not recommended for low back pain' cannot be justified when our view are taken into consideration. We commend the following papers to your attention:* 8. Deyo RA, Walsh NE, Scoefeld LS, Ramamurthy S. Can trials of physical treatments be blinded? The example of TENS for chronic pain. American Journal of Physical Medicine and Rehabilitation. 9. Poitras S, Brosseau L Evidence –informed management of chronic low back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound and thermography. The Spine Journal 2008;8:226-233.	

						10. Marchand S, Charest J, LI J, Chenard JR, Lavignollle B, Laurencelle L. Is TENS purely a placebo effect? A controlled study on chronic low back pain pain 1993;54:99-106. 11. Topuz O, Ozfiden E, Ozgen M,Ardic FO. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskeletal Rehabil 2004;17:127	
SH	North West Pain Group	3	Full	200		*Radiofrequency Facet Joint Denervation* is a treatment for pain from lumbar facet joints. In the absence of a clear clinical diagnosis of facet joint pain, the only way of providing this information is by a diagnostic block of local anaesthetic on the medial branch of the primary dorsal ramus of the lumbar segmental nerve. Consistent response to multiple blocks has been described in a well designed study as a way of improving the success of the technique. It is more logical to use medial branch nerve blocks rather than facet joint injections to select patients for Radiofrequency Denervation as it is the nerve that is lesioned by the radiofrequency procedure. Radiofrequency Denervation is a specialist medical technique. The technique involves the production of a controlled lesion which coagulates nerve fibres adjacent to the cannula. As this lesion spreads only laterally, rather than circumferentially from the cannula tip, best practice requires that the cannula is positioned parallel to the nerves supplying the facet joints.[1] Any comment on the value of of *Radiofrequency Facet Joint Denervation* must therefore consider that best practice consists of (1) undertaking the procedure on	In the context of this guideline non-specific pain is that for which there is not a serious cause (tumour sepsis, fracture) In the absence of evidence that any specific interventional techniques are effective, even on carefully selected subjects then there is no necessity to consider these as a different sub-group.

						patients selected after multiple diagnostic nerve blocks and (2) placing the radiofrequency cannula parallel to the nerves supplying the facet joints when performing the procedure. If the literature is considered without reference to these important factors in study design, the value of the procedure will not be demonstrated. It follows that a competent reviewer needs to be familiar with these concepts and the seminal literature that underpins the technique. In this respect , your reference to work of van Wijk (your reference 143) in which a decision was made 30 minutes after a single diagnostic block is flawed. Likewise your reference to LeClair (your ref 93) uses the response to facet joint steroid as a prerequisite for study of facet joint denervation. This may not be a valid way of selecting patients for this procedure, and may overdiagnose facet joint pain. We consider that the LeClair study failed to recruit the right patients, whose findings have already been considered in the systematic review of Boswell (your ref 19) and Manchikanti [2] . We consider that there is a further technique flaw in the van Wijk paper . These authors recognise the value of a properly placed, parallel lying cannula but in our view the images they provide fail to show this. *We present for your information evidence in support of radiofrequency lesioning that is not considered in your guideline*: Nath, Sherdil, Nath, Christine Ann and Petterson, Kurt, 2008.[3] This was a very rigorously conducted study which (1) selected the right group of patients - patients who had	

						consistently more than 80% pain relief with each of the three local anaesthetic nerve blocks and (2) did execute the procedure correctly - radiofrequency canula placed parallel to the nerves supplying the facet joints. In addition they performed multiple lesions at each level taking in to account the variations in anatomy Despite the treatment group having higher pain at base line they reported a 35% reduction of back pain (calculated from data in the article) while the sham group had only 16% at 6 months. 30% pain relief is generally considered to clinically significant in the context of chronic pain management.[4] Van Kleef et al 1999.[5] They studied 31 patients; 15 patients undergoing active treatment and 16 sham. They found the treatment group had more patients with success 66.7% Vs 37.5% (2 point reduction in VAS or >50% pain reduction in global perceived effect) and more mean pain relief 46.2% Vs 7.7%(calculated from the data in the article) at two months. Although recruitment of the patients on the basis of 50% pain relief with single diagnostic nerve blocks falls short of the 'gold standard' (see above), this failure should have reduced the treatment effect. However, despite this flaw and risk of reduction the study found in favour of Radiofrequency Facet Joint Denervation. It is an example, from one of the world's leading exponents of the technique, of the technique at its best, using motor stimulation of the multifidus muscle to provide evidence of the proximity of the cannula to the nerve , an innovation in technique. We consider that there are two RCTs of Radiofrequency Facet Joint Denervation that match our standard of	

						technical rigour in terms of study design and the technique of the procedure. Each found jn favour of the procedure of Radiofrequency Facet Joint Denervation beneficial in chronic back pain.[5,6] This finding is also supported by the technically most rigorous study of all Radiofrequency Facet Joint Denervation studies carried out by Dreyfuss et al 2000 [7] who • selected the appropriate patients (double diagnostic nerve blocks consistently > 80% pain relief). • performed the denervation not only by placing the canula parallel to the nerve • verified the successful denervation by electromyographic studies . This study showed that at 12 months 87% patients achieved at least 60% pain relief and 60% patients achieved at least 90% pain relief with Radiofrequency Lumbar Facet joint Denervation. We believe that it is unsound to dismiss a major study which has important implications for practice just because of its failure to adhere to a strict RCT design. Its description of the technique and the care with which the patients were selected suggests that this provides corroborating evidence to support the available good evidence from RCT. *We commend the following literature to the CDG in support of our claim that radiofrequency denervation*	

						deserves serious consideration of its worth in low back pain 1.Bogduk N Macintosh J Marsland A. Technical limitations to efficacy of radiofrequency nurotomy for spinal pain Neurosurgery 1987;20:529-35 2.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. *Pain Physician* 2002;5:405-418. 3. 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. Spine. 2008 May 20;33(12):1291-7; 4.Farrar JT, Young JP, LaMoreaux L, Werth Jl, Poole M Clinical Iimportance of changes in chronic pain intensity on a 11 point numerical pain rating scale Pain 2001;94:149-58 5.Gallagher J, Vadi PLP, Wesley JR. Radiofrequency facet joint denervation in the treatment of low back pain - A prospective controlled double-blind study to assess its efficacy. *Pain Clinic* 1994; 7:193-198. 6.van Kleef M, Barendse GAM, Kessels A, Voets HM, Weber WE, de Lange S. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. *Spine* 1999; 24:1937-1942. 7. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain.	

						Spine 2000; 25:1270-1277.	
SH	Pain Concern	1	Full	General		This document should greatly improve the management of chronic non-specific low back pain. It is a terrific piece of work. Well done.	Thank you for your comment.
SH	Pain Concern	2	Full	100	17	The number of NHS physiotherapists trained to offer manipulation is too small to be able to cope with the recommendations. And if people are referred to private practitioners such as chiropractors and osteopaths what reassurances are there that they will treat for no more than 12 weeks? (One study found that they tended to overmedicalise their patients, treating them longer than could be justified) Chiropractors still use xrays. How will this be managed? If pharmacological management of low back pain is to succeed patient concordance is important. What reassurances will there be that private complementary practitioners will not offer advice conflicting with that recommended in this guideline regarding medication? How will this be managed?	Service delivery is outside of the remit of this guideline. We have been commissioned by NICE to produce guidance for the NHS, although we would hope that people purchasing treatment privately would find these guidelines useful when choosing treatments.
SH	Pain Concern	3	Full	125		Regarding use of TENS, what circumstances are meant by not routinely? It would be more helpful to have more positive, specific guidance, especially as, if it helps, TENS is cheap, empowers the patient, doesn't require regular visits to therapists (unlike other stimulation therapies eg acupuncture)	This was taken back to the GDG and the recommendation was amended by removing the word "routinely"
SH	Pain Concern	4	Full	General		The recommendations are likely to be controversial, most particularly with regard to epidurals. Medics may need persuasion to come on board.	Noted. Thank you for your comment
SH	Pain Concern	5	Full	General		Good patient information will be needed to accompany the guidelines.	This is currently being considered.

SH	Pfizer Ltd	1	NICE	9	15-19	Pfizer welcome the linking of recommendations to the NICE clinical guideline 59 “Osteoarthritis: the care and management of osteoarthritis in adults” with regards the use of NSAID/Cox-2 inhibitors and the co-prescription of PPI. We are aware that the osteoarthritis guideline recognised that NSAID and COX-2 inhibitors are increasingly regarded as a single drug class of NSAIDs but the separate terms were used for clarity because of the differences in side effect profile. We request the same approach is adopted for this guideline and that COX-2 inhibitors are explicitly stated as an option wherever NSAIDs are recommended.	The wording of the pharmacological recommendations have been edited to ensure clarity
SH	Pfizer Ltd	2	NICE	10	1-2	We request Cox-2 inhibitors are explicitly added as an option alongside opioids. Evidence from a 6 week head to head trial of celecoxib versus tramadol could be added to the guideline to support this recommendation. In a multicenter, parallel group, double-blind, double-dummy, active comparator study, O’Donnell et al (SEE ATTACHED ABSTRACT) showed celecoxib 200mg BID was significantly more effective than tramadol hydrochloride 50mg QID in the treatment of pain associated with CLBP. Celecoxib was also better tolerated with fewer patients experiencing adverse events and discontinuing treatment.	Thank you for your suggestion. The wording of the recommendations have been revised. We have clarified within the pharmacological chapter that NSAIDS and COX-2 may be regarded as a single and drug class the use of the two terms is for clarity and differences in side effects. NOTE FOR NICE – We have not received this abstract and cannot track down this paper
SH	Pfizer Ltd	3	NICE	21		We request COX-2 inhibitors are explicitly added to the “Drug therapies” box in the algorithm as an alternative	Thank you for your suggestion the algorithm will be revised following

						treatment option to mild opioids. This is based on the evidence provided above of the superiority of celecoxib to tramadol and also recognition that COX-2 is a NSAID with a differing side effect profile.	stakeholder comments
SH	Prince's Foundation for Integrated Health	1	Full	General		Despite its inclusion in the list of references, no attention is paid to the Alexander technique research paper published in the BMJ (Little, P et al, 2008. Randomised controlled trial of Alexander technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. *British Medical Journal*, 337, p438–452.) The researchers concluded that, 'One to one lessons in the Alexander technique from registered teachers have long term benefits for patients with chronic back pain.' The research appears robust and was peer reviewed before publication in the BMJ. Accordingly, the omission of Alexander technique lessons from Guideline recommendations Section 1.2 Information, education and patient treatment preferences, seems unwarranted. We urge you to reconsider this omission and recommend Alexander technique lessons as an approved option for the treatment of chronic low back pain.	The Alexander Technique paper has now been included in the reviews for advice to exercise, exercise programme and massage.
SH	Royal College of Anaesthetists	1	Full	General		The Faculty of Pain Medicine of the Royal College of Anaesthetists is grateful for the opportunity to respond to this consultation. The full Guideline consultation was reviewed by all members of the Board of the Faculty as well as by XXXX and XXXX.	Noted
SH	Royal College of Anaesthetists	2	Full	General		The Faculty of Pain Medicine of the Royal College of Anaesthetists is responsible for training, assessment, professional standards and continued professional development of specialist medical practitioners involved in the treatment of pain in the UK. It supports a multidisciplinary approach to pain services and research	Noted

						into improving treatments. The Faculty's response to NICE is submitted in this context.	
SH	Royal College of Anaesthetists	3	Full	General		Low back pain is an important topic. It represents a heavy clinical burden with wide-ranging socioeconomic consequences for the health service and the economy as a whole.	Noted.
SH	Royal College of Anaesthetists	4	Full	General		Serious concerns exist about the title of the Guideline. The use of acute and chronic in the same title is confusing. It might be clearer to say "management between 6 weeks and a year". The real problem however is the term non-specific low back pain. This means different things to different people. For most professionals non-specific low back pain means pain for which no pathological cause can be identified. Again the title could be changed to say "low back pain without an identified cause". For most professionals who treat these patients the crucial distinction is between back pain only and back pain with leg pain. Again this could be made transparent in the title and that might be very helpful for the reader. It is important because the recommendations here would not apply to people with leg pain, and yet one can read the title and the recommendations without this being clear	Noted. We have asked NICE to change the title of the guideline.
SH	Royal College of Anaesthetists	5	Full	General		Unfortunately there is a significant lack of high quality evidence on the management of non-specific low back pain. The available evidence is often very weak and there is a danger of reaching unjustified conclusions and of making recommendations that are not based on reliable evidence.	Noted. The GDG have to use the best available evidence to base recommendations on along with their expertise in the subject. Details of how the GDG came to their decisions are in the evidence to recommendations section of each chapter.
SH	Royal College of Anaesthetists	6	Full	General		Serious concerns have been expressed about the way in which the Guideline Development Group selected and interpreted the data.	Noted. Details of the methodology used are in Chapter 3, and evidence to recommendation

							columns in the individual chapters describe the GDG's interpretation of the data.
SH	Royal College of Anaesthetists	7	Full	General		It is surprising that there are recommendations for acupuncture and spinal surgery (for pain of up to one year duration) even though evidence is conflicting and these techniques have not been recommended by other recent guidelines (e.g. European guidelines for the management of chronic non-specific low back pain Eur Spine J 2006;15(suppl2);s192-300.)	One large well conducted UK-based RCT consisted of the population of interest, showed a positive effect of acupuncture. The accompanying health economic analysis showed it to be cost-effective. All the other papers included a population with LBP over longer duration than 12 months. The GDG agreed that it was appropriate to include those with recurring episodes of LBP which could include those whose last episode was longer than 12 months previously. Evidence was also found in support of spinal fusion.
SH	Royal College of Anaesthetists	8	Full	General		Assuming that this guideline is for patients with back pain and not leg pain (p14 line 26) then the evidence should be drawn from that patient group, and not from studies of patients who have back and leg pain. Similarly this guideline is for patients with pain of duration from 6 weeks to 1 year, yet some of the trials that have been quoted involve patients with pain of duration greater than one year. This may be a more general problem in the interpretation of the literature than just the instances that were commented upon below.	Noted. Section 3.4 mentions when studies with population with pain over 1 year would be included. When selecting studies, if it was unclear whether the study population was relevant for the guideline, the clinical advisor was consulted. If there was still uncertainty the GDG made the final decision as to the suitability of the paper.
SH	Royal College of	9	Full	Gene		A clear distinction should be made for patients with	The guideline is relevant to both

	Anaesthetists			ral		recurrent episodes of low back pain and those patients with a first episode of non-specific low back pain.	groups if they have back pain between 6 weeks and one year
SH	Royal College of Anaesthetists	10	Full	7	14 - 18	The order of key priorities is bizarre - spinal manipulation, then acupuncture before any form of exercise.	This was taken back to the GDG who amended the recommendations order.
SH	Royal College of Anaesthetists	11	Full	7	16	There is no valid evidence for acupuncture (see below). Acupuncture is not recommended in the European guidelines for the management of chronic non-specific low back pain (Eur Spine J 2006;15(suppl2);s192-300.)	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.
SH	Royal College of Anaesthetists	12	Full	11	6	ineffective should be insufficient	The wording has been changed.
SH	Royal College of Anaesthetists	13	Full	11	20	ineffective should be insufficient	Wording was changed in the text
SH	Royal College of Anaesthetists	14	Full	12	2	This is a common misreading of the evidence - 2 of the 3 trials in neuropathic pain show SSRIs to be as effective as tricyclics with fewer adverse effects.	Thank you for your comment but we are uncertain which papers within the systematic review you are referring to. Neuropathic pain is outside of this scope.
SH	Royal College of Anaesthetists	15	Full	12	11	There is no valid evidence to support acupuncture (see below).	Evidence suggests that seeing an acupuncturist was better than

							usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.
SH	Royal College of Anaesthetists	16	Full	12	13	Unclear what this means - botox? epidural? facet joint? trigger point?	The GDG amended the recommendation to clarify.
SH	Royal College of Anaesthetists	17	Full	12	16	Spinal fusion seems a bit drastic in this context. See below.	See answer to comment 18
SH	Royal College of Anaesthetists	18	Full	12	20	Are the authors really suggesting that spinal fusion should even be considered in a patient with non-specific low back pain (i.e. no pathological cause identified) of less than one year duration and who is exhibiting psychological distress? If there is no identifiable pathological lesion then what is the indication for surgery – pain, psychological distress?	The recommendation is to refer people for an opinion by a specialist spinal surgical service
SH	Royal College of Anaesthetists	19	Full	17	26	bed rest not best rest and relieving not reliving	corrected
SH	Royal College of Anaesthetists	20	Full	29	5 -26	This section admits to some degree of uncertainty about these therapies (manual therapy, manipulation and acupuncture) and also that there is not a consistent response across the patient population. Is it too early to	The uncertainty is around the package not individual therapies If anything, the existing evidence

						be producing a guideline for anything other than exercise?	supporting the use of exercise is weaker than that for either manipulation or acupuncture.
SH	Royal College of Anaesthetists	21	Full	29	11	There is a bald statement that acupuncture is a cost effective management option without any citation. This should be challenged because in the absence of valid evidence of efficacy how can it be cost-effective?	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care. A well conducted UK based cost effectiveness analysis study showed acupuncture to be a cost effective treatment
SH	Royal College of Anaesthetists	22	Full	30	1 -15	This section admits to some degree of uncertainty about psychological therapies and also that there is not a consistent response across the patient population. Is it too early to be producing a guideline for anything other than exercise?	The GDG were unable to make a recommendation for psychological therapies based on the evidence found which is why they considered this to be a high research priority.
SH	Royal College of Anaesthetists	23	Full	50	12	Why should a patient with non-specific low back pain (no pathological cause identified) of less than one year duration be referred for spinal fusion?	The care pathway shows that only patients with non specific low back pain of less than one year

							who have failed to respond to at least one course of treatment and who continue to have severe disability following a combined physical and psychological rehabilitation programme *may* be considered for referral for surgery
SH	Royal College of Anaesthetists	24	Full	137	20 onwards	An example of the confounding influence of including inappropriate studies. The evidence here was drawn from studies of patients who have back and leg pain so are of questionable validity for these guidelines.	This was taken back to the GDG who decided to keep this evidence in. The systematic review reported results from studies including a mixed population (some with sciatica some without). We removed the paper on sciatica from this and based on the evidence that there was no effect we changed the recommendation. We deleted the statement that there was an increase in pain in those with leg pain
SH	Royal College of Anaesthetists	25	Full	164 - 176		Confused presentation – it would be sensible to say that analgesia in this situation (as for any nociceptive pain) should follow the 3 step analgesic ladder (1) paracetamol, NSAIDs/coxibs (2) minor opioid as second stage and (3) strong opioid as third stage. Strong opioids should not be presented as a first line treatment of choice for “short term use” for a chronic condition of greater than 6 weeks duration. Have the potential long term consequences of such a recommendation been considered?	Thank you. The order of drug recommendations have been changed to indicate a stepped approach.
SH	Royal College of Anaesthetists	26	Full	164	21	ineffective should be insufficient	changed
SH	Royal College of Anaesthetists	27	Full	165	1	Why is etoricoxib 60 mg here?	The recommendation is taken directly from the OA guideline

SH	Royal College of Anaesthetists	28	Full	165	11	ineffective should be insufficient	Changed
SH	Royal College of Anaesthetists	29	Full	165	16	This is a common misreading of the evidence - 2 of the 3 trials in neuropathic pain show SSRIs to be as effective as tricyclics with less adverse effects.	The evidence for antidepressants comes from a Cochrane review (Urquhart 2008). The results presented in the guideline are those from the Cochrane review. Pooled analysis of 2 trials failed to show a difference in pain between tricyclics and placebo, and another pooled analysis found SSRIs to be no more effective than placebo for pain. No comparison tricyclics vs SSRIs were presented.
SH	Royal College of Anaesthetists	30	Full	166	15	Once again an example of the confounding influence of including inappropriate studies. The evidence is drawn from studies of patients who have back and leg pain so is of questionable validity for this guideline.	Out of the 4 studies comparing NSAIDs to placebo only one mentions low back pain due to sciatica. The others accept patients with some radicular pain but not below the knee and without neurological signs. This fits our population. The study comparing NSAIDs to paracetamol did not include patients with sciatica.
SH	Royal College of Anaesthetists	31	Full	177 - 179		If the patient is depressed antidepressant use should follow depression guideline. If the patient has neuropathic pain then antidepressant use should follow the existing algorithms. If the patient does not have neuropathic pain and is not depressed then they should not be prescribed antidepressants.	Agreed. Thank you for your comment.
SH	Royal College of Anaesthetists	32	Full	180 - 185		The acupuncture trials and systematic review presented here have been heavily criticised elsewhere - one would	The evidence was reviewed following NICE's reviewing

						have no idea that that was the case reading this guideline. All but one trial in the Furlan review included patients with chronic (>12 months) pain. This could easily be construed as a biased reading (bias admitted p185 line 5) of the evidence - bias in the sense of including data selectively, data which would be excluded if the pain duration of greater than a year was invoked. That may not matter, but the guideline actually recommends acupuncture (up to 10 sessions over up to 12 weeks). That is a serious resource commitment to an intervention which many would regard as ineffective and with the recommendation based on data from a chronic (> 1year) patient group. Acupuncture is not recommended in the European guidelines for the management of chronic non-specific low back pain (Eur Spine J 2006;15(suppl2);s192-300.	protocol. One large well conducted UK-based RCT consisted of the population of interest, showed a positive effect of acupuncture. The accompanying health economic analysis showed it to be cost-effective. All the other papers included a population with LBP over longer duration than 12 months. The GDG agreed that it was appropriate to include those with recurring episodes of LBP which could include those whose last episode was longer than 12 months previously.
SH	Royal College of Anaesthetists	33	Full	198		The scope of this Guideline specifically sought "consideration of indications for referral for surgery". The Guideline is dealing with non-specific low back pain without leg pain (pain for which no pathological cause has been identified). Instead of concentrating upon indications for surgery the Guideline has examined specific surgical techniques. Here we read that the Guideline Development Group corrected a published meta-analysis and their correction reversed the authors' conclusion that cumulative evidence did not support spinal fusion. Perhaps more crucial is that at least 2 of the 4 trials included in that review did not exclude leg pain - see Fritzell and Fairbank - so the conclusion that spinal fusion is appropriate in the context of the current guideline - back pain not leg pain - seems a bit unwarranted. Also the studies included patients with pain of more than 12	Erratum has been published. Ibrahim T, Tleyjeh IM, Gabbar O. Surgical versus non-surgical treatment of chronic low back pain: a meta-analysis of randomised trials International Orthopaedics. Category Erratum DOI 10.1007/s00264-008-0665-1 r Data from Fritzell was excluded from consideration as 2/3rds had sciatic pain

						months duration. The inclusion of spinal fusion as an option for patients with non-specific low back pain with no leg pain and less than one year duration is a long way from conventional care. Many would regard this as a highly inappropriate recommendation for the management of non-specific low back pain (i.e. pain for which no pathological cause can be identified).	Fairbank included subjects with referred pain. No specific mention is made of sciatica in the paper Presumption is that patients with sciatica were not part of this study
SH	Royal College of Anaesthetists	34	Full	198	30	This was a meta-analysis and not an RCT.	Agree this has been corrected
SH	Royal College of Anaesthetists	35	Full	General		Conclusion National guidelines for this common clinical problem would be very helpful but these current recommendations are seriously flawed and not suitable for a NICE publication. We believe that there are insurmountable problems with the methodology used by the Guideline Development Group, the strength of available evidence, the interpretation of the data and therefore the conclusions and recommendations. Significantly more work needs to be undertaken on this topic with input from others who will be able to assist in the appropriate interpretation of the available (but scant) evidence.	The methodology used follows the NICE Guideline development methods, which is available from the NICE website. Recruitment to the Guideline Development Group was made following an open and transparent process. The group is made up of a range of health professionals and patient members with expertise in the different areas being considered by this guideline. The GDG are qualified to assess the evidence presented and consider the resulting recommendations without input externally.
SH	Royal College of Nursing	1	Full	General	General	With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests	Thank you.

						on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The RCN welcomes this document. It is timely and comprehensive.	
SH	Royal College of Nursing	2	Full	7	14	From 14 onwards: Perhaps it might be beneficial to make it clear that mono-therapy is first line and then move towards combined therapies if these have not worked. Currently it is written sequentially but as the word consider appears some practitioners may move straight to the combined therapies.	The care pathway has been amended to clearly show that mono-therapy is first-line treatment, with combined therapies if unsuccessful
SH	Royal College of Nursing	3	Full	17	26	This should read 'bed' not best	corrected
SH	Royal College of Nursing	4	Full	17	27	Surely this should be paracetamol in the first instance and/or NSAIDs?	corrected
SH	Royal College of Nursing	5	Full	28	9	'Some researchers' – it would be useful to specify or cite who they are?	Thank you for your comment we will clarify this
SH	Royal College of Nursing	6	Full	General		The evidence used seems quite old, is there no more up to date evidence to back this up?	The bibliographic databases were searched up to the present day and any relevant studies were then identified and selected.
SH	Royal College of Nursing	7	Full	41		Would the search strategy not be better in a table with the number of articles accessed?	A number of searches using different strategies were carried out during the development of this guideline. These will be made available in an appendix on publication
SH	Royal College of	8	Full	60 - 62		The discussion on evidence for and against use of MRI and X-ray does acknowledge that for some patients there	noted

	Nursing					was a higher degree of satisfaction, this needs consideration as part of the way the educational message is put across in the media and by HCPs. Thus the patient's expectations on this can be properly managed.	
SH	Royal College of Nursing	9	Full	63	11 - 12 13 - 14	This part of the guideline talks about taking into account patients' preferences and expectations but this will be guided by any previous knowledge or treatments and should be part of the thrust in a media campaign so real expectations are possible.	Noted. Thank you for your comment
SH	Royal College of Nursing	10	Full	68	20	This should read 'eight'	Change made
SH	Royal College of Nursing	11	Full	78	5.4.3	*Evidence statements for patient preference and expectations of treatments* "The final recommendation was based on group consensus and generic NICE guidance on patient centred care" – As noted in comment 9 above, managing the patient expectations could be a real barrier to successful outcome. Thus needs to be addressed as part of any media / professional campaign to introduce the use of this set of NICE guidelines. It could perhaps be said to be outside the remit of the GDG but the way this is handled before patients come for any treatment should not be ignored. This would certainly fit with some of the recommendations on long-term conditions and the emphasis of working in partnerships with patients / providers.	This is outside the guideline's remit
SH	Royal College of Nursing	12	Full	165	Line 6	Talks about 'specialist assessment' and one could assume this was under the remit of pain management, but care should be taken as access to such services is not universally easy.	Noted. We anticipate that following this guideline such services will become more easily accessible.
SH	Royal College of Nursing	13	Full	168	10.3.4.1	Discussion is on use of Paracetamol or NSAID and in some cases can be used together. Also mentions costs and prescribing but these are available over the counter, so should acknowledge OCR acceptable.	Over the counter medications are outside of the remit of this guideline

						This section also mentions the side effects of NSAID but documentation from assessment stage would have that noted and the HCP should include in discussion stages with patient on use of medication.	
SH	Royal College of Nursing	14	Full	170	4	Typo - should read 'their'	changed
SH	Royal College of Nursing	15	Full	173	10.4.3	*Evidence statements opioids* - The GDG suggests limited evidence for use of opioids but in real terms the need to increase, for some patients the level of medication means that some flexibility should be given to clinicians in practice.	Agree. This is reflected in the recommendations
SH	Royal College of Nursing	16	Full	132	Table	TENS evidence is level 1+ and was not accepted however, education booklet was 1- and was accepted by GDG. This may require further clarification or addition of potential to consider TENS.	The grading of papers reflects methodology and risk of bias. The GDG were presented with 3 papers for the TENS review, one of which was graded 1+. The GDG based their recommendation on that paper. The review on education booklets identified 3 studies, all graded 1-. However the GDG felt and decided based on consensus that education booklets had a role and should be recommended.
SH	Royal College of Nursing	17	Full	198	27	We have some concerns that a GDG member recalculated the figures for the spinal fusion finding a benefit from surgery. We would like further clarification of this point especially as the final way out of the guideline is to offer MRI for potential to have spinal fusion.	Erratum ahs been published. Ibrahim T, Tleyjeh IM, Gabbar O. Surgical versus non-surgical treatment of chronic low back pain: a meta-analysis of randomised trials International Orthopaedics. Category Erratum

							DOI 10.1007/s00264-008-0665-1 r
SH	Royal College of Nursing	18	Full	199	28	Continuing from point 17 above. The document states here that there is little evidence that surgery is as effective as cognitive behavioural therapy (although we note their reservations about this) however there is still a recommendation towards spinal fusion. Perhaps the evidence sits better without the surgical recommendation.	The only patients who would be considered for surgery are those who would already have had a course of intensive physical and psychological intervention. The guidance is for consideration of a surgical referral – not fir surgery itself
SH	Royal College of Nursing	19	Full	gene ral		This is a good piece of work which should inform practice.	Thank you
SH	Royal College of Nursing	20	Full	Gene ral	Acup unctu re	The GDG are recommending this as part of the pathway but access via the NHS is limited in some areas and needs to be flagged up to commissioners of service. Otherwise this will result in unequal access to care, and/or inability to implement guidelines.	Noted. Service delivery is outside of the remit of this guideline. Exercise and manual therapy is recommended as well as acupuncture
SH	Royal College of Nursing	21	Full	Gene ral	Surg ery	It was nice to see that consideration had been given to alternatives for intervention, surgery, if the pain had not settled. Whilst the recommendations for the patient to be seen by a specialist spinal surgeon are sound, it would be nice if this could be cross-referenced to the recommendations made on 18 week pathway for spinal surgical patients.	Thank you for your comment. The 18 week pathway is a generic NHS imperative. The incremental approach of this guideline does not fit easily within the 18 week pathway. It would be exceptional to reach CPP within 18 weeks of presentation. 'We anticipate that the 18 week clock' would start ticking from the time when the decision to refer for a surgical opinion was made. Operationalising this is outside the remit of the GDG

SH	Royal College of Nursing	22	NICE	12 /21	5	It should be highlighted here that an approach consistent with the theory of concordance needs to be taken. This means that patients must be involved in the decision-making. This will improve adherence to whatever therapy is decided upon. The implementation model therefore needs to build in time associated with this type of process. For maximal effect, the practitioner and patient need to build a relationship and this takes time. It will not fit into the current Government objective to cut waiting time as longer appointments will be needed.	Patients having the opportunity to make informed decisions about their treatment and care is stated in the patient-centred care section of the guideline
SH	Royal College of Nursing	23	Full	Gene ral	Gene ral	The launch should be used as an opportunity to link with a public health advertisement about the reality of treating LBP. In some Government papers / NSF and policy statements, much is made of working with patients in 'partnership'. We fully concur with this, but part of the problem in treating LBP is matching the expectations of patients with the interventions possible. In some ways one could say that this is 'treating the patient' before they are needing intervention, and of course the specific remit of this group is 6 weeks to 12 months.	Noted. Thank you for your comment.
SH	Royal College of Nursing	24	Full	Gene ral	Gene ral	There does not seem to be any mention under 'Patient expectations', that in many instances LBP will never be completely eliminated and that people need to understand this. Sometimes it is a matter of managing it. Also LBP does not always mean 'serious back injury' and often people can work with the condition. There is often the expectation that 'I must be completely pain free before I can return to work', the right rehabilitation and work could be beneficial in helping the patient to return to normal life. (The feeling of not been able to return to work causes distress and this can be reflected in the patients' ability to be rehabilitated).	Noted. A key message the GDG wanted to emphasise is the idea of self management of the condition by the patient. Return to work was not one of the outcomes of interest and was outside the remit. There is another guideline in development on the management of Long term sickness and incapacity for work, which includes those off work with back pain

SH	Royal College of Nursing	25	Full	General	General	Should this include a cross reference to the work done via Department for Work and Pensions (DWP) on support for people returning back to work who have been off work for health reasons; a significant portion of whom are linked to Musculoskeletal conditions? As mentioned earlier, from an occupational health point of view, rehabilitation and reintroduction of work is pivotal to 'normal life' and for some this means coping with LBP rather than being 'cured'	We cross refer to another NICE guideline currently in development on management of long term sickness and incapacity for work which includes those off work with back pain.
SH	Royal College of Nursing	26	Full	General	General	We suggest that at launch comment should be made on the reality that possibly this may not hold out the hope of cure but stress more on it enabling patients to control/live with LBP.	Thank you for your suggestion
SH	Royal College of Physicians	1	Full	General		The Royal College of Physicians wishes to endorse the response of the BSR to this consultation.	Thank you.
SH	Royal College of Radiologists	1	Full	General		The Royal College of Radiologists has been asked to review and comment on the draft NICE "Low back pain" guidance. I will comment on the imaging aspects of the document only. These are at variance with "Making the Best Use of a Radiology 6th Edition" published by the RCR earlier this year and bought by the Department of Health for dissemination to hospital trusts and other professionals in the UK. This 6th edition was developed by experts in the field after considering the previous 5 and reviewing the strongest peer reviewed literature evidence. The writing of them followed a Delphi consensus project. The RCR feel that these guidelines are based on the best evidence and good practice. It would be undesirable to have further imaging guidelines for imaging in low back pain which were at variance.	The recommendations made regarding imaging are for the population within the remit for the guideline and not general guidance. We searched and reviewed evidence for this population following the NICE systematic methodology and this was presented and considered by the GDG
SH	Royal College of Radiologists	2	Full	General		Finally the algorithm at the end appears to contradict some of what's in the text.	The care pathway will be revised before publication

SH	Salford Royal Foundation NHS Trust Pain Clinic	1	Full	General	General	The credibility of this document at the outset is undermined by the lack of a Pain Management Clinician on the GDG , who is registered within the Pain Faculty of the Royal College of Anaesthetists. Chronic Pain management which these proposed guidelines include, is best managed by an MDT including Doctors, Physiotherapists and Psychologists, which reflects the membership of The British Pain Society. We think the remit given 6/52 to 12/12 is unnecessarily restrictive given what we know about chronic pain (i.e. a surprisingly high % have pain & disability that persists beyond the 6/52 period). A few refs: Philips, HC & Grant L. The evolution of back pain problems: a longitudinal analysis. Behav Res Ther, 1991; 25(5): 435-41. Basically 40% of 117 patients followed from acute onset complained of pain @ 6/12 - 20% moderate to severe. von Korff M & Saunders K. Spine, 1996 Dec 15; 21(24): 2833-7; discussion 2838-9. 33% reported intermittent or persistent pain @ 12/12 following onset, 1:7 severe pain, 1:5 substantial activity limitations.	The Clinical Advisor on the group is a Professor of pain management who practices within the NHS. Recruitment to the GDG follows an open and transparent process where stakeholders are notified of the expertise we require and asked to consult with their members. It is not part of the process that people have to belong to any particular organisation. We specify in the guideline that those delivering the recommended interventions should have the necessary qualifications and competencies. The proposed constituency of the group was presented at the Stakeholder meeting at the start of the development period and no concerns were raised.
SH	Salford Royal Foundation NHS Trust Pain Clinic	2	Full	27	flow chart Box titled 'core	Clarification about where this should be delivered, ie Primary or secondary care.	Service delivery is outside the remit of the guideline

					therapies'		
SH	Salford Royal Foundation NHS Trust Pain Clinic	3	Full	27	flow chart box titled 'Courses of therapy' ACUPUNCTURE	Evidence for effectiveness of acupuncture is poor Bandolier Pain site states in its review of Acupuncture and Back Pain…… The question is whether this review provides evidence of lack of effect, or lack of evidence of effect. The inability of the four highest quality blinded trials to show a statistically significant short-term improvement must be worrying for those providing acupuncture services, and for the health services or individual who purchase acupuncture. A sceptical view seems to be most appropriate until trials of high quality prove that to be wrong. Reference: 1. E Ernst, AR White. Acupuncture for back pain: A meta-analysis of randomised controlled trials. Archives of Internal Medicine 1998 158: 2235-2241.	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.
SH	Salford Royal Foundation NHS Trust Pain Clinic	4	Full	164?	12.2.1	The primary objective of a Pain Management Programme is NOT pain relief but to reduce Pain associated disability and distress Ref Surgical stabilisation of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: cost utility analysis based on a randomised controlled trial Oliver Rivero-Arias, Helen Campbell, Alastair	Noted The outcomes sought when searching the available evidence were pain, disability and distress. The recommendations are based on the data on all thereof these outcomes.

						Gray, Jeremy Fairbank, Helen Frost, James Wilson-MacDonald for the Spine Stabilisation Trial Group BMJ 2005 330: 1239.	The cost effectiveness was additionally considered by the GDG
SH	Society and College of Radiographers (SCoR)	1	Full	General	General	The guidelines need to be clear that they are only applicable to episodic back pain if one episode has persisted for at least 12 weeks, as per The COST B13 European Guidelines for the Management of Low Back Pain. S208.(European Commission 2006). Users of this guideline may currently define chronic as episodic hence the distinction needs to be made more clearly.	The scope for this guideline was low back pain duration of at least 6 weeks and up to 1 year. The guideline includes recurrent episodes within the time frame stated, however we agree this may not be clear and the text has been edited to clarify the target population .
SH	Society and College of Radiographers (SCoR)	2	Full	General	General	The COST B13 European Guidelines are well written, easy to read and well researched. Therefore, The SCoR is unsure why NICE does not adopt these guidelines and merely update them with any new evidence post 2006. Both sets of guidelines are very similar in their recommendations with the exception of acupuncture.	NICE develop evidence based guidelines using a particular methodology. This is available from the NICE website.
SH	Society and College of Radiographers (SCoR)	3	Full	11	General and 2.7.	Throughout the document, reference is made to 'psychological factors' but not social factors, despite a growing body of evidence suggesting social factors also influence outcomes in CLBP. Also, many of the included studies have used the SF 36 scale which measures psychosocial function. The SCoR suggest changing the slant from psychological to psychosocial and incorporating the evidence that demonstrates both psychological and social factors influence outcome.	Noted. Whenever the SF-36 scale was used in the studies the results were reported.
SH	Society and College of Radiographers (SCoR)	4	Full	General	General	These guidelines appear to 'medicalise' CLBP and do not have enough emphasis on reassurance to the patient that their condition is not serious.	In the revision of the guideline the GDG is emphasising a key message of advice and information to promote self management of low back pain.

							This will be made clearer in the guideline.
SH	Society and College of Radiographers (SCoR)	5	Full	General	General	Throughout the document there are references to both 'non specific low back pain' 'low back pain' and 'chronic low back pain'. For ease of reading, one consistent term should be used, such as 'chronic non specific low back pain' which can be abbreviated to CNSLBP.	Agreed. This will be addressed
SH	Society and College of Radiographers (SCoR)	6	Full	General	General	Some of the guidelines are recommended on the basis of good quality evidence, whilst others are recommended on consensus of the GDG. Where the latter is true this needs to be clearly stated on the resultant short format of the guidelines to prevent the opinion being taken as evidence based fact. Absence of evidence is not evidence of absence. In addition, it appears some treatments are not recommended despite evidence (which is being classified as weak) showing some benefit (i.e. low level laser therapy). This is confusing for the reader, particularly as other guidelines are being recommended on the basis of consensus alone, for which the evidence is even weaker. Some evidence has been included which, it may be argued, is not entirely relevant to this guideline (i.e. some included RCT's have been undertaken outside of the UK, or include acute/sub-acute populations). In contrast some evidence has been excluded because it was ruled as not relevant to the actual question. Hence the selection of evidence for each guideline appears inconsistent throughout the document and there are no clear explanations indicating why each piece of evidence was included/excluded.	The guideline developers are required to provide the full detail of the evidence and grading of studies in the full version of the guideline, and to provide a quick guide to the recommendations in the NICE version. All the recommendations within the guideline have been made by the group with the information available following a systematic process of looking for and reviewing the evidence available. The reasoning behind the GDG's decision to recommend an intervention or not is described in the relevant Evidence statement Table, in the evidence to recommendation column. Noted. The general methodology that was followed for identifying and selecting evidence is described in chapter 3.
SH	Society and College of	7	Full	11	General	The recommendation for offering manual therapy, acupuncture and/or structured exercise programme is	Thank you. The wording of the recommendations has been

	Radiographers (SCoR)				1.8.1.	confusing. In sub note 1 under 'Key priorities for Implementation' it suggests a choice of any of these therapies may be offered as a stand alone, taking into account patient preference. However in sub note 2, Section 1.3.3 it suggests that the choice of exercise and manual therapy should be offered AND a course of acupuncture. Therefore it is unclear whether acupuncture should be offered as a stand alone or whether it should be used in conjunction with manual therapy/exercise (See comments below in Section 11). In section 1.8.1 the guidelines again suggests acupuncture can be used as a stand alone therapy.	reviewed and modified.
SH	Society for Back Pain Research	0	Full	GENERAL		The membership of the society were widely consulted and encouraged to comment. Very many positive comments were made in praise of the main thrust of the document and the quality of evidence considered in the development of the guidance. We recognise the hard work that has gone into the draft and understand the importance of positive feedback for the group that have devoted time to this topic. The comments we have made are intended as positive and constructive to assist in the eventual implementation of them.	Thank you
SH	Society for Back Pain Research	1	Full	General		There is a need for a measure of treatment effect. Some treatments are obviously more effective than others and it is not apparent or clear.	We have reported treatment effects when included in the papers.?
SH	Society for Back Pain Research	2	Full	General		A timeline of which treatment first and a hierarchy of benefit and cost would contribute to the utility of the guidance	Noted. The algorithm has been amended to clarify the hierarchy and timeline of treatment.
SH	Society for Back Pain Research	3	Full	General		Non specific back pain is a diagnosis of exclusion of serious spine disorders and neural compression. MRI or other imaging may be required to establish that it is indeed non specific back pain.	Noted. Section 4.1 covers this point.
SH	Society for Back Pain Research	4	Full	General		Psychosocial: There is no mention of identifying and addressing psychosocial obstacles to recovery	We did consider psychosocial screening and whether it was

						(yellow/blue flags) – whilst the evidence on effectiveness may be limited, the principle is well accepted and is recommended in previous guidelines.	possible to identify which people may gain greatest benefit from treatments but we did not find any papers with our included outcomes. However the GDG considered this was an important area for further research and this has been included as a key research recommendation within the guideline.
SH	Society for Back Pain Research	5	Full	General		Work: There are no recommendations in respect of helping patients back to work, yet this is a major individual and social outcome (and the subject of considerable government interest). There is considerable evidence from the vocational rehabilitation as well as back pain fields that communication between healthcare and employer is crucial: should this issue not be covered in the guideline?	Another guideline currently in development is specifically focusing on the management of long term sickness and incapacity for work.
SH	Society for Back Pain Research	6	Full	General		Patient education: this is recommended but without advice on its content ('consistent with this guideline' won't do the trick) – the European prevention guidelines tried to tackle this problem by making the distinction between biomedical and biopsychosocial [Information and education about back problems, if based on biopsychosocial principles should be considered, but information and education focused principally on a biomedical or biomechanical model cannot be recommended].	Thank you for your comment, this will be addressed in the revision of the guideline
SH	Society for Back Pain Research	7	Full	20	16 ,17	Given the detail of the Musculoskeletal Services Framework and the promotion of interface services (iCATs, MCATs), clarify if these guidelines are relevant for care within those services. currently mentions primary and secondary care settings only	Thank you for your comment, this has been clarified
SH	Society for Back Pain Research	8	Full	45	5	refers to 'intensive' combined physical and psychological interventions, but it is not clear what intensive means. A definition is provided later in the guideline, but either	Link made.

						define it here in a footnote or make a clear link to the definition later in the guideline.	
SH	Society for Back Pain Research	9	Full	28 - 30		screening protocols: easy to use decision tools/aids are needed to help clinicians select patients for targeted treatments. This should be a research priority given the need to help patients access care without excessive delay. This recommendation about screening protocols could go further, rather than only calling for further research on screening protocols, further research also needs to develop and test simple ways of better matching patients to different treatment options, for use by busy clinicians. Future research needs to address how best to profile / subgroup / screen patients for targeted treatments.	Thank you for your comment.
SH	Society for Back Pain Research	10	Full	28 - 30		In the guideline, patients with complex distress problems are recommended to go through 'core' treatment first and only those who continue to have problems then get access to combined psychological and physical (CPP) interventions. This means unfortunate delays for the relatively small proportion of patients who are at highest risk of poor outcome. These patients are the most complex patients, in physical and psychological terms. Delays in appropriate treatment for this group will serve to encourage chronification of their symptoms and make them more recalcitrant to treatment. Further research needs to work out not only which patients might benefit most from exercise, manual therapy and acupuncture, but also which patients might benefit most from early interventions that target key psychological obstacles to recovery. Leaving this group to go through unhelpful monotherapies first before accessing more appropriate targeted treatment is not best practice. The problem is	The research recommendation explains that currently there is no UK study that demonstrates that targeting treatments based on a risk factor profile leads to improved outcome or cost effectiveness

						that we do not yet know how to systematically identify these patients early in their episode of pain. Work is underway in the UK to do this (see Hill et al 2008 for an example of a subgrouping tool for primary care patients with low back pain and the StarTBack trial by Hay et al which is in progress, testing usual care versus a subgrouping for targeted treatment approach).	
SH	Society for Back Pain Research	11	FULL	28 - 30		The guideline states there are no studies that show benefit of screening or subgrouping for targeted treatment approaches, but it could mention that such studies are ongoing within the UK (eg. The ARC funded StarTBack trial led by Keele University, Hay et al which is due to be completed in autumn 2009) and make a statement that such evidence will be viewed in the updated guideline. This would make readers of the guideline aware that such research is underway and could serve to better identify patients for different treatments.	Thank you for your comment. We are unable to comment on ongoing trials, however as part of the guideline development process consideration will be given to new evidence that may change a current recommendation when considering an update to the current guideline.
SH	Society for Back Pain Research	12	Full			. It is a pity that this chapter did not attempt to provide guidance on how a biopsychosocial assessment can be conducted successfully, and how to reasonably assess key risk factors or obstacles to recovery in this patient population. It was also a pity that the content of this chapter did not provide any guidance on how to incorporate assessment findings (for example on key obstacles to recovery) into decision-making, with the patient, about treatment decisions. The chapter is titled 'Assessment' but the content of the chapter does not really provide guidance on the assessment of a patient with low back pain of more than 6 weeks and less than 12 months – rather it is very limited to guidance about diagnostic testing. Could something be added which states the scope of this chapter more accurately and/or explain the breadth of other issues of patient assessment	Title has been changed

						that this chapter does not address. If the reason for the lack of detail on other issues of assessment is related to the lack of available evidence, then a clear statement about this would be useful.	
SH	Society for Back Pain Research	13	FULL	8	14	Guidance for MRI SHOULD include recommendation for scan if neural compression a possibility. Sciatica and spinal stenosis are very treatable.	Section 4.1 in the Assessment and Imaging chapter covers this point.
SH	Society for Back Pain Research	14	FULL	8	12	Sub groups may benefit where evidence is not present i. e. elderly patient may benefit from corset to initiate process of mobilisation when medication may risk falls or sedation	Noted. Sub group analysis was outside the scope.
SH	Society for Back Pain Research	15	FULL	15	7,8	Concern that Rh Arthritis is given as specific cause of back pain. This could result in primary care screening for RF and referral to rheumatology if positive	Agree. The Box of specific causes of LBP has been modified and rheumatoid arthritis removed from it.
SH	Society for Back Pain Research	16	FULL	27		Algorithm omits imaging for neural compression. SERIOUS risk that the message is imaging only required for cauda equina.	Neurological disorders are outside of the scope of this guideline.
SH	Society for Back Pain Research	17	FULL	27		Algorithm	
SH	Society for Back Pain Research	18	FULL	110 111		The terms 'manual therapy' and 'manipulation' are used interchangeably throughout the guideline which will serve to cause confusion. Can the terms be used consistently throughout and a definition given to explain what is meant by the chosen term. The term 'manual therapy' encompasses high velocity thrust techniques and lower velocity mobilisations for example and thus is preferable. The recommendation to provide up to 12 sessions of manual therapy will be a considerable challenge for implementation. Presumably the guideline group are not recommending how, or who, delivers these services and they will leave it up to local decision-makers as to how these services are provided?	Thank you for your comment. The chapter was amended to improve consistency of terminology.
SH	Society for Back	19	FULL	156		The development of primary care-based / or interface	Noted

	Pain Research			159		clinic-based pain management programmes with multidisciplinary input would be a welcome service addition as well as upskilling primary care professionals (GPs, physiotherapists and so on) to more systematically identify and target treatment to complex patients with significant physical and psychological obstacles to recovery. This type of intervention would be more like the lower intensity pain management programme delivered by the physiotherapists in the trial by Critchley et al (2007) mentioned on page 156/157. The cost-effectiveness analysis of this trial showed the brief pain management programme to be cost-effective, but there was considerable uncertainty around the estimates. No cost-effectiveness studies were found for intense pain management programmes (combined physical and psychological packages) yet further modelling based on one study (Haldorson) and a number of assumptions suggested that for those people with a poor prognosis where a monotherapy had failed, a more intensive CPP would yield more QALYs and be more cost-effective (page 158, lines 22-24). This all feels rather spurious and slightly different assumptions could lead to very different recommendations. Given the lack of good quality cost-effectiveness data on brief and intense combined physical and psychological interventions, it would be better for the guideline to highlight these issues as topics for further research and refrain from recommending intense CPP over brief mixed CPP packages, for this patient population, until robust RCT evidence is available from UK settings.	The GDG has made screening to facilitate treatment recommendations, including the intensity of treatment approaches a research recommendation.
SH	Society for Back Pain Research	20	FULL	180 - 191		The RCT's of highest quality (three) show no benefit when acupuncture is compared to sham. Why is the recommendation so high for up to 10 treatments when	The evidence suggests that seeing an acupuncturist was better than usual care but not

						there is no effect when taking the best level 1 evidence. The recent systematic review of acupuncture was not available at the time of draft. It is now available and should be included. Effectiveness of Acupuncture for Low Back Pain: A Systematic Review Yaun et al . Spine: Volume 33(23), 1 November 2008, pp E887-E900	much difference between acupuncture and sham. However, acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore this should be considered as a possible treatment. Three of the five studies describe duration of treatment as up to 10 sessions. The GDG used this information to inform their recommendation on the number of sessions. Thank you for mentioning the recent systematic review. We considered it and… Thank you for mentioning the recent review by Yuan et al. We obtained a copy and found that the included studies were either already included in the guideline (through inclusion in the Cochrane review or separate inclusion) or they were excluded because of sample size or design. Moreover the conclusions are consistent with the recommendations from this guideline
SH	Society for Back Pain Research	21	FULL	General		Red flags may not be present and first assessment. A definite red flag is failure to improve with time in the presence of a non variable pain. Repeat clinical	Agreed. The algorithm and text now mention to keep the diagnosis under review.

						reassessment needs to be stressed with this in mind. Reassessment must be carried out by someone suitably skilled to recognise serious spine pathology.	
SH	Society for Back Pain Research	22	FULL	General		The title. To have the acute management of patients with chronic non-specific back pain is unnecessarily complex. Can the word 'acute' be omitted?	Agreed. We are recommending to NICE that the title be changed.
SH	Society for Back Pain Research	23	FULL	10	9	In section 1.5.4, the terminology is odd and inconsistent with other sections when it states that TENS should not be offered 'routinely'. Does this mean at all? To be consistent with other sections, this needs to be clarified.	Thank you. This was taken back to the GDG who amended the recommendation to keep the terminology consistent.
SH	Society of Orthopaedic Medicine	1	Full	General		There is inadequate evidence to support NICEs guideline of not offering traction due to the increased risk of aggravating symptoms. Current literature provides conflicting evidence for the efficacy of traction and this has been interpreted, in error, to mean that traction is an ineffective modality for the treatment of lumbar disc herniation (Unlu *et al* 2008). Reviews of clinical trials of traction for low back pain with or without sciatica have found it to be effective in improving pain, compared to placebo, sham or other treatments (Macario *et al* 2008). According to Beurskens et.al (1995) the supposed mechanical effects of traction are vertebral separation and widening of the intervertebral foramen which suggests short-term effects. Data does exist supporting the use of traction to widen the intervertebral space, reduce disc protrusion and intradiscal pressure and improve motor evoked potentials and leg mobility (Unlu *et al* 2008). Part of the applied traction force is needed to overcome opposing forces of friction of the body on the table-top, muscle contraction, spinal curvatures, ligamentous resistance and friction of the machinery. Lumbar traction forces below 20% of the body weight can be regarded as sham (or low dose) traction and a few case reports suggest some danger when the force applied exceeds	This was taken back to the GDG who removed the note about increasing risk of aggravating symptoms. Thank you for referring to studies. The study by Beursken was included in the systematic review by Clarke. Macario and Harte were picked up in the update searches but were excluded because of study design. Unlu was excluded because of inadequate control. The study by Ozturk was not picked up in the database searches because there was no mention of low back pain in the abstract. Regardless, the population was inappropriate for the guideline as over 80% had sciatica

						50% of body weight (Beurskens *et.al* 1995). Despite the lack of research to support the use of traction a UK-wide survey indicated that 41% of therapists used traction with 5% of LBP patients, who almost exclusively presented with 'nerve root' problems (Harte *et al* 2007). A study by Ozturk *et al* (2006) demonstrated that continuous lumbar traction significantly reduced the size of disc herniations, and improvement in patients straight leg raise, sciatic pain and motor loss. This was a prospective, randomized, controlled study, of 46 patients with lumbar disc herniation, and randomized into two groups as the traction group (24 patients), and the control group (22 patients). The control group had physical therapy (hot packs, ultrasound and diadynamic currents) and the treatment group had all of the above plus 15 mins of continuous traction daily, starting at 25% of body weight, increasing to 50% of body weight. The patients had their disc herniations confirmed by CT scan prior to entering the study and then they were scanned again after and the scans interpreted by a "blind" expert radiologist. The study concluded that lumbar traction significantly reduced the size of disc herniations, and patients with greater herniations tended to respond better to traction. Broadly based research trials into traction for low back pain may produce conflicting evidence due to the presence of clinically diverse subgroups in the low back pain population who may respond differently to different types of treatment. Preliminary work into subgroups suggests that traction may be effective for patients with radicular pain and neurological deficit (Unlu *et al* 2008). In addition physical therapy is characterised by diverse combinations of treatments but in studies traction and	

						other modalities are often used in isolation. Explanatory trials subjecting all non-specific LBP patients to the same treatments may not therefore provide the answers sought. (Harte *et al* 2007). Pragmatic randomised trial designs may be a more suitable means of investigating the use of traction in the physiotherapy treatment of low back pain. They reflect the clinical environment allowing therapists the flexibility to treat patients individually using a polytherapy approach, based upon clinical reasoning, within a wider research protocol (Harte *et al* 2007). In a study by Unlu *et al* (2008) the outcomes of treatment with intermittent traction, ultrasound, and low-power laser therapies were measured and compared in patients presenting with acute leg pain and low back pain caused by lumbar disc herniation (LDH). Outcome measures were magnetic resonance imaging (MRI) and clinical parameters (lumbar spine physical examination, severity of pain, Roland Disability Questionnaire and Modified Oswestry Disability Questionnaire). MRI's were done before and immediately after treatment. Measures were carried out at baseline, immediately after, and at 1 and 3 months after treatment. Significant reductions in pain and disability scores and size of the herniated mass on MRI were found between baseline and follow-up periods. There was no significant difference between the 3 treatment groups at any of the follow up assessments. This study showed traction, ultrasound, and laser therapies were all effective in the treatment of this group of patients with acute LDH but there was no difference between the treatment groups.	

						In a review of case notes of patients treated with traction, Macario (2008) found that after 8 weeks of treatment, pain and analgesic use had significantly reduced and activities of daily living had improved. Patients in this study had unsuccessful treatment with other conservative modalities. The review consisted of an audit of 100 outpatients with discogenic LBP lasting more than 12 weeks treated with a 2-month course of mechanical traction. Treatment was delivered for 28 to 30 minutes daily for the first 2 weeks, three times per week for two more weeks, tapering to one session the last week for an average of 8 weeks. The weight was raised in increments of 5 to 10 lb per session for the first three sessions as tolerated until a final weight of 50% body weight plus 10 to 20 lb. No complications were noted in the 94 patients studied that completed treatment. Based on survey data suggesting that traction is most frequently used in clinical practice to treat nerve root problems, Harte *et al* (2007) carried out a feasibility study comparing the difference between two treatment protocols, manual therapy, exercise and advice, with or without traction in the management of acute/sub acute LBP with 'nerve root' involvement. Improvement occurred in both groups throughout the trial but with little difference demonstrated between the groups; however this could be due to small sample size involved. There were also some differences between the groups in baseline demographics and measures which may have affected the results but these would be overcome if this study were to be developed into a larger randomised trial. As no control group was used in any of these studies (Unlu *et al* 2008, Macario *et al* 2008, Harte *et al* 2008)	

						improvements may have been attributable to the passage of time and the self limiting nature of most episodes of acute leg and low back pain. An older study by Beurskens *et al* (1995) compared static traction with 'sham traction'. Static traction was given until the patient indicated that the tolerance for pulling was reached with a minimum force of 35% and a maximum of 50% of body weight. Sham traction was given by a brace around the iliac crest which became tighter in the back and patients were advised they should feel pulling from the braces which was slowly increased to a maximum of 20% of bodyweight. This blinded patients to treatment allocation. The research physiotherapist carrying out pre and post treatment measures was also blinded to treatment allocation. This study found that the effect of traction did not depend on the amount of force applied. Patients with non-specific LBP were selected for this study and the ambiguity in diagnosis may be one reason why there appeared to be no difference in the effects of traction and 'sham traction'. No distinction was made between patients with disc, facet joint or muscular pain. Subgroup analyses were performed with regard to appropriateness for traction according to the physiotherapist, and radiation below the knee to try and address this issue. No effect of traction was found in any of the subgroups. <u>Summary comments</u> ▪ Traction is a frequently used treatment by physiotherapists, particularly for radicular/neuro symptoms ▪ Lumbar traction can reduce the size of disc herniations, with greater herniations tending to	

						respond better to traction ▪ Traction in excess of 50% of body weight is the only mention of adverse affects but Marcario *et al* (2008) used more than 50% body weight and reported no ill affects. ▪ Studies have weak methodologies, no control groups, samples consisting of a mixture of sub-groups (non-specific back pain, nerve root pain, muscular pain, facet joint pain) ▪ Studies tend to use traction in isolation which does not reflect clinical reality where it may be one component of a physiotherapy management package. ▪ Pragmatic RCT's of traction as a part of a broader protocol would address this. Therefore, taking into account all of the evidence, the SOM believes that the draft NICE guideline discouraging the use of traction is fundamentally flawed and we would strongly urge this position, and the evidence for it, to be reviewed. <u>References</u> Beurskens, de Vet, Koke, Lindeman, Regtop, van der Heijden, Knipschild (1995) Efficacy of traction for non specific low back pain: a randomised clinical trial. Lancet 16;346 (8990):1596-600 PMID 7500752 Harte, Baxter, Gracey (2007) The effectiveness of motorised lumbar traction in the management of LBP with lumbo-sacral nerve root involvement: a feasibility study. BMC musculoskeletal disorders 29; 8;118 PMID18047650 Ozturk, B., *et al* (2006). Effect of continuous lumbar	

						traction on the size of herniated disc material in lumbar disc herniation. Rheumatology Int, 26: 622-626. Macario, Richmond, Auster, Pergolizzi (2008) Treatment of 94 outpatients with chronic discogenic low back pain with the DXR9000: a retrospective chart review Pain Practice 8 (1): 11-17 PMID 18211590 Unlu, Tasci, Tarhan, Pabuscu, Islak (2008) Comparison of 3 physical modalities for acute pain in lumbar disc herniation measured by clinical evaluation and magnetic resonance imaging. Journal of manipulative and physiological therapeutics 31 (3): 191-8 PMID 18394495	
SH	Society of Orthopaedic Medicine	2	Full	10	15	Quote from consultation guideline document: "1.5.6 Do not offer traction because of the increased risk of aggravating symptoms." There is a lack of evidence that traction worsens symptoms, in fact there is emerging evidence that traction is of value in certain subgroups of low back pain patients, particularly those with radicular or neuro symptoms and in combination with other treatments. Conflicting evidence highlights the need for quality research into the efficacy of traction in various subgroups of low back pain patients in appropriate settings. However, NICE will effectively preclude such research in the UK if health professionals are advised against this treatment modality in the first place. It would be a great shame to abandon a potentially beneficial treatment modality just because it is perhaps not always targeted at the most appropriate patients. Conversely, efforts should be going into researching and	Thank you for your comment. This was taken back to the GDG who amended the recommendation for traction. The evidence was based on a mixed population of patients with and without sciatica.

						demonstrating which patients will benefit from traction and under what circumstances.	
SH	Society of Orthopaedic Medicine	3	Full	49	16	Quote from consultation guideline document: "The syndrome of radicular pain due to nerve root compression (sometimes called sciatica) is a different clinical syndrome; its management is not part of this guideline." This implies that the basis of the draft NICE guideline does not include radicular pain, however the evidence (stated on pages 138-139) in support of the LBP guideline *does* include radicular pain. This contradiction is fundamental and would appear to invalidate the resulting guideline.	This went back to the GDG who confirmed that radiculopathy is not included in this guideline. The evidence on pages 138-139 originally included a population with sciatica; this has now been removed. However results from a mixed population (some with and some without sciatica) remains as this is how the authors have reported the results
SH	Society of Orthopaedic Medicine	4	Full	125	9	Quote from consultation guideline document: "8.2.6 Do not offer traction because of the increased risk of aggravating symptoms." There is a lack of evidence that traction worsens symptoms, in fact there is emerging evidence that traction is of value in certain subgroups of low back pain patients, particularly those with radicular or neuro symptoms and in combination with other treatments. Conflicting evidence highlights the need for quality research into the efficacy of traction in various subgroups of low back pain patients in appropriate settings. However, NICE will effectively preclude such research in the UK if health professionals are advised against this treatment modality in the first place. It would be a great shame to abandon a potentially beneficial treatment modality just because it is perhaps not always targeted at the most appropriate patients.	This was taken back to the GDG who agreed the evidence did not show an increased risk of aggravating symptoms. The recommendation was amended accordingly not to mention aggravating symptoms.

						Conversely, efforts should be going into researching and demonstrating which patients will benefit from traction and under what circumstances.	
SH	Society of Orthopaedic Medicine	5	Full	136	8 , 9	Quote from consultation guideline document: "Literature searching retrieved 262 papers of which 5 were ordered for this question. Four were excluded and one systematic review was included." A great deal of literature and evidence has been ignored in developing the draft NICE guideline that specifically relates to advising against traction. It is a great concern that the basis of this particular NICE position is just one paper, albeit a systematic review of 25 RCTs. This particular paper that provides evidence for the NICE position was published in 2006 which is a concern because at least three more recent studies have been published which indicate evidence to the contrary. These studies are referred to in more detail within the comment number 1 submitted by the Society of Orthopaedic Medicine. Briefly, the literature we have found indicates the following: ▪ Traction is a frequently used treatment by physiotherapists, particularly for radicular/neuro symptoms ▪ Lumbar traction can reduce the size of disc herniations, with greater herniations tending to respond better to traction ▪ Traction in excess of 50% of body weight is the only mention of adverse affects but Marcario *et al* (2008) used more than 50% body weight and reported no ill affects. ▪ Studies have weak methodologies, no control groups, samples consisting of a mixture of sub-groups (non-specific back pain, nerve root pain,	This was taken back to the GDG who removed the note about increasing risk of aggravating symptoms. Thank you for referring to 3 more recent studies. These had been picked up in the update searches but were excluded because of study design (Macario, and Harte) or because of inadequate control (Unlu)

						muscular pain, facet joint pain) ▪ Studies tend to use traction in isolation which does not reflect clinical reality where it may be one component of a physiotherapy management package. ▪ Pragmatic RCT's of traction as a part of a broader protocol would address this. Taking everything into account, we believe that the draft NICE guideline on the use of traction does not take into account the most recent literature on the subject, and that this position must be reviewed accordingly.	
SH	The British Society for Rheumatology	1	Full	8 15	10 8	A: Clinical Assessments: It is, no doubt, paramount to mention that nothing can replace a comprehensive clinical history taking and a thorough examination whether the back pain is under or over 6 weeks. No two patients with back pain will necessarily have a similar cause. **1.** Although Non-specific back pain (NSBP) has clearly been defined in the document some patients given this diagnosis suffer from inflammatory back disease (with or without obvious sacroiliitis) which may be missed at an early stage if the relevant history and examination is not performed by an expert in the field. It is not unusual to see undiagnosed inflammatory spinal pain (ISP) treated in the belief that it is NSBP, with marginal or poor response, leading to significant delay in accurate diagnosis and denying them appropriate therapy and information about the condition. Rheumatologists are often seeing such cases in the clinic. **2.** Although the guideline states that 'the diagnosis	Thank you for your comment. We have included Ankylosing Spondylitis or other inflammatory disorders within the box of specific causes of back pain and have recommended that the diagnosis be kept under review when treating people with NSLBP.If the clinician should be concerned that there may be a specific cause the guideline states they should arrange relevant investigations and a recommendation has been made to this effect.

							of NSBP is dependent on the clinician being satisfied that there is not a specific cause for their patient's pain', it is likely that precise causes will be overlooked or missed in the early stages due to lack of appropriate assessment and investigation. An exact diagnosis may be possible, if not from a clinical assessment, then from imaging which may require specific direction. Thus we have seen many patients with an initial diagnosis of NSBP who have a spondylolysis or listhesis; asymmetrical strain from anatomical anomalies; scoliosis; facet overgrowth; intervertebral splinting with increased movement above and below; discitis and, as mentioned, inflammatory spinal disease. History-taking in back pain should include an enquiry about associated stiffness and extra articular features commonly associated with sero- negative spondarthritides. The pathway must therefore state a specific mechanism for active searching for and identifying ISP.	
SH	The British Society for Rheumatology	2	Full	17 & 49	32 12-13	**3.**	It is alarming to see that Rheumatoid Arthritis (RA) has been repeatedly mentioned as a specific cause of Back pain throughout the document. Most rheumatologists agree that RA is inappropriate as a *specific* cause for back pain (although it is not unusual to see the presence of rheumatoid factor (RF) in certain families or certain specific age groups with or without back pain lasting longer than 6 weeks). GPs reading the document may feel that back pain and RF positivity means RA, and will inappropriately refer these patients to secondary care with this presumptive diagnosis. It needs to be made clear through the document that RA is an unusual direct	The text was amended to remove rheumatoid arthritis as a specific cause of low back pain

							cause of low back pain. However patients with RA are not precluded from having back pain and receiving appropriate management.	
SH	The British Society for Rheumatology	3	Full	general		**4.**	There is a greater argument for Polymyalgia Rheumatica (PMR) being mentioned in the document as many elderly or not so elderly patients (age criteria is still >50 years) with NSBP may have proximal girdle spinal pain, classically with stiffness, for over 6 weeks to 3 months (according to the ACR criteria). Some of these patients also respond to NSAIDs in the early stages and they again need to be appropriately assessed and investigated by an expert, to avoid delay in diagnosis and efficacious therapy.	Thank you for your comment This is not included within the scope of this guideline.
SH	The British Society for Rheumatology	4	Full	17	14 - 32	**5.**	It is also important to understand that there are more than just spinal causes for back pain, however rare they may be, such as retro-peritoneal fibrosis, intramuscular TB, growths from retroperitoneal structures, vasculitis of large vessels etc. Perhaps these causes should be mentioned within or outside their broad headings as they are more likely than to be causes of back pain than Rheumatoid Arthritis. At the end of the day Guidelines are to help the unwary clinician. In summary, to 'lump' all causes of back pain lasting longer than six weeks as NSBP may not be in the best interest of long term outcome of patient care, as some patients may have a clearly identifiable cause with very effective treatment outcome. Assessments of all these causes of NSBP is a challenge to most doctors, both in primary and secondary care, and requires a large number of investigations as therapies can be more 'toxic'	Specific reference to rheumatoid arthritis has been removed. We have added more explicit statement that diagnosis does need to kept under review. It is beyond the scope of this guideline to discuss all the rare possible causes of low back pain. In practice, to create a focus on these possible causes is likely to be detrimental to overall care of patients with low back pain.

						and run a risk of organ damage in the absence of a confirmed diagnosis.	
SH	The British Society for Rheumatology	5	Full	50	16 - 20	B: Investigations Imaging: 1. It is understandable that all attempts should be made to avoid unnecessary exposure to radiation. However targeted imaging is extremely beneficial in confirming a clinical suspicion such as degenerative arthritis of facet joints or even congenital or acquired spinal deformities. Many of the perceived limitations of X-ray relate to the disconnect between requesting clinician, patient and radiologist. A primary care physician requests a film giving a reason which why may or may not reflect the exact clinical picture; the radiologist reports a film (which may or may not be appropriate for the actual diagnosis) but does not see the patient. The referring primary care physician reads a report but does not see the film. Thus direct correlation of patient findings and X-ray is impossible; this is why the expert specialist is so important. Some reference should be made to the benefit of imaging when properly targeted.	Based on the review of RCT evidence the guideline indicates when imaging should be used in this patient group.
SH	The British Society for Rheumatology	6	Full	50	7 ,8	2. It is not unusual in more resistant back pain to discover so called 'Red Flag' signs even after 6 weeks when imaging may be more pertinent to arrive at a precise diagnosis and advise therapy.	The GDG have recommended that diagnosis be kept under review.
SH	The British Society for Rheumatology	7	Full	50	9 ,13	3. MRI of sacroiliac joints may sometimes be required in suspected cases of sero negative spondyloarthritis lost in the background noise of non specific back pain of more than six weeks.	This is outside of the remit of the guideline

SH	The British Society for Rheumatology	8	Full	50	5 -13	4. There is no mention of isotope bone scanning. However there may be a role in a selected population with NSBP of more than 6 weeks; it can be very useful in the elderly for detection of sacral insufficiency fracture and in early sacroiliitis in young adults. Was any evidence searched?	This is outside the remit of the guideline
SH	The British Society for Rheumatology	9	Full	12	5 -8	C: Management Anti-depressant use: In item 1.7.13: it is recommended that people starting anti depressants should be reviewed at least monthly. Is this evidence based? Many patients are on antidepressants for treatment of 'fibromyalgia' but most are not reviewed that frequently. Is it a specific recommendation for the management of NSBP?	This was taken back to the GDG who changed the wording of the recommendation.
SH	The British Society for Rheumatology	10	Full	gene ral		Psychological Assessments: Is it not advisable to attempt to identify early evidence of psychological disturbance in patients with NSBP in order to devise a clear management pattern in such cases? There some Scandinavian studies where the early targeting of risk factors of chronicity of back pain has yielded better outcome	A research recommendation has been written on the need/use of screening protocols (including psychological screening).
SH	The British Society for Rheumatology	11	Full	gene ral		Other Conservative treatments: Overall this part of the guideline is well researched. The evidence base is poor in parts but this may reflect the inclusion in trials of patients with several different specific diagnoses that have been lumped together as NSBP when they are not. Thus a patient with a spondylolysis misdiagnosed as NSBP and treated with facet injections is unlikely to respond.	Noted. Thank you for your comment
SH	The British Society for Rheumatology	12	Full	102	29	Lumbar Corset: It may be appropriate to use in some subjects because the patient feels reassured and gains confidence. Therefore it may be worth considering in	Noted

						some elderly subjects where the instillation of such confidence outweighs the risk of muscle loss.	
SH	The British Society for Rheumatology	13	Full	180	4	Acupuncture: It has been recommended extensively but on the basis, in our view, of very few good well controlled randomised trials. There is no mention of 'Acupressure' in the document. It is interesting that in real life many patients respond to many other measures such as Reiki and Pilates therapy although the exact role in terms of evidence base is unclear in the treatment of NSBP. Can the GDG reflect anything on this?	Acupuncture was identified as an important question by the GDG and the stakeholders. Reiki as a form of massage would be covered under the section on massage in the Manual therapies chapter. Pilates would be included under exercise therapy. The GDG did not look for specifically named therapies only those which might come under each of the questions
SH	The British Society for Rheumatology	14	Full	196	20 - 22	IDET, PIRFT, Radiofrequency Facet Joint Dennervation: The current document advises against the referral for all the above, but 'pain clinics' are still performing them. We are unclear, again, whether negative trials reflect heterogeneity of the study groups (in other words, that some patients treated with these therapies have never been fully investigated to exactly identify which facets should be targeted).	The available evidence do not support the notion that these treatments are effective. The review group did not find any evidence to identify any sub-group that would be more likely to benefit from these treatments, or that failure to show a benefit was due poor targeting of the interventions.
SH	The British Society for Rheumatology	15	Full	100	10 - 14	Manual therapies: There are numerous anecdotal reports of serious damage caused by significant manipulation in improperly diagnosed patients who have in fact got spinal metastases, disc prolapses etc. In addition young patients may run the risk of vertebro basilar accidents. We request some more detailed acknowledgement of potential risks.	This is mentioned in the Evidence to Recommendations table 7.4.2
SH	The British Society for Rheumatology	16	Full	180	6	Interventional treatments 1) Injections to Back: It is unclear whether it includes epidural injections and facet joint	This was taken back to the GDG who clarified the wording of the recommendation

						injections, or any other intervention.	
SH	The British Society for Rheumatology	17	Full	general		General comments BSR acknowledges and appreciates the hard work that has gone into the development of this Guideline on a difficult subject. It also appreciates that although the scientific community tries to put value to a scientific work when it is supported by the appropriate level of evidence through RCTs or systematic reviews, in real life patients do not understand the evidence or indeed trial methodology. Most scientists and scholars agree that 'Absence of Evidence' does not mean 'Evidence of Absence'. There are a few 'typos' in the current document in Page: 28; line 12: trial not trail Page: 138: 8.6.3: The sentence is probably not correct, and we recommend a re-check.	Noted. Thank you the typo will be corrected and the sentenced checked.
SH	The Chartered Society of Physiotherapy	1	Nice	General	General	The draft NICE guideline does not appear to cover everything that is defined within the scope as being part of the guidelines remit. For example, the scope defines that in the 'Clinical Management' section "Advice and implementation of lifestyle interventions as part of clinical management. For example: • self-management strategies • 'back schools' • patient education and advice • cognitive behavioural pain management • workplace interventions and return-to-work interventions (example, occupational and ergonomic interventions)" will	The NICE version of the guideline only includes the recommendations, for full details of all the interventions considered and reviewed please see the full guideline. Workplace interventions and return to work were not covered in any detail as this is included within the public health guidance –managing long-term sickness and incapacity for work – which is currently in development.

						be covered and yet workplace interventions are not specifically listed within the draft NICE guideline	
SH	The Chartered Society of Physiotherapy	2	NICE	7	1.1.3	It should be made clear that only once a diagnosis of non-specific LBP has been made should MRI be considered only within such tight parameters. MRI is a useful diagnostic tool that may be considered when diagnoses wider than those listed in 1.1.2 are still being considered, and we have had feedback to suggest that our members feel that MRI is being 'withdrawn' as a diagnostic tool for them to use in their diagnostic decision making process.	The starting point of this guideline is the management of people who have had low back pain for more than six weeks when specific causes would normally have been excluded. Where there are concerns that there may be a serious cause for low back pain (sepsis , tumour, fracture) then imaging is needed.
SH	The Chartered Society of Physiotherapy	3	NICE	8	1.4.1	Whilst this statement is intended as a guide only, it is likely that this will be seized on by patients as being their 'entitlement' to receive the full quota of intervention and may make management more difficult when clinicians feel that this level is not indicated but the patient expects it. Conversely, commissioners may seize this as being a maximum level of services and commission services accordingly and deny any greater treatment even for those patients who are continuing to show clinical improvement with continued intervention.	the number of sessions recommended is based on the trial evidence.
SH	The Chartered Society of Physiotherapy	4	NICE	8	1.5.6	It needs to be clearly specified whether this is the continuous bed rest from of traction, or whether mechanical traction that is offered on an out-patient basis in physiotherapy departments is included within this	The evidence relates to continuous and autotraction

						definition.	
SH	The Chartered Society of Physiotherapy	5	NICE	9	1.6.1	Psychological treatment programmes are limited in many NHS Trusts due to either , or both or, a lack of trained psychologists or physiotherapists with expertise in cognitive therapy. Therefore it is likely in most NHS Trusts that this intervention will not be able to be delivered.	Service delivery is outside of the remit of this guideline
SH	The Chartered Society of Physiotherapy	6	NICE	11	1.8.2	Does this include epidural injections and facet joint injections, which many patients actually respond very well to?	Yes; this is because the group did not find any evidence that these were effective or any evidence to indicate that they may be particularly beneficial in ay identifiable sub-group.
SH	The General Chiropractic Council	1	NICE	general		The guideline recommendations are broadly in line with the evidence and expert consensus on assessment and intervention for sub-acute non-specific low back pain. The evidence on acupuncture, however, seems to be of a lower standard than is normally required to make a recommendation for support. For purposes of commissioning, there is a considerable danger of lining up patients for a 'course' of manipulation, then perhaps exercise and then perhaps acupuncture. This should be strictly avoided as back pain in populations does not respond well to mono-therapies. The whole evidence-based package of care should be preferred. This would be done by commissioning expert practitioners with special skills and training in clinical assessment and the integration of these treatments, as opposed to generalists with an interest but skills in only one or two	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care.

						aspects.	The GDG is not aware of any evidence that failure to benefit from one of the recommended therapies necessarily means that an individual will not respond to one of the alternative therapies. Thus, it is reasonable to give people to opportunity to try more than one therapies. How these different therapies are delivered is outside the remit of this guideline
SH	The General Chiropractic Council	2	NICE	6	18	Suggest this should read as follows: Consider referral for an opinion on spinal stabilisation surgery for people who have completed an optimal and comprehensive package of care including a combined physical and psychological treatment programme and who have persistent severe non-specific low back pain for which the patient would consider surgery. *(and replace all future references to spinal fusion)*	Thank you for your suggestion This recommendation has been revised by the GDG
SH	The General Chiropractic Council	3	NICE	7	6	We know what you are getting at, but simply repeating P6 line 14 in the context of assessment will cause confusion if the word 'management' is used. X-rays are also a cheap and effective alternative to MRI if hip disease or previous trauma are issues and these situations are not uncommon.	The recommendations on Page 6 are the key priorities identified by the GDG. The evidence showed no clinical benefit for X-ray in the treatment of non specific low back pain. and thre aer associated with the use of x-rays.

SH	The General Chiropractic Council	4	NICE	12	23	Screening protocols should not be fixated on psychological factors. When there is high pain at onset, social factors such as poor housing, social isolation, poor access to transport and co-morbidities have considerable effects on outcomes.	We agree that many social factors might affect outcome from low back pain. These, however, unlike psychological risk factors are unlikely to be amenable to change as part of routine clinical care.
SH	The General Chiropractic Council	5	NICE	14	15	We agree that the effects of therapies on subgroups are important to research but could some indication of where to look for these subgroups be offered? We are thinking particularly of mechanical subgroups, since the interventions of manipulation, exercises and spinal stabilisation surgery that are recommended frequently target mechanical factors.	It is possible that a wide range of different factors might predict response to different treatments. There are insufficient data at present for the GDG to make a recommendation on which may be the most fruitful line of enquiry.
SH	The Society of Teachers of the Alexander Technique (STAT)	1	Full	31	4	We consider the description of the Alexander Technique in the glossary is misleading. We request it be changed to the version below –	The description has been modified in the glossary
SH	The Society of Teachers of the Alexander Technique (STAT)	2	Full	31	4	The Alexander Technique is a taught self care discipline that enables an individual to recognise, understand and avoid habits adversely affecting muscle tone, coordination and spinal functioning. Priority is given to habits that affect freedom of poise of the head and neck and that lead to stiffening and shortening of the spine, often causing or aggravating pain. Using a combination of professional hands-on practical guidance and verbal explanation, the teacher helps an individual experience the benefits of applying the AT principles and skills and educates them in self-care. Learning to live and react in a more poised and coordinated way allows lengthening of the spine, decreases pain and promotes health and well-being.	see above

SH	The Society of Teachers of the Alexander Technique (STAT)	3	Full	68 72	17 14	The recent ATEAM RCT of lessons in the Alexander Technique is referred to here but not in the short draft. Many hasty readers of the guideline will not be made aware of the RCT evidence for benefits.	Noted.
SH	The Society of Teachers of the Alexander Technique (STAT)	4	Full	72	14	The summary of the ATEAM trial interventions and results is muddled. It is incorrect to refer to AT and exercise 'treatments' – interventions is better. Patients received a 'prescription' for aerobic exercise of their choice – most chose walking. This followed 6 lessons in the AT so that patients could use their AT knowledge while exercising. The conclusion about 'structured programmes' is misleading. A correct overall conclusion is that six one-to-one AT lessons followed by an exercise prescription were effective in reducing pain and functional disability and about 70% as effective as 24 lessons. K B, one of the trial authors	Noted. The narrative has been modified.
SH	The Society of Teachers of the Alexander Technique (STAT)	5	Full	General		Perhaps the timing of the NICE draft report prevented full consideration of the BMJ publication of the ATEAM back pain RCT results. Maybe the lack of a published economic analysis of the trial interventions was a significant factor; the good news is that an economic analysis has been accepted for publication and is expected to appear soon.	Thank you for the information. The ATEAM trial results (both clinical and economic analyses) was included in the review
SH	The Society of Teachers of the Alexander Technique (STAT)	6	Full	General		To quote an unsolicited medical opinion of the ATEAM trial: 'The results are the most statistically significant and clinically relevant data with respect to any treatment modality for back pain hitherto trialled. The guideline developers may have concluded that "more research is needed" before recommending the AT, but the quality and clearly demonstrated effectiveness of AT lessons exhibited by this trial necessitate their inclusion in the NICE guidance.'	The ATEAM trial paper was included within the exercise and massage reviews.

SH	The Society of Teachers of the Alexander Technique (STAT)	7	Full	7	7 9 10 12	The first recommendation criterion used by the GDG is clearly met by the ATEAM trial patients' outcomes after 6 one-to-one lessons in the AT followed by a prescription for exercise, such as walking or similar activity. Such a recommendation is 'likely to have a high impact on patients' outcomes, in particular pain, disability or psychological distress'. In addition a recommendation for AT lessons is 'likely to lead to a more efficient use of NHS resources and promote patient choice'.	Exercise programmes are already a key priority. Specific types of exercises cannot be recommended. In the exercise chapter suggested content of exercise programmes are given.
SH	The Society of Teachers of the Alexander Technique (STAT)	8	Full	General		The criteria in the NICE SCOPE remit are matched by the entry criteria for patients in the ATEAM trial. Considering the remarkable results and the strong emphasis on self care education in Alexander Technique lessons, we are asking that the Guideline Development Group (1) gives full consideration to the ATEAM trial results together with the forthcoming economic analysis, and (2) includes Alexander Technique lessons in the NICE guidelines as an effective resource for the management of patients with chronic and recurrent low back pain.	The ATEAM trial paper was included within the exercise and massage reviews.
SH	The Society of Teachers of the Alexander Technique (STAT)	9	Full	General		It would be unreasonable for NHS patients to have to wait for the next revision of the NICE guidelines before discovering the benefits of attending lessons in the Alexander Technique.	The ATEAM trial paper was included within the exercise and massage reviews.
SH	The Society of Teachers of the Alexander Technique (STAT)	10	Full	7	13	We suggest adding: – 'Consider offering a series of six one-to-one Alexander Technique lessons over a period of four to six weeks, followed by an exercise prescription for walking or similar activity, for example swimming.'	We do not recommend specific types of exercise programme. There are suggested contents in the exercise chapter recommendation section.

						(immediately before manual therapy and acupuncture needling).	
SH	The Society of Teachers of the Alexander Technique (STAT)	11	NICE	6	2	1 We suggest adding: – 'Consider offering a series of six one-to-one Alexander Technique lessons over a period of four to six weeks, followed by an exercise prescription for walking or similar activity, for example swimming.' (immediately before manual therapy and acupuncture needling).	Thank you for your suggestion
SH	The Society of Teachers of the Alexander Technique (STAT)	12	NICE	7 13	17 7	AT lessons merit inclusion as the *par excellence* option for the practical education of back pain patients in self-care and rehabilitation.	AT has been included in the exercise programmes and advice to exercise reviews. Specific types of exercise cannot be recommended but an additional recommendation gives suggestions of content of exercise programmes
SH	The Society of Teachers of the Alexander Technique (STAT)	13	Full	General		The ATEAM RCT evidence and companion economic analysis study suggest that a series of six one-to-one Alexander Technique lessons followed by an exercise prescription (such as for walking) is one of the most effective and cost-effective interventions yet identified for the management of back pain in primary care.	The ATEAM trial paper was included within the exercise and massage reviews.
SH	UCL Hospitals NHS Foundation Trust	1	Full	general		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	Noted. The remit of the guideline was for low back pain

						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 (recognised by reference to the broader chronic pain literature on p30 lines 2-3), 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 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.	
SH	UCL Hospitals NHS Foundation Trust	2	Full	general		I feel the role of pain clinics has been overlooked. The vast majority of patients should be treated in primary care and I have worked extensively with my local PCT to improve, enhance and develop these services. However, there remains a group of patients who are difficult to treat. This guideline should recognise that a properly managed pain clinic with appropriate multiprofessional resources (with psychologists, physiotherapists and doctors) has an important role to play in planning care and treatment. These services are not mentioned once. Pain clinics exist as a multiprofessional repository resource to provide services across multiple PCT boundaries because even many larger PCTs cannot sustain the training and educational resources to have appropriately skilled staff. Sometimes these services have been devolved to PCTs but this is not the only model that exists and works.	How services are delivered is outside of the remit of this guideline. It is also outside of our remit to say who should deliver interventions, beyond that health professionals should have the necessary qualifications and competencies to treat people.
SH	UCL Hospitals NHS Foundation Trust	3	Full	7	7	Although psychological outcomes are highlighted as important (first point in priorities and in outcomes of most	Psychological distress as an out come was looked for in searches

						KCQs in 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 chapter11. This is largely for the reasons given 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 absence from work, etc.	for each question. Where this was reported in a study it has been included in the review of the evidence. It is not part of the review process to report on what was not found. The lack of psychological outcomes in studies has been included in the methods section.
SH	UCL Hospitals NHS Foundation Trust	4	Full	9	6	Why do these not include reference to yoga and Alexander technique, available in the community (albeit not specific to lbp), which are more consistent with self-management and maintenance than therapies provided only in the health service.	Yoga and Alexander Technique references were included in the review. Specific types of exercise could not be recommended. Instead a recommendation suggests possible content of exercise programmes
SH	UCL Hospitals NHS Foundation Trust	5	Full	11	1	For the purposes of pharmacology, a group defined just as sub-acute lbp is probably rather heterogeneous, so the likelihood of finding one clear effective drug across all seems low. There is a place for recommending good prescribing habits, any drug tried with clear goals and time scale, and reviewed within the timescale in the light of those goals, which should include improving function, mood and sleep which are adversely affected by pain. There is also a place for recommending the opioid prescribing guide of the British Pain Society and corresponding information booklet for patients: see www.britishpainsociety.org.uk/	Thank you for your comment. There is a recommendation for referral for specialist assessment when prolonged opioid use is required.
SH	UCL Hospitals NHS Foundation Trust	6	Full	12	11	Don't think that volunteer study results should be given as much weight as they are in summary. The recommendation for acupuncture seems much stronger than the evidence warrants, and inconsistent with the	Noted thank you

						judgements made in the remainder of the report.	
SH	UCL Hospitals NHS Foundation Trust	7	Full	12	16	It is unusual and questionable to recommend surgery based on failure of other methods. Presumably this was a way of reading the Fairbank study reviewed, but it seems most confusing for the patient.	Two systematic reviews of four randomised controlled trials (including the Fairbank trial) both concluded that for selected people spinal fusion may be beneficial. The guideline recommends referral for consideration of surgery for people similar to those included in the RCTs included in the systematic reviews. These referrals should only be considered after an intensive course of a combined physical and psychological intervention.
SH	UCL Hospitals NHS Foundation Trust	8	Full	27		Acupuncture is listed as a core therapy and recommendations are for a specified course of treatment. The evidence presented is not strong enough to promote this therapy which is likely to provide small and non sustained benefits. I would also like to understand how the number of treatments advocated is so specific (similarly for osteopathy). It strikes me that this recommendation is partisan and inappropriate to be published as it stands. I have no objections to acupuncture being recommended, but not as strongly as is stated.	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care. Three of the five studies describe

							duration of treatment as up to 10 sessions so this was used to base the recommendation
SH	UCL Hospitals NHS Foundation Trust	9	Full	27		'MRI should only be performed in the context of a referral for an opinion on spinal surgery'. The evidence provided demonstrates that some people benefit in mental health scales, from reassurance, and feel more satisfied having had an MRI yet the conclusion that is arrived at is 'No evidence of clinical or cost benefit'. I cannot understand this conclusion. I feel that targeted patients who are failing to progress do benefit from the reassurance of a scan and have very often specifically requested this. I feel more latitude in this is required.	Agree. Table 4.3.3 explains the GDG's decision in the evidence to recommendation column.
SH	UCL Hospitals NHS Foundation Trust	10	Full	27		Not recommended = 'Stand alone educational programmes'. I do not fully understand what is meant by this.	Education should not be offered on it's own but as a part of other interventions being offered.
SH	UCL Hospitals NHS Foundation Trust	11	Full	29	27	The third research suggestion, p30 lines 9-10, makes good sense. There is far too much atheoretical research which leads to idiosyncratic treatment content and poorly generalisable findings. In this light, the first research suggestion (lines 6-7) and comment following (11-13) is naïve, since it has already been done many times in the general chronic pain canon of studies and little further usefulness lies in this direction. Individual studies, as suggested, based on robust theory and applied with attention to analagous studies in the mainstream literature would be far more use than lots of pragmatic jumbles of treatment content carried out by inexperienced/untrained therapists. Far too little reference is made to the more advanced findings from mainstream (mental health) psychological trials.	Noted
SH	UCL Hospitals NHS Foundation Trust	12	Full	31	4	Why not define psychology/psychological? There's obvious confusion over what it means throughout this document, sometimes used to mean therapeutic application of psychological principles and practices by	This has been/ added to the glossary

						trained practitioners, and in other places loosely referring to cognitive, emotional and behavioural variables.	
SH	UCL Hospitals NHS Foundation Trust	13	Full	63	6	There are inconsistencies which may indicate the group's professional preferences. The evidence and the summary about educational materials clearly states that there is no evidence but they go on to say it 'may have a role' and it appears as a core therapy. This is inconsistent. Once again, care needs to be taken and this point readdressed. I wholeheartedly agree with the point but care must be taken in this public document.	The review identified one small study suggesting that standalone educational programmes may be helpful. The GDG agreed this provided insufficient evidence to recommend educational programmes as a standalone intervention. However a key message of the guideline is to promote self management and to this end the GDG have made a recommendation for educational advice to patients as part of a self management strategy
SH	UCL Hospitals NHS Foundation Trust	14	Full	141	3	The suggestion for referral for 'combined physical and psychological treatment' needs to suggest where, e.g. to a pain clinic offering this service. These need to be run by experts used to managing these patients.	Service delivery is not within the remit of NICE clinical guidelines. We agree that the interventions we are recommending should be carried out by people with the necessary competencies.
SH	UCL Hospitals NHS Foundation Trust	15	Full	196	3	I do not understand that the first part of section 12 states 'The scope of this document specifically precluded recommendation regarding surgery' and the guidance then goes on to promote surgical treatment for this group. It goes on to state that 1-2% of patient suffering serious harm is an acceptable level. I suggest that these more difficult patients should first be assessed by experts in pain or at least this should be on offer too. I also find it very difficult to accept the conclusion that fusion surgery should be promoted as the a next step.	The scope states that indications for referral for surgery would be included within this guideline. In order to recommend who should be referred for specialist assessment we needed to identify which surgical approaches had some evidence for effectiveness and then from these studies identify the characteristics of those recruited in order to make a recommendation . Referral for consideration of

							spinal fusion is only recommended for people who have continuing severe problems following an intensive course of combined physical and psychological treatment and who have had optimal treatment for any psychological distress. There is a significant morbidity and mortality associated with spinal surgery. Assessing the comparative risk and benefits of surgical procedures, and producing the information needed to inform a discussion between a patient and their surgeon, is beyond the scope of this guidelines
SH	UCL Hospitals NHS Foundation Trust	16	Appendix B	3		A better question would be 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.	Noted. A research recommendation has been made on the effectiveness of screening protocols to identify those with a poor outcome profile in order to target treatments more effectively
SH	University College London Hospitals NHS Foundation Trust John Lee	1	Full	27		I welcome the draft NICE guidelines on chronic back pain. However, I feel parts of it require re-consideration because the evidence presented and the conclusions reached appear to lean too far towards opinion and too close to limited evidence. I am fearful that if the guidelines are published as they stand, they will be challenged extensively and undermined. I also feel that that in their current form, some patients will not get access to the right care at an optimal time.	Evidence suggests that seeing an acupuncturist was better than usual care but not much difference between acupuncture and sham. However acupuncture needling not based on acupuncture points is used as an active form of treatment by some practitioners, therefore the GDG

						Acupuncture is listed as a core therapy and recommendations are for a specified course of treatment. The evidence presented is not strong enough to promote this therapy which is likely to provide small and non sustained benefits. I would also like to understand how the number of treatments advocated is so specific (similarly for osteopathy). It strikes me that this recommendation is partisan and inappropriate to be published as it stands. I have no objections to acupuncture being recommended, but not as strongly as is stated.	decided it should be considered as a possible treatment. Additionally, one well conducted large UK-based RCT with relevant population found that acupuncture was associated with an improvement in pain, at 24 months, compared to usual care. Three of the five studies describe duration of treatment as up to 10 sessions so this was used to base the recommendation. The maximum number of sessions of manual therapy recommended was based on the sessions provided in the large study for which economic data was available.
SH	University College London Hospitals NHS Foundation Trust John Lee	2	Full	27		'MRI should only be performed in the context of a referral for an opinion on spinal surgery'. The evidence provided demonstrates that some people benefit in mental health scales, from reassurance, and feel more satisfied having had an MRI yet the conclusion that is arrived at is 'No evidence of clinical or cost benefit'. I cannot understand this conclusion. I feel that targeted patients who are failing to progress do benefit from the reassurance of a scan and have very often specifically requested this. I feel more latitude in this is required.	Agree. Table 4.3.3 explains the GDG's decision in the evidence to recommendation column.
SH	University College London Hospitals NHS Foundation Trust John Lee	3	Full	27		Not recommended = 'Stand alone educational programmes'. I do not fully understand what is meant by this.	Education should not be offered on it's own but as a part of other interventions being offered.
SH	University College	4	Full	27		There are inconsistencies which may indicate the groups	The review identified one small

	London Hospitals NHS Foundation Trust John Lee					professional preferences. The evidence and the summary about educational materials clearly states that there is no evidence but they go on to say it 'may have a role' and it appears as a core therapy. This is inconsistent. Once again, care needs to be taken and this point readdressed. I wholeheartedly agree with the point but care must be taken in this public document.	study suggesting that standalone educational programmes may be helpful. The GDG agreed this provided insufficient evidence to recommend educational programmes as a standalone intervention. The rationale behind this decision is given in the evidence to recommendations section. However a key message of the guideline is to promote self management and to this end the GDG have made a recommendation for educational advice to patients.
SH	University College London Hospitals NHS Foundation Trust John Lee	5	Full	27		The suggestion for referral for 'combined physical and psychological treatment' needs to suggest where, e.g. to a pain clinic offering this service. These need to be run by experts used to managing these patients.	Service delivery is not within the remit of this guideline Health professionals delivering these treatments would be expected to have the necessary qualifications and competencies.
SH	University College London Hospitals NHS Foundation Trust John Lee	6	Full	164?		I do not understand that the first part of section 12 states 'The scope of this document specifically precluded recommendation regarding surgery' and the guidance then goes on to promote surgical treatment for this group. It goes on to state that 1-2% of patient suffering serious harm is an acceptable level. I suggest that these more difficult patients should first be assessed by experts in pain or at least this should be on offer too. I also find it very difficult to accept the conclusion that fusion surgery should be promoted as the a next step.	The scope states that indications for referral for surgery would be included within this guideline. In order to recommend who should be referred for specialist assessment we needed to identify which surgical approaches had some evidence for effectiveness and then from these studies identify the characteristics of those recruited in order to make a recommendation . Referral for consideration of spinal fusion is only

							recommended for people who have continuing severe problems following an intensive course of combined physical and psychological treatment and who have had optimal treatment for any psychological distress.
SH	University College London Hospitals NHS Foundation Trust John Lee	7	Full	General		I feel the role of pain clinics has been overlooked. The vast majority of patients should be treated in primary care and I have worked extensively with my local PCT to improve, enhance and develop these services. However, there remains a group of patients who are difficult to treat. This guideline should recognise that a properly managed pain clinic with appropriate multiprofessional resources (with psychologists, physiotherapists and doctors) has an important role to play in planning care and treatment. These services are not mentioned once. Pain clinics exist as a multiprofessional repository to provide services across multiple PCT boundaries because even many larger PCTs cannot sustain the training and educational resources to have appropriately skilled staff. Sometimes these services have been devolved to PCTs but this is not the only model that exists and works.	How services are delivered is outside of the remit of this guideline. It is also outside of our remit to say who should deliver interventions, beyond that health professionals should have the necessary qualifications and competencies to treat people.
SH	Welsh Pain Society	1	Full	General		• Use of MRI should only be used in the context of referral for an opinion on spinal fusion. We wonder why it has not been used for patients with neuropathic pain due to isolated disc disease. A disectomy may be more appropriate in certain patients rather than spinal fusion which has its own not insignificant problems.	Neuropathic pain is outside of the remit of this guideline.
SH	Welsh Pain Society	2	Full	General		• I am aware of other groups that have highlighted the potential advantages of injections of therapeutic substances into the back so I will not	Noted. Thank you for your comment

						expand here but we would like to highlight the fact that we feel that this does have a place in well chosen patients	
SH	Welsh Pain Society	3	Full	10	1.7	• Within 1.7 pharmacological therapies – neuropathic agents are not mentioned at all. Those patients with significant neuropathic pain as assessed by a validated scoring system such as S-LANSS may benefit from a trial of a neuropathic agent. Also the British Pain Society have provided some excellent guidance on the use of strong opioids. Within this it is stated that the opioid medications should be used as part of a treatment plan. This needs to be strongly stated otherwise opioids have the potential of not being used just for short term treatment.	A separate guideline on pharmacological management of neuropathic pain is currently under development. Recommendation states opioids should be for short term use and cautions are given when prescribing this medication
SH	Wyeth Pharmaceuticals	1	full	49	10 - 14	The diagnosis and management of specific causes of LBP has not been adequately addressed in the draft guideline. This is of great importance as a potentially high proportion of patients suffering from inflammatory back pain could be misdiagnosed as having non-specific LBP, without appropriate investigations and hence loosing the opportunity of potential therapeutic intervention. The scope of the guidelines is too restricted and does not adequately define how to differentiate between diagnoses.	Outside the scope of the guideline
SH	Wyeth Pharmaceuticals	2	Nice	6	14	X-ray of the sacroiliac joint can be vital in establishing the diagnosis of inflammatory back pain (no allowance given for misdiagnosis). This has not been acknowledged in the guideline.	recommendation to review diagnosis has been added
SH	Wyeth Pharmaceuticals	3	Nice	6	16	MRI should also be directly available for general practitioners to aid a specific diagnosis of back pain.	Agreed. This guideline addresses non specific low back pain

SH	Wyeth Pharmaceuticals	4	Nice	7	8 -10	MRI should be arranged as soon as possible after suspicion of inflammatory back pain.	MRI is recommended if this is suspected
SH	Wyeth Pharmaceuticals	5	Full	15	3-7	Non-specific low back pain should be a diagnosis of exclusion. Appropriate investigations can be conducted to enable this. For example if RA is suspected, a GP can conduct anti-ccp blood test. These types of investigations are not listed in the current guideline.	Thank you. Box 1 has been edited
SH	Wyeth Pharmaceuticals	6	Nice	21	App c	The algorithm does not give assessment times of follow-up. This could lead to inadequate management of the patient and potential misdiagnosis.	The advice to review diagnosis has been added to the algorithm
SH	Wyeth Pharmaceuticals	7	Nice	9	17 - 19	Not every patient who is prescribed an NSAID requires a proton pump inhibitor. Guidance should acknowledge methods to focus on moderate to high risk patients for gastrointestinal problems.	This has been revised to specify that this applies to people over 45
SH	Wyeth Pharmaceuticals	8	Full Nice	Gene ral		This guidance works on the assumption that all patients with LBP receive a correct diagnose at initial presentation. Ultimately the guidance may cause further delay to these patients.	Noted. The GDG have recommended that diagnosis should remain under review
SH	Wyeth Pharmaceuticals	9	Full Nice	Gene ral		Are all primary care units equipped enough to manage patients to the level of needing a spinal fusion? The recommendation is too specific to spinal fusion.	Service provision is outside the remit of the guideline. Spinal fusion is the only surgical intervention for which positive data was found
SH	Wyeth Pharmaceuticals	11	Full Nice	Gene ral		Many of the recommended activities would not generally be funded by the NHS – is there any consideration for patients who could not financially fund these activities. Access to these therapies will also be varied.	Once published NICE will work with the NHS on implementing the recommendations made within this guideline NICE to reply?
SH	Wyeth Pharmaceuticals	12	Full	11	5 -6	What is considered a adequate time for 'short term' trial of NSAIDs	This will depend on the patient.
SH	Wyeth Pharmaceuticals	13	Full	11	14 - 16.	Need to identify what time is meant by 'short term trial'	This will depend o n the patient

SH	Wyeth Pharmaceuticals	14	Full	17	28 - 32	This needs to be established at the beginning of these guidelines- or eliminated by a clearer pathway of assessment, More useful to have a initial diagnostic step	Agreed. The GDG have recommended that diagnosis be kept under review
SH	Wyeth Pharmaceuticals	15	Full	General		Will there be a review of waiting times for services to meet the criteria of these guidelines – e.g time waiting for physio referral and treatment?	Service delivery is outside of the remit of this guideline
SH	Wyeth Pharmaceuticals	16	Full	16	20 - 31	Costs given are for total back pain and not specific to this potentially very small group	Agreed. “Low back pain” has been replaced with “back pain” in this section. This section is labelled “Costs of back pain”, and it is clear from the text that the costs quoted relate to this whole population, rather than some subgroup
SH	Wyeth Pharmaceuticals	17	Full Nice	General		Prevalence is given for all LBP not the small specific group which this guideline is aiming at.	Noted
SH	Wyeth Pharmaceuticals	18	Full Nice	General		Treatment times are built in to be up to 12 weeks without including the possible need for re-assessment to reconsider diagnosis and what symptoms one should look out for.	An additional recommendation has been made to keep diagnoses under review