National Institute for Health and Care Excellence
Low Back Pain (update)
Scope Consultation Table
21st October – 18th November 2013

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1.	SH	AbbVie	1	4.3.1	There is low awareness of axial spondyloarthropathy/ankylosing spondylitis amongst non- rheumatologists and patients with inflammatory back pain are under recognised as they represent a small group (15%)1, of all patients presenting with chronic back pain. Therefore there is a diagnostic delay of between 8-11 years for patients with ankylosing spondylitis 2,3. Although inflammatory causes of back pain are outside the scope of this guideline, in the section (4.3.1) which deals with systematic assessment of non-specific low back pain, it would be useful to highlight the need to identify and exclude inflammatory back pain, in order to raise awareness amongst primary care practioners and reduce the delay faced by these patients. 1 Underwood MR et al. Br J Rheumatol. 1995 Nov; 34 (11): 1074-7 2 Feldtkeller E et al. Rheumatol Int 2003; 23: 61-6 3 Khan MA et al. Ann Rheum Dis 2002; 61 (suppl 3): iii3-7	Thank you for your comment and useful information. NICE will be developing a guideline on seronegative arthropathies which will begin development shortly.
2.	SH	Acupuncture Association of Chartered Physiotherapists	1	1.	The term persistent was challenged by the attendees at the scoping group as it was felt that the scope would be too broad and not patient- friendly in terms of interpretation.	Thank you for your comment. This has now been removed from the title, which is now reworded as: Low back pain and sciatica: management of non-specific low back pain and sciatica.
3.	SH	Acupuncture Association of Chartered Physiotherapists	2	3.1a	Insertion of the word "chronic"- chronic needs to be defined as how is this different to "persistent"? The document should use similar terminology throughout.	Thank you for your comment. This has been amended to 'low back pain'. Any terms used in the development of the guideline will be specifically defined.
4.	SH	Acupuncture Association of Chartered	3	3.1d	Timings are crucial from a health and economic perspective. Therefore timings for interventions need to be considered in either a pathway or stepped approach e.g. surgery is expensive but then	Thank you for your comment. Timings will be considered when the evidence is reviewed, including timeliness of

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		Physiotherapists			to refer everyone at 2 weeks to specialist assessment (Physio etc) would also be expensive. Consideration of stepped approaches to input would be useful in terms of compliance for implementation.	assessment.
5.	SH	Acupuncture Association of Chartered Physiotherapists	4	3.1d	Complementary/alternative- Acupuncture is considered as adjunct to other therapeutic and management strategies within physiotherapy scope of practice as pain relief is primarily the main part of the patient's focus as many outcome measures acknowledge. Therefore acupuncture needs to be considered as both a single treatment strategy AND as part of multimodal strategies. In physiotherapy practice, CG88 has been well-implemented and therefore it could be argued that a new review of acupuncture is unwarranted if it is as a result of a perceived lack of compliance.	Thank you for your comment. The intention is that treatments will be considered on their own, and in combinations if evidence is identified. This will be determined by the GDG when the protocols for the review questions are drafted, and specified in the appropriate review protocols.
6.	SH	Acupuncture Association of Chartered Physiotherapists	5	3.1e	Lewis et al (2011) considered economic evaluation/clinical effectiveness for acupuncture and sciatica. Care should be taken when conducting searches as defining the terms sciatica/radicular/ nerve root symptoms as limiting searches to specific terminology may result in bias.	Thank you for your comment. Systematic literature searches will be undertaken during guideline development. Searches will utilise database indexing and natural language terms in order to retrieve all relevant material while balancing sensitivity and precision. Please see the NICE Guidelines Manual for further information on development methods: http://publications.nice.org.uk/the-guidelines-manual-pmg6
7.	SH	Acupuncture Association of Chartered Physiotherapists	6	3.2c	The inclusion of the Pulse article research has revealed a potential bias against acupuncture and it is misleading and incorrect regarding current practice in the NHS. There are many reasons why implementation of CG88 has been poor and any argument should not be based just on the perceived lack of uptake of acupuncture. There are many biases against acupuncture within this document suggesting that the questions were not specific enough or directed at practitioners. For example, many commissioners are unaware that acupuncture is within Physiotherapy scope of practice and is used widely for pain relief within the NHS. Many NHS Physiotherapy departments have	Thank you for your comment**.** The Pulse survey, based on a Freedom of Information request of 127 Primary Care Organisations (PCOs) showed that only 15% of these PCOs had any record of funding acupuncture for low back pain. Whilst acupuncture may be delivered by physiotherapists as part of their scope of practice, the survey shows that this work is not commissioned. This implies a failure of commissioners to adequately

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					taken steps to ensure that they do comply with the guidance (for CQC purposes and to ensure best practice) and have audited compliance. In addition, many GP practices still send their patients to other venues for treatment so it is hardly surprising that "only 15% offered acupuncture in their practices". In the document one even stated that they would not accept acupuncture unless it showed "clinical exceptionality" which is unrealistic for any treatment strategy for such a varied client group.	fund a NICE recommendation and does not imply a bias against acupuncture. We have also now included a reference to a recent abstract which also highlights that the guidance has not been implemented in primary care, which is not specific to acupuncture.
8.	SH	Acupuncture Association of Chartered Physiotherapists	7	4.1.1d	Issue with the word "chronic". As this is a common theme throughout the document, it suggests that the GDG already has difficulties with consistent terminology.	Thank you for your comment. This wording has now been amended.
9.	SH	Acupuncture Association of Chartered Physiotherapists	8	4.1.2c	See above- as "acute" also needs defining if it is to be used within the document. Hence perhaps the standard definitions (as defined in the research literature) do not fit with the practicalities (as stated in the scoping group feedback) of implementation and may be a further barrier to good compliance in the next guidelines.	Thank you for your comment. The full guideline will contain a glossary in which these terms will be clearly defined.
10.	SH	Acupuncture Association of Chartered Physiotherapists	9	4.3.1d	It is imperative that all non-pharmacological interventions have the same statistical tests applied to them and be consistent in the research questions and the type of evidence considered. Recommendations should not be made just on the basis of cheaper but less effective treatments (for example hot baths/orthotics in the OA knee guidelines) unless the care is given in a stepped approach or as part of a care pathway.	Thank you for your comment. The methodology of systematic reviews will be consistent according to the NICE methods manual http://publications.nice.org.uk/the-guidelines-manual-pmg6 . While the type of evidence considered for reviews may differ, this will be reflected in the quality rating of this evidence. The GDG will always consider the quality of the evidence in developing recommendations. The GDG must consider cost effectiveness for each intervention reviewed.
11.	SH	Acupuncture Association of Chartered	10	4.4d	Adverse events should be considered over equivalent time frames. For example, when the literature is accessed for adverse events in acupuncture (Ernst) the time frame considered is 40	Thank you for your comment. The GDG will consider the need to specify timepoints for measurement of outcomes

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		Physiotherapists			years. Any pharmacological or pharmacological intervention should be considered over comparable time spans for parity.	per review.
12.	SH	Acupuncture Association of Chartered Physiotherapists	11	4.5	Patient choice should also be taken into consideration.	Thank you for your comment. We agree this is an important factor. The lay members of each GDG are vital in representing the patient perspective. The guideline will also cross refer to the NICE guideline CG138 Patient experience in adult NHS services, in which patient choice is a key focus of the recommendations.
13.	SH	Arthritis and Musculoskeletal Alliance	1	General Comment	ARMA welcome the widening of the scope of the review.	Thank you for your comment.
14.	SH	Arthritis and Musculoskeletal Alliance	2	General Comment	Back pain can be treated and managed in primary and secondary settings; ARMA does not feel that this is sufficiently demonstrated nor explained in the Draft Scope, and is a key aspect which should be expanded upon.	Thank you for your comment. The scope states that the guideline will apply to all settings in which NHS funded care is provided.
15.	SH	Arthritis and Musculoskeletal Alliance	4	3.3.2	(a) We suggest that this statement also acknowledges the availability of other primary health care practitioners, not just GPs, and that patients have the access to these care providers. (b) ARMA suggest the inclusion of exercise to improve outcomes. Physical activity has been greatly recognised to reduce lower back pain symptoms, and so should be accordingly incentivised.	Thank you for your comment. The intention of this section is just to provide background information and we do not agree that it needs to be reworded. Exercise is included within the list of possible interventions in 3.2b.
16.	SH	Arthritis and Musculoskeletal Alliance	5	4.1.1	(a) No comment. (b) No comment (c) ARMA advise the consideration of subgroups – people with back pain generally suffer from comorbidities too, and so these needs must also be considered. In addition it would also be useful to include subgroups for emergency referrals, and for those who have exhausted all recommended treatment interventions.	Thank you for our comments. 4.1.1 c states subgroups that will apply for the whole of the guideline. Additional subgroups may be identified for specific review questions, determined by the GDG and detailed in the review protocol.
17.	SH	Arthritis Care	1	General, &	Arthritis Care welcomes the proposed update of the NICE	Thank you for your comments. Any

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				para 4.3.1	guideline on low back pain (LBP). We note both that this is a review of the whole previous guideline and the poor compliance with previous guideline. We believe that a coordinated programme of activity is needed to address the burden of musculoskeletal disease, of which low back pain is an important component. For example, we welcome the inclusion of exercise in the list of issues covered for the management of LBP. People with osteoarthritis can experience improvements in their condition, including pain levels, through undertaking general exercise, muscle strengthening, and weight loss, as per NICE clinical guidance (GC59). We submit that all of these interventions should be included in the remit of the update.	interventions that fall within the review protocols will be considered if evidence is identified. The protocols will be drafted by the GDG based on the areas specified in the scope once development begins.
18.	SH	Arthritis Research UK Primary Care Centre, Keele University	1	General	We welcome the widening of the scope of the review, as this will mean the guidelines are more clinically relevant (particularly including leg pain/sciatica), however we note the substantial increase in workload associated with this review for the GDG. In particular it will be difficulty to provide clinically useful guidance for this large population – will guidance be broken down to either i) duration of condition or ii) other. We would welcome the guidance recommending a holistic assessment of the patient's condition including risk stratification.	Thank you for your comment. We acknowledge the breadth of this scope and large workload involved. The work plans and timelines for this guideline will be planned accordingly. The GDG will consider how best to sub-divide the areas for review and for presentation of the final guidance during development, with the intention of producing user friendly guidance.
19.	SH	Arthritis Research UK Primary Care Centre, Keele University	2	4.1	Population – we recognise the reduction of duration of symptoms to weeks but query the rationale behind 2 weeks – is there a clinical rationale for this? We are unaware of any difference in patient's prognosis if their pain has lasted 10 days versus 15 days for example.	Thank you for your comment. The cut-off point for presentation has now been removed from the scope.
20.	SH	Arthritis Research UK Primary Care Centre, Keele University	3	4.1	We are delighted to note that suspected radicular pain/sciatica is included in this review.	Thank you for your comment.
21.	SH	Arthritis Research	4	4.1.1.d	We note that the cut-off point of 12 months has been removed and	Thank you for your comment.

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		UK Primary Care Centre, Keele University			welcome this, however this will mean that a new body of literature will now become relevant for review by the GDG relating to the management of chronic pain syndrome.	
22.	SH	Arthritis Research UK Primary Care Centre, Keele University	5	4.2	Could this be reworded to "all settings in which NHS **funded** care is received". Colleagues who attended the scoping workshop believed this had been agreed. It is important this includes 'NHS funded care' to take into account the implications of commissioning of 'any qualified provider' from NHS commissioners who will potentially be commissioning care from private providers for NHS patients.	Thank you for your comment. This has been amended in the scope to better reflect where there guidance will apply,
23.	SH	Arthritis Research UK Primary Care Centre, Keele University	6	4.3.1	We are delighted to see that prognostic factors are included – as we believe that the categorisation of acute/subacute/chronic is now less valid with strong evidence for stratification of patients according to their risk of ongoing disability. There needs to be guidance for the assessment of patients in primary care (including evidence for imaging/screening for prognostic factors etc).	Thank you for your comment.
24.	SH	Arthritis Research UK Primary Care Centre, Keele University	7	4.3.1	The review of pharmacological intervention should include anti-inflammatories opioids, muscle relaxants (including benzodiazepines), antidepressants, anticonvulsant neuromodulators and antibiotics in certain subgroups of LBP (colleagues attending the scoping workshop believe this was agreed). In addition we would highlight the need for the review to include the role of anti-TNF therapies in the management of sciatica.	Thank you for your comment, these pharmacological treatments are included within the overarching headings stated in the scope. Anti-TNF therapies for sciatica will be considered under the heading of injection therapies.
25.	SH	Arthritis Research UK Primary Care Centre, Keele University	8	4.3.1	Will non-pharmacological interventions include modalities such as Ti-chi and yoga?	Thank you for your comment. If evidence is identified for these modalities, they will be considered within exercise therapies, but reviewed as separate treatment options.
26.	SH	Arthritis Research UK Primary Care Centre, Keele University	9	4.3.1	We are pleased to see the review including multi-modal therapies as this reflects direct clinical care (with clinicians often utilising packages of care) but can we clarify that the review group will allow the combination of packages of care (e.g. combining several types of non-pharmacological and pharmacological therapies in combination)	Thank you for your comment. The scope has been re-worded as 'Combined therapies' to more directly reflect what is intended. Any combinations that are identified in the literature will be considered, including combinations of

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						packages of care.
27.	SH	Arthritis Research UK Primary Care Centre, Keele University	10	4.3.1	Psychological interventions – again we see this as one of the 'combination' therapies and wonder why this is considered separately (see point above). Clinicians use physical and psychological interventions in combination and for the guidelines to be relevant for clinicians (and hence increase uptake/adoption of the guidance in practice) the guidelines need to reflect this.	Thank you for your comment. We acknowledge that psychological interventions may be given in combination with other therapies. The intention is that psychological therapies given alone, or in combination with other therapies included in the guideline scope, will be included if evidence is identified in the literature.
28.	SH	Arthritis Research UK Primary Care Centre, Keele University	11	4.3.1	Injection therapies – will this included all types (i.e. imaging guided and non-guided injection therapies)?	Thank you for your comment. These will be covered within the scope of the guideline.
29.	SH	Arthritis Research UK Primary Care Centre, Keele University	12	4.3.1	We would query why there is a specific heading for surgery whilst there is no specific section highlighting the need for referral for specialist (not necessarily surgical) opinion. Colleagues attending the scoping workshop felt that this was a key area that needed addressing. We would recommend that the GDG considered a heading: "Indication for onward specialist referral" which allows for referral for other interventions such as specialist spinal physiotherapy; imaging/MIR; pain management specialists; as well as specialist surgical opinion.	Thank you for your comment. The guideline will cover referral for specialist assessment. We are unable to cover all options for referral, but will look at types of surgery specifically, and therefore referral for surgery is the only option specifically detailed in the scope.
30.	SH	Arthritis Research UK Primary Care Centre, Keele University	13	4.4.	Work loss and early retirement due to LBP should be considered as an outcome? Section 3.1b highlighted the issue of work but this is not included as an outcome. We would recommend that reduction in work loss and early retirement due to LBP should be seen as an outcome because of LBP's contribution to these two areas.	Thank you for your comment, outcomes for each condition will be determined per review question in the protocols. The outcomes listed in the scope are the key ones that will be considered across the guideline and are not all-inclusive.
31.	SH	Arthritis Research UK Primary Care Centre, Keele University	14	4.4	Time to recovery – again this should be considered as an outcome. Evidence from trials for sciatica have shown that patients can improve quicker with some treatments – time to recovery therefore seems to be an important outcome and there is danger that relevant evidence will be missed if this is not included.	Thank you for your comment, outcomes for each condition will be determined per review question in the protocols. The outcomes listed in the scope are the key ones that will be considered across the

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						guideline and are not all-inclusive.
32.	SH	BackCare	1		Several studies show that back pain and physical factors are not associated once you account for psychosocial factors. Furthermore, the attribution of physical causes is a risk factor for nonspecific symptoms. This suggests that we are unwittingly driving the increase of back pain through public health and primary care messaging.	Thank you for your comment. The assessment of psychosocial factors and role of psychological therapies are included within the scope of this guideline.
33.	SH	BackCare	2		Psychosocial factors are consistent predictors of back pain, and "low back pain" is common to several validated assessments of somatisation. The evidence suggests that nonspecific back pain is fundamentally psychosomatic.	Thank you for your comment. The guideline intends to review psychosocial factors as prognostic indicators for non-specific low back pain and psychological therapies in the management of non-specific low back pain.
34.	SH	BackCare	3		In comments on the scope, group #4 said, "psychological interventions do not need to be led by a psychologist." It is quite alarming to think that psychological interventions are being dispensed like mechanical recipes. Should surgeons lead surgery?	Thank you for your comment. The guideline will indicate the skills required by the clinician to deliver interventions, rather than their profession.
35.	SH	BackCare	4		The re-emphasis of the Alexander Technique in the guidelines is to be commended as it has been improperly represented to date. The AT model integrates cognitive and affective dimensions. AT is not merely postural education. This is a vital distinction to make.	Thank you for your comment.
36.	SH	BackCare	5		The Danish antibiotics trial did not use an active placebo control. Bioclavid has very obvious side effects. Without an active placebo control the results cannot be distinguished from a placebo effect in patients who realised they were in the 'right' group.	Thank you for your comment. The GDG will consider the quality of available evidence for each separate review in forming their recommendations.
37.	SH	BackCare	6		The stance of smoking cessation should be strengthened by actually stating specific evidences, namely that (a) surgical and non-surgical back pain treatments statistically fail in smokers, (b) heavy occupational lifting only predicts back pain in smokers, (c) smoking dependency is strongly associated with dysfunction on several psychological assessments.	Thank you for your comment. Smoking cessation will be considered within the heading of lifestyle interventions if thought appropriate by the GDG.
38.	SH	BackCare	7		Even the magic bullet will not work on a non-compliant patient. Similarly, if guideline implementation remains poor, then even the best guidelines in the world are useless. This process is subject to	Thank you for your comment. The adherence of various clinicians to NICE guidance does not fall within the remit of

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					its weakest link. If GPs constitute the weakest link, this must be remedied in a technical and evidenced-based manner, no less.	this guideline.
39.	SH	British Acupuncture Council	1	General	For a guideline that covers many different types of therapeutic option there should be an evidence framework that is relevant to all of them, and which is applied evenly across the board. It is critically important to recognise and deal appropriately with complex interventions (Craig et al 2008), that have multiple, interacting components and largely unknown underlying mechanisms. Physical and psychological interventions are of this type, as is acupuncture. Acupuncture involves diagnostic procedures, a therapeutic relationship, touch, needle insertion, needle manipulation, ongoing selection of needling locations, patient education and patient self help measures, all of which may be therapy-specific to some degree (Paterson and Dieppe 2005). The use of sham controls is challenging for complex interventions: they cannot be considered placebos in the same way as in drug trials. For example, there is no credible placebo for acupuncture; even the 'gold standard' is seriously flawed (Lund et al 2009). Sham acupuncture interventions usually try to control for just one or two of the components, not the whole therapy. It would be similarly inappropriate to extract a single CBT item and use it to represent the therapy. Many different sham acupuncture approaches are represented in the published acupuncture for back pain RCTs. Most of them are obviously active and none of them are considered to be inert placebos. They function as alternative forms of acupuncture, diluting it to differing degrees. Hence the specific treatment effects may be underestimated. On the other side of the balance, poor blinding could over-estimate the effect. We don't know the relative sizes of these conflicting factors and the interpretation of sham acupuncture data is fraught with difficulty and conflict. Hence sham comparisons are only minimally useful for assessing	Thank you for your comment. We acknowledge the issues around selecting the appropriate comparator for acupuncture and other complex interventions. The GDG will consider the appropriate comparators, outcome measures and study designs for each review question when the protocols are agreed. Methodology applied will be consistent for all interventions reviewed and will be in accordance with the NICE guidelines manual: http://www.nice.org.uk/guidelinesmanual

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					benefits and harms. These are pragmatic questions that require pragmatic data: comparisons against waiting list, usual care or other competing treatments. Sham trials answer questions about performance of an intervention under ideal experimental conditions, not those relevant to normal clinical practice. They are poorly equipped to help NHS commissioners, clinicians or patients. Other non-pharmacological therapies (e.g. exercise, manual therapies) may also be considered complex interventions with no feasible placebo. They will all have different amounts and types of evidence but it is crucial for the credibility of the guideline that they are all examined consistently: - Research questions should be of a similar form for all - The same definition of clinical effectiveness - The same type of primary data used for recommendations - The same treatment of data quality issues. Comparative effectiveness research could be used as the over-arching framework for the guideline. There is a sound rationale for favouring it over explanatory research for answering real-world questions and it is particularly well suited to complex interventions (Witt et al 2012). Hence the research question for all non – pharmacological therapies could be of this form (as in SIGN's current Chronic Pain guideline): 'In patients with low back pain what is the effectiveness of treatment X compared with no treatment X or other interventions on pain scores, functional ability, quality of life etc.'	
40.	SH	British Acupuncture Council	2	General	Given the technical and conceptual difficulties discussed above, and given that poor take-up of acupuncture in primary care was a driver for this guideline update, it does not inspire confidence to find that there will be no place for an acupuncturist in the main GDG. The group looks to be top heavy with doctors. To be sufficiently competent and credible in respect of acupuncture the	Thank you for your comment. After careful consideration it has been decided that an acupuncturist is not needed as a full member of the guideline development group (GDG). Should the GDG feel that more specialist input is required for

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					guideline needs an acupuncture voice in the decision-making body. Such a person would need to be both an acupuncturist and an academically well-regarded researcher, with experience of quantitative trial methodology, systematic review and economic analysis (there are only half a dozen in the UK). References Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M: Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:979–983 Paterson C, Dieppe P. Characteristic and incidental (placebo) effects in complex interventions such as acupuncture. BMJ 2005;330:1202–1205 Lund I, Nasland J, Lundeberg T. Minimal acupuncture is not a valid placebo control in randomised controlled trials of acupuncture: a physiologist's perspective. Chin Med 2009;4:1 Witt CM, Chesney M, Gliklich R, Green L, Lewith G, Luce B, McCaffrey A, Rafferty Withers S, Sox HC, Tunis S, Berman BM. Building a strategic framework for comparative effectiveness research in complementary and integrative medicine. Evid Based Complement Alternat Med. 2012;2012:531096	particular review questions; an acupuncturist will be co-opted to the GDG and will be invited to relevant GDG meetings.
41.	SH	British Acupuncture Council	3	4.3.1	We welcome the re-categorisation of acupuncture from invasive procedure to non-pharmacological intervention. However, it remains to be seen whether it will be treated appropriately as a complex intervention (see discussion in comment 1 above)	Thank you for your comment.
42.	SH	British Acupuncture Council	4	4.5	We hope that there will be equipoise in the way in which the different interventions are investigated and their data analysed and interpreted, in order to deliver credible recommendations (see comments in 1 above).	Thank you for your comment. Data analysis in systematic reviews will be according to the methodology of the 2012 NICE methods manual for all interventions.

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43.	SH	British Acupuncture Council	5	4.5	It is inappropriate to measure the cost-effectiveness of acupuncture against sham, as has been acknowledged by NICE elsewhere. The NHS is interested in the practical benefits and opportunity costs, not those related to one version of acupuncture vs another. Furthermore the incremental cost of acupuncture versus sham acupuncture could be zero, or even negative, given similar practitioner costs and the greater cost of sham devices. There is existing high quality cost-effectiveness data for LBP and acupuncture (e.g. Lin et al 2011) References Lin CW, Haas M, Maher CG, Machado LA, van Tulder MW. Cost-effectiveness of guideline-endorsed treatments for low back pain: a systematic review. Eur Spine J. 2011 Jul;20(7):1024-38.	Thank you for your comment. We acknowledge the issues around selecting the appropriate comparator for acupuncture studies. The GDG will consider the appropriate comparators, outcome measures and study designs for each review question when developing the protocols.
44.	SH	British Association Of Spine Surgeons	1	3.2e Pg 4	We challenge the contention in the scope that the evidence behind surgery/intervention for radicular pain is limited (3.2e Pg 4). We accept that the rationale for intervention in low back pain is much more controversial.	Thank you for your comment. We believe there is uncertainty about long term effectiveness and therefore do not agree this needs rewording in this section. We will review this within the guidance.
45.	SH	British Association Of Spine Surgeons	2	General	We support the need for a root and branch revision of the NICE LBP guidance, and welcome the opportunity to contribute. We support the inclusion of radicular pain in the Guidance, as many patients will present with a mixture of both presentations.	Thank you for your comment.
46.	SH	British Association Of Spine Surgeons	3	4.1.1 pg 5	We support the removal of the artificial 12 month limit on the guidance, and welcome the identification that early intervention at 2 weeks may be necessary, rather than commencing intervention at 6 weeks.	Thank you for your comment. The scope of the guideline has now been further amended to include people from onset of symptoms.
47.	SH	British Association Of Spine Surgeons	4	General	We suggest that the Guidance should focus on making a clear diagnosis of where pain may arise, if that is possible by history, examination and appropriate investigation, at an early stage, so	Thank you for your comment. Systematic assessment of low back pain is included within the scope.

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					that the most appropriate treatment (which may be surgical in the first instance) can be offered. Patients in whom a clear diagnosis cannot be made – 'non-specific mechanical pain' – should be offered whatever evidence based therapy that is clinically and economically viable to deliver.	
48.	SH	British Association Of Spine Surgeons	5	4.4-4.5	We strongly support the focus on the collection and publication of validated outcome data. The guidance should make specific reference to a clear and accurate economic assessment of the resources required to deliver recommended therapies	The guideline development group will consider the clinical and cost effectiveness of all areas reviewed for the guideline. Following publication, NICE will develop a costing tool to assess the cost impact of the recommendations and aid implementation.
49.	SH	British Association Of Spine Surgeons	6	General	We support the scope of investigation as stated	Thank you for your comment.
50.	SH	British Chiropractic Association	1	General Comment – Composition of Guideline Development Group	The BCA is concerned that only one place is allocated on the GDG for "manual therapy" practitioners. Chiropractors, manipulative physiotherapists and osteopaths are being commissioned as AQPs in the NHS to provide MSK services and since the majority of patients will be seen in primary care, manual therapists have a key role in the delivery of successful outcomes for patients. This has been demonstrated in the North East Essex Case Study. We therefore request that two places are made available on the GDG for manual therapy practitioners to maintain a better balance between primary and secondary care.	Thank you for your comment. The guideline development group does include a physiotherapist as well as an additional position for the therapist with an interest in spinal manipulation.
51.	SH	British Chiropractic Association	2	Section 1 Guideline Title	The BCA would propose that the title of the revised Guidelines should be changed to reflect their scope and extended as follows: "**Low back pain, sciatica/radicular pain: early management of persistent non-specific low back pain".**	Thank you for your comments. We have amended the title to: Low back pain and sciatica: management of non-specific low back pain and sciatica.
52.	SH	British Chiropractic	3	Section 1.1 Short Title	The BCA would propose "**Low Back pain/radicular pain/sciatica**	Thank you for your comment. We have amended the short title to: Low back pain

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		Association				and sciatica.
53.	SH	British Chiropractic Association	4	Section 3 – Need for the Guideline – 3.1 Epidemiology (d)	The section on manual therapies should read "**manual therapies (for example massage, mobilisation and joint manipulation) as undertaken by chiropractors, manipulative physiotherapists and osteopaths".** The section on invasive procedures should read "**invasive procedures (for example, facet joint, epidural injections, dry needling and medical acupuncture) as are available in primary health care settings".**	Thank you for your comment. This section of the scope is intended to give an overview of the broad range of therapeutic modalities available rather than specific detail of each therapy. This has therefore not been reworded.
54.	SH	British Chiropractic Association	5	Section 3 – 3.2 – Current Practice	(a) The BCA suggests that this paragraph be reworded to say "**People with low back pain may go to their GP or other primary health care practitioners for initial treatment and consequently, in most cases, their care will be managed in a primary care setting.** (b) Management – the BCA proposes that this paragraph be revised as follows: "**management – (once the aetiology has been identified as non-specific) a combination of lifestyle advice, conventional treatment such as pharmacological therapy and exercise and keeping active".** **If pain persists, refer for manual therapies, psychologically informed therapies, exercise and invasive procedures such as medical acupuncture. Surgical intervention may be offered to those who have completed an optimal package of care.** (c) The BCA proposes that this sentence should be added to the text "**Providers of manual therapy may also offer medical acupuncture as part of a package of care.** (d) No change. (e) The BCA proposes that the use of the word "spontaneously" is misleading in this context as this is not always the case. Therefore, this section might read "**In the majority of cases, symptoms caused by a**	Thank you for your comment. Paragraph 3.2 (a) has been amended as suggested. Paragraph 3.2 (b) (c) and (e) remain unchanged as it was felt that the suggested wording would not add further clarity to the present wording.

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					herniated disc resolve with conservative management including manual therapy".	
55.	SH	British Chiropractic Association	6	Section 4 – The Guideline – 4.1 Population – 4.1.1 Groups that will be covered	(a) The BCA notes that no sub-groups have been identified as needing specific consideration. We would propose that this should be reviewed as patients with high bio-psychosocial co-morbidities have specific needs which should be taken into account.	Thank you for your comment. We agree that people with co-morbidities require consideration when treatments are considered. This applies to all therapeutic areas, and will be considered by the GDG when recommendations are drafted if specific to this population.
56.	SH	British Chiropractic Association	7	4.1.2 – Groups that will not be covered	(c) The BCA believes that the use of the word "acute" in this paragraph is misleading. We propose that this sentence should be revised to say "**People with low back pain (less than 2 weeks duration).**	Thank you for your comment. The duration limit has now been removed following other stakeholder comments and therefore this bullet point has been removed.
57.	SH	British Chiropractic Association	8	4.3 Management	(d) The BCA proposes that the section on manual therapies be reworded as follows: **"manual therapies, including spinal manipulation, mobilisation as practised by chiropractors, manipulative physiotherapist and osteopaths; and massage".** The BCA proposes that the section on acupuncture should read:- **"medical acupuncture and dry needling".**	Thank you for your comment. We have worded this as 'manual therapies including massage' as a broad heading which may also include spinal manipulation and mobilisation. The specific therapies to be included will be defined by the GDG when developing the review protocols. Acupuncture has been also stated as a general heading, which may also include dry needling. This will also be defined in the review protocols.
58.	SH	British Chiropractic Association	9	4.3.2	(a) The BCA would pint that that some cases of spondylolisthesis may appear stable and consequently do respond to physical therapy.	Thank you for your comment. The management of spondylolisthesis is beyond the scope of this guideline.
59.	SH	British Chiropractic Association	10	4.4. Main Outcome	The BCA is concerned that the outcome measures being considered do not look at psychosocial factors. The Bournemouth Questionnaire (BQ) is proposed as a better alternative as it is a well validated outcome measure for back pain and takes into account psychosocial factors.	Thank you for your comment. The questionnaires stated are examples of those that will be included. Others will also be included if identified in the literature.
60.	SH	British Institute of	1	4.3.1. b)	Under "self-management strategies" we feel the scope should add	Thank you for your comment and this

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		Musculoskeletal Medicine			: " including advice on Rest (defined as a temporary restriction of activities with the intention to unload malfunctioning structures, reduce concurrent pain and influence rate of recovery). Guidance to sufferers on the specific indications for rest and clear parameters for its use including the transition towards normal activity as impairment reduces." Specific advice that avoids the mixed messages many people receive that may go on to be contradicted by their own immediate experience. Background: over the last seventeen years, the data used for guidelines and evidence reviews of the effects of rest or activity on acute low back pain has uniformly relied on a small number of trials. The reliance put on their small or absent effects has led to a move away from the excessive use of rest of the past but has gone on to assume no beneficial effects from rest at all. The trials reviewed have not been designed or had the power to shown absence of effect while strong contrary evidence has been ignored on the basis of evidence selection criteria that were chosen in the full knowledge of the studies available and therefore not secure from bias. Comment on the evidence base for this advice has come from eminent (Koes B. Evid Based Med 2010; 15(6): 171-20) and less eminent sources (MacDonald R. International Musculoskeletal Med. 2013; 35(3): 121-5). Until the issues raised in these commentaries have been addressed, advice on rest vs activity may have to be changed or health practitioners allowed to give advice based on their own clinical judgment in individual situations.	useful information. This will be covered by the scope of the guideline.
61.	SH	British Institute of Musculoskeletal Medicine	2	4.4	Understanding and Self-efficacy: The two most common issues for those seeking treatment for LBP are " What's causing my pain? What can I do to get rid of it?". Those who feel they understand the cause of their pain are more compliant with subsequent management and make fewer demands on healthcare resources. (Patient satisfaction with medical care for low-back pain. Deyo RA, Diehl AK. Spine	Thank you for your comment and useful information. This will be covered within the scope of the guideline under the heading "self-management strategies"

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					1986;11(1):28-30**.** Patient Expectations of Treatment for Back Pain; A Systematic Review of Qualitative and Quantitative Studies. Verbeek JMD, Sengers M, et al Spine 2004; 29(20): 2309–18). Considerable training and resources are aimed at enabling health care practitioners to provide this information. Not to monitor the outcomes of this process certainly risks unmet need and/or wasted resources and may fail to identify opportunities for secondary prevention. To assess perceptions of self efficacy, Multidimensional Health Locus of Control questionnaires are available mainly for research purposes and would be cumbersome in clinical use. A single question in a PROMS assessing confidence in self-managing future episodes of LBP could be used. As such confidence is sought by patients, its acquisition could be a justifiable outcome in itself; evidence that it predicts less future LBP is not presented.	
62.	SH	British Institute of Musculoskeletal Medicine	3	4.1.1 a) & b)	Advice for those whose backpain or radicular pain has not resolved within two weeks is often contingent on a review of that given at the outset to which adherence may have been inadequate. As the principles of the regime being monitored will not essentially differ between the first two weeks and the ensuing period, guidance would not be specific to the latter period. Actions and information given during the initial fortnight may initiate some of the perceptions and behaviours that have been linked to persistence so we recommend that it would be rational for the guideline to apply from onset.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms.
63.	SH	British Institute of Musculoskeletal Medicine	4	4.3.2 a)	We are uncertain, apart from fracture, how "conditions with a select and uniform pathology of a mechanical nature (for example, spondylolisthesis, scoliosis, vertebral fracture or congenital diseases)" can be managed outside the scope of non-specific back pain and or radiculopathy with which they are often co-morbid. Until their contribution to the overall impairment reaches a level where surgical intervention is considered, they are managed in conjunction with the non-specific back pain in the causation of	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the

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					which they may be a contributory factor.	scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
64.	SH	British Orthopaedic Association	1	General	Is the title now appropriate given that radicular pain has been included? Suggest: LBRAD (acronym)	Thank you for your comment. We agree that the title needed amending and have changed it to: Low back pain and sciatica: management of non-specific low back pain and sciatica
65.	SH	British Orthopaedic Association	2	3.1 d)	The role of education remains understated. Use of electronic media campaigns in Australia had significant effect in reducing consultation for LBP. It is likely that similar benefit would result if this was implemented in the UK.	Thank you for your comment. Patient education is included in the scope of this guideline and will be covered, However, population based campaigns are beyond the scope of this guidance.
66.	SH	British Orthopaedic Association	3	3.1 e)	Suggest ' surgical treatment may be considered if specific criteria are met. E.g. included for illustration : *Conservative modalities of treatment have failed and :* *symptoms are persistent and disabling.* *The extent of degenerative changes is limited* *That there is an identifiable source of symptoms.* *The patient wishes to consider surgical intervention.* *The patient is fit to undergo the procedure proposed.*	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
67.	SH	British Orthopaedic Association	4	3.1 f)	Insofar as the treatment options for low back pain are identified in (e), there should be similar reference to the available treatment modalities for radicular syndromes and sciatica including surgery.	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
68.	SH	British Orthopaedic Association	5	3.2 b)	Is the phrase 'once non-specific aetiology has been diagnosed' not in itself tautologous? Should this read 'if no cause can be identified for symptoms at that time'? What is meant by Physiotherapy? This is a nonspecific term open to various interpretation.	Thank you for your comment. This section of the scope is intended for background information in the scoping only and we therefore do not agree this needs rewording.
69.	SH	British	6	3.2 c)	Is there any documentation of the provision of either high or low	Thank you for your comment. This

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		Orthopaedic Association			intensity CPP programs? An impression is that the provision of these programs is probably worse than that of spinal manipulation or acupuncture.	section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
70.	SH	British Orthopaedic Association	7	3.2c)	This also begs the question, in the current resource restricted environment, about the anticipated level of implementation of this guideline. As referred to later it does not seem that the scope has addressed the level of mandate that the guidance will carry. It seems likely that unless subject to external peer review assessment or without significant financial incentive to CCG's, they may, irrespective of the evidence supporting CPPs, ignore this for financial reasons.	Thank you for your comment. The cost impact of each guideline is considered by the implementation team following the systematic review of clinical and cost effectiveness of each intervention. Implementation tools will also be produced to support the guideline when it is published, taking considerations of CCGs into account.
71.	SH	British Orthopaedic Association	8	3.2 e)	Should the last sentence read 'In cases where progressive motor deficit is present and/or there are symptoms or signs of sphincter involvement urgent surgical intervention should be offered if there is imaging confirmation of neurological compromise.'?	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
72.	SH	British Orthopaedic Association	9	3.2e)	It seems illogical that whilst progressive neurological deficit is identified in this section that this does not then go on to include cauda equina syndrome which is simply an extension of the same process. It is strongly recommended that Cauda equina syndrome should be included within this guideline.	Thank you for your comment. The recognition of serious conditions (including cauda equina) is covered within the scope of this guideline (section 4.3.1 a) while the subsequent management of these conditions will not be covered.
73.	SH	British Orthopaedic Association	10	4.1.1 a)	It seems illogical to use age threshold of 18 or older (with the exception that this may be a reflection of the arbitrary divisions used for provision of care in the secondary sector). For all practical purposes there is little difference in the treatment required for the young adult (14 or older) compared with those over 18..	Thank you for your comment. The age threshold for the guideline those aged 16 or older.
74.	SH	British Orthopaedic	11	4.1.1a)	At the opposite end of the spectrum it used to be a widely held belief that disc prolapse did not occur in the elderly. Whilst this is	Thank you for your comment. The GDG will consider the need to separately

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		Association			less common, experience confirms that this is often the cause of acute deterioration of previously minor stenotic symptoms. This may be equally debilitating in the elderly and if fit may merit the usual consideration of surgical options as appropriate	analyse strata or subgroups of the population when outlining the protocols for each separate review.
75.	SH	British Orthopaedic Association	12	4.1.1 b)	It is welcomed that the guideline will address sciatic symptoms that have not resolved within two weeks of onset. It is felt that to include all of those with 'suspected radicular pain' within this definition is likely to unnecessarily swamp a viable sciatica service (including many of those of working age) with large numbers with minor stenotic symptoms.	Thank you for your comment. The GDG will consider, in agreeing review protocols, the need for any stratification of the population (for example according to severity of symptoms) within their recommendations.
76.	SH	British Orthopaedic Association	13	4.1.1 c)	Are statistics available that define the numbers with sciatica within two weeks of onset? In the prior section 3.1.f, no definition was given of the duration of symptoms to be included in the definition of the annual incidence of an episode of sciatica. Should some qualification of the severity of radicular pain be included to moderate the numbers that might otherwise present? It is suggested that this should be reworded 'people with **disabling** radicular pain **with root tension** that has not resolved within two weeks of onset' (to differentiate this from the onset of minor lateral canal stenotic symptoms). Also if this clinical guideline is to be practically useful it will be necessary for it to contain clear definition of the differing types of radicular syndrome and accompanying degree of neurological impairment together with timelines for referral, investigation, and potential intervention. It is suggested that specific consideration should be given to people of working age rendered incapable of work in consequence of their symptoms. In the same way that members of the armed services are afforded special consideration it is suggested that for macro-economic reasons it is important to minimise the number of people who are avoidably off work.	Thank you for your comment. The scope has now been amended to include people from onset of symptoms. The GDG, when agreeing review protocols, will discuss the need to consider different subgroups, and will also agree the priorities for economic analysis. NICE do not consider time lost from work for clinical and cost effectiveness as this can be seen to disadvantage those who are not of working age. We will however consider return to work as an outcome for appropriate review questions.
77.	SH	British Orthopaedic Association	14	4.1.1 d)	It is supported that the cut-off point of 12 months has been removed.	Thank you for your comment.

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78.	SH	British Orthopaedic Association	15	4.1.2 a)	Response by bullet point: • It is only possible to define that low back pain is due to a specific mechanical spinal pathology if the clinical presentation is supported by appropriate imaging findings. It is unclear what the term select and uniform means. • It is suggested that inflammatory arthritic disease should be mentioned under a separate bullet point to visceral conditions presenting with back pain. • Cauda Equina syndrome is usually due to a primary mechanical failure of the intervertebral disc with secondary neurological consequence (which should be included in this guideline) as opposed to primary intrinsic neurological disorders which should not be included in the scope of this document.	Thank you for your comment. The diagnosis of back pain due to specific aetiology (including spondylolisthesis), and the recognition of serious conditions (including CES) will be covered within the scope of this guideline, however, the subsequent management of these conditions will not be covered. We agree that inflammatory conditions should be mentioned under a separate bullet point to visceral causes of back pain and have amended the scope accordingly,
79.	SH	British Orthopaedic Association	16	4.1.2 c)	It seems illogical to use age threshold of 18 or older (with the exception that this may be a reflection of the arbitrary divisions used for provision of care in the secondary sector). For all practical purposes there is little difference in the treatment provided for the young adult (14 or older) compared with those over 18.	Thank you for your comment. The age threshold for the guideline is those aged 16 or older.
80.	SH	British Orthopaedic Association	17	4.1.2 d)	Careful consideration is required with regard to differing time thresholds for assessment for these different conditions. Some of those with acute low back pain will be in the prodromal phase of a disc protrusion. In addition many relatively central disc protrusions present with little radicular pain but marked dural tension. Would it be preferable to have a uniform time threshold for initial triage for all spinal pain sufficient to warrant medical assessment?	Thank you for your comment. The scope of this guideline has now been amended to include people from onset of symptoms.
81.	SH	British Orthopaedic Association	18	4.3.1 f)	Should spinal cord stimulators and implantable pumps be included in this section? They do require inclusion and in particular have a role in the management of chronic pain in the absence of surgical options.	Thank you for your comment. Spinal cord stimulation is covered by NICE technology appraisal (TA) 159 (Spinal cord stimulation for chronic pain of

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						neuropathic or ischaemic origin). This guideline update will cross-refer to this TA.
82.	SH	British Orthopaedic Association	19	4.3.1 h)	Indications for surgery. This should also include some recommendations with regards to the type of surgery appropriate to the conditions in question.	Thank you for your comment. The specific surgical techniques appropriate to review as part of this guideline will be defined by the GDG. Recommendations will be given based on this evidence.
83.	SH	British Orthopaedic Association	20	4.4 d)	Adverse events should also be included in the critical list as many of these are not readily, if at all, reversible and are of lasting consequence.	Thank you for your comment; this will be considered when outcomes are agreed for each review protocol.
84.	SH	British Orthopaedic Association	21	Composition of guideline development group.	It is welcomed that a radiologist has been included in the Co-opt list. It is however suggested that a diagnostic radiologist should be included in the full membership of the GDG. It is also suggested that an interventional radiologist should be included in the Co-opt list. In some centres a majority of nonsurgical back pain patients are assessed and managed by Orthopaedic physician colleagues if this is beyond the scope or ability of physiotherapist colleagues. It is suggested that consideration be given to inclusion of an orthopaedic physician on the co-opt if not full list.	Thank you for your comment. After careful consideration it has been decided that a radiologist is not needed as a full member of the guideline development group (GDG). Should the GDG feel that additional input is required from an interventional radiologist this expertise may be sought, later in the development process, if required.
85.	SH	British Orthopaedic Association	22	Research Recommendations	The following is an extract from the National Spinal Taskforce report (2013): "In recent years an increasing and appropriate focus has developed on the evidence base underpinning medical interventions. This has been classified in terms of its strengths and weaknesses with double blind RCTs being regarded as the gold standard for most interventions. NICE has recognised that in some surgical areas this is neither always feasible nor the most appropriate method. It is also relevant that from concept through ethical approval and procedure performance to gain sufficient numbers to adequately power a trial, a minimum of two year follow-up, data collation,	Thank you for your comment and this information. The guideline will be developed as per the NICE guidelines manual 2012, using the best available evidence where available. This is not restricted to RCT evidence only.

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					processing, write-up, submission, re-editing, publication and dissemination usually takes a decade. As a result, when attempting to introduce new technology, there is frequently a minimal or absent historical evidence base. It is perceived that in the current financial climate this will be taken as justification not to support innovation in UK spinal surgery. The life expectancy of advice before it is superseded is short. This reduces the incentive for companies to support this type of research. In addition many procedures that are currently being undertaken have a limited evidence base but as perceived by the authors of this report, seem from impression or cohort studies to be of possible potential value. It is unlikely that all of these will in the short term be assessed on an RCT basis. The alternatives are to discontinue commissioning these or to require the proponents to optimise their assessment process using recognised outcome measures and engage in studies for a defined period to justify or deny continued use. If the invitation to participate in such a process is rejected, then continued financing would reasonably be questioned. It is recognised that in the current financial climate surgeons are unlikely to be permitted the time (by Trusts) to set up such a process properly with the necessary independent assessment of outcome. It is suggested that a process should be developed with HTA, clinical trials units and RDS to draft trial design, obtain ethical approval (if necessary for what is an audit of current practice), assess outcomes independently, collate the data and present and publish the results in collaboration with their surgical colleagues. Within a three to five year time frame this should place all procedures on a more robust evidence base. To discontinue familiar current procedures on the basis of an absence of evidence to date would be to spurn a readymade opportunity both to identify procedures that may be of value and also to waste a potential lever to improve outcome assessment.	

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					Many of these studies require networks of surgeons. Commissioners should look at a provider network in terms of its research capacity as an essential part of quality assessment. "	
86.	SH	British Osteopathic Association	1	3.1 D	We feel it important to specify those expertly trained and competent to provide 'spinal manipulation' as part of or over and above simple manual therapy. Whilst the professions providing these interventions may be secondary, in terms of providing guidance it needs to educate, direct and inform those using it and this is better enabled by clearly stating those professional groups who provide spinal manipulation, osteopathy clearly being in this group. It will help GP's and other health professionals to widen their referral and patient choices.	Thank you for your comment. Specifying the competency of practitioners is not the purpose of NICE guidance, but it is expected that any intervention should only be provided by those trained in and competent in its delivery.
87.	SH	British Osteopathic Association	2	4.1 A, B,C	We agree with these changes and think they are helpful	Thank you for your comment.
88.	SH	British Osteopathic Association	3	4.1.2 A	We feel that patients with Ankylosing spondylitis who are not in an acute inflammatory state can benefit from manual therapy and reduce their medication.	Thank you for your comment. The management of patients with ankylosing spondylitis falls outside the remit for this guideline. The management of this condition will be covered in an up-coming clinical guideline.
89.	SH	British Osteopathic Association	4	4.1.2 C	Patients with acute low back pain of less than 2 weeks may be a sub group who have chronic episodic back pain, this may be part of the development of chronic behaviour and so should be managed early	Thank you for your comment. The scope has been amended to cover people from onset of pain (or first presentation to a health care professional) with a view to providing guidance for early treatment.
90.	SH	British Osteopathic Association	5	4.3.1 D	As in 1 above it is more helpful to clearly identify those professions who can evidentially provide safe effective treatment thereby enabling referrer and patient choice	Thank you for your comment. The guideline will indicate the skills required by the clinician to deliver interventions, rather than their profession.
91.	SH	British Osteopathic Association	6	4.3.2 A	Spondylolisthesis and scoliosis should not be excluded as these condition can often be helped symptomatically with manual therapy. Also these conditions may be a finding clinically they may	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to

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					not be the cause of the patients pain.	radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
92.	SH	British Osteopathic Association	7	4.4 A, B	We agree some standard in outcomes need to be addressed, the NRS for pain is simple to use and the Roland Morris or Oswestry would be useful functional measures.	Thank you for your comment and useful information. The outcomes provided are key examples and specific outcomes will be determined by the GDG when the review protocols are drafted.
93.	SH	British Osteopathic Association	8	General	We feel that first contact for low back pain may be much better addressed not via the GP route, but through a multidisciplinary team (MDT). Those professionals identified from the guidelines, working as extended scope practitioners (ESP) would identify mechanical, pathological, complex and psychological presentations through skilled triage and arrange referral or requests for imaging, injecting, CBT, exercise therapy etc appropriately. Unresponsive cases being returned to the MDT for a more collaborative approach. By dealing with patients quickly and clinically appropriately at the start we will then reduce returnees to the system freeing up time/costs. Using ESP's whether they are Osteopaths, Physiotherapists or other MSK specialists will free up GP time and costs but more importantly will drive up standards of care and quality for patients	Thank you for this information. The structure of services will not be covered by this guideline. However, in not specifying the profession required to undertake each diagnostic procedure or intervention, but rather specifying the skills required, the configuration of services may be organised to best fit local need.
94.	SH	British Pharmacological Society (BPS)	1	4.3.1 c)	Members of BPS have raised concern regarding the use of analgesic drugs in the long term treatment of pain. BPS would therefore welcome an assessment of which analgesics should be used, in which order and at what doses.	Thank you for your comment. Analgesics are included within the scope.
95.	SH	British Pharmacological	2	4.3.1 d)	Members of BPS do not believe there is robust evidence of efficacy for acupuncture or chiropractic in the management of	Thank you for your comment. The GDG will consider both acupuncture and

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		Society (BPS)			back pain. However, this should be considered in scope for discussion for the Guideline Development Group (GDG) to allow the GDG to assess the quality of the available evidence.	chiropractic within the evidence reviews for this guideline and base recommendations on the evidence identified.
96.	SH	British Pharmacological Society (BPS)	3	General	BPS would recommend that NICE ensure a clinical pharmacologist is included in the GDG	Thank you for your comment. After careful consideration it has been decided that a clinical pharmacologist is not needed as a full member of the guideline development group (GDG). However, should the GDG feel that more specialist input is required for particular review questions, a clinical pharmacologist may be co-opted to the GDG.
97.	SH	British Society for Rheumatology	1	General	It is concerning that psychological outcomes have not been included. Pain is both a sensory and emotional experience. Many treatments for low back pain aim to improve psychological wellbeing, rather than reducing the sensory component of pain (e.g. cognitive behavioural therapy). The guidelines may be biased to non-psychological treatments if psychological outcomes are not reviewed. The increased scope compared to the 2009 guidelines, to include now back pain from 2 weeks with no upper limit on duration, and to include radicular pain, is admirable and in my view appropriate. However, this is now a very broad scope and the GDG will need to focus on specific questions for their systematic reviews. It will be important that that focus includes interventional therapies for specific indications (ie for back pain, for radicular pain), and includes behavioural therapies (including exercises). A difficulty with the previous guidelines was the boundary between what is specific and non-specific and the place of imaging in defining this distinction will be important.	Thank you for your comment. The outcomes listed in the scope are intended as broad headings and are not intended to be all inclusive. The GDG will agree the appropriate specific outcomes per review question which may include various psychological outcomes.
98.	SH	Chartered Society of Physiotherapy	1	General	We welcome the widening of the scope of the review, as this will mean the guidelines are more clinically relevant and therefore	Thank you for your comment.

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					more likely to be implemented.	
99.	SH	Chartered Society of Physiotherapy	2	General	Given the broader scope we note the substantial increase in workload associated with this review for the GDG. A particular challenge will be to provide clinically useful guidance for all patients within the scope of the guideline. Regarding the onset deadlines, there are advantages and disadvantages to all combinations. Guidelines that include either primary or secondary prevention open up a whole new area of literature that may prove to be too much for this update and may dilute the work done. When the "clock" starts will need to be carefully considered: possibly from onset not treatment. The guidance will need to be broken down further for example into i) duration of condition or ii) area of symptoms or iii) prognostic indicators.	Thank you for your comment, this will be considered. The scope has been amended to include people from the onset of pain (or first presentation to a healthcare professional). The GDG will agree how the evidence should be stratified in detailing each review protocol.
100.	SH	Chartered Society of Physiotherapy	3	General	The decision regarding what type of literature to include is extremely important. Limiting the previous guideline to RCT evidence may have contributed to the low implementation, however widening the types of literature included would make the scope of the guideline even larger. We do think that great care is taken to manage the situation should it be decided that if non-RCT evidence is included for one area/intervention how any recommendation statement is graded: what reasoning is provided. The GDG will need to be aware of how this may be interpreted and will need to manage such a situation with great skill and care	Thank you for your comment. Development of this guideline will follow the NICE guidelines manual and current best practice in evidence based medicine. Grading of level of evidence is performed according to the GRADE system and will be clearly detailed within the methodology of the guideline and each review question discussion when the guideline is published.
101.	SH	Chartered Society of Physiotherapy	4	General	It will be important for the guidelines to differentiate between what is normal aging (degeneration), and what we know from the prevalence of imaging findings in asymptomatic populations.	Thank you for your comment. We agree that this is important and it will be considered.
102.	SH	Chartered Society of Physiotherapy	5	General	We suggest the inclusion of evidence relating to the sub-classification of LBP / radiculopathy and targeted treatments based on these sub-classifications	Thank you for your comment. Risk stratification of patients with low back pain is covered within the scope of this guideline.
103.	SH	Chartered Society of Physiotherapy	6	General	It would be useful to consider referral thresholds and timelines for patients with these conditions	Thank you for your comment. If evidence for appropriate timings of intervention or

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						referral are identified within the review questions, this will be considered.
104.	SH	Chartered Society of Physiotherapy	7	General	The term sciatica is not useful and should be replaced throughout the document, with consistent use of another term, for example leg pain of spinal origin	Thank you for your comment. While there is, unfortunately, no consensus on the correct terminology for leg pain secondary to nerve root compression/pathology, 'sciatica' (to mean leg pain secondary to lumbar nerve root compression/pathology) is widely used by both patients and clinicians and is the prevalent term used in the literature.
105.	SH	Chartered Society of Physiotherapy	8	3.2b	Non-Specific Low Back pain is a diagnosis of exclusion. Therefore we suggest a rewording *'…once specific pathologies have been excluded, the diagnosis of non-specific LBP is made.'*	Thank you for your comment. We have reworded this section.
106.	SH	Chartered Society of Physiotherapy	9	3.2c	We suggest NICE/ GDG reflects very carefully on why this may be so: what was it about the previous guideline that led to poor implementation?	Thank you for your comment. The reasons for poor implementation were considered when the decision to update this guideline was made and will be addressed within the development of the updated guidance.
107.	SH	Chartered Society of Physiotherapy	10	4.1	Population – we recognise the reduction of duration of symptoms to weeks but query the rationale behind 2 weeks – is there a clinical rationale for this? We are unaware of any difference in patient's prognosis if their pain has lasted 10 days versus 15 days for example.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms.
108.	SH	Chartered Society of Physiotherapy	11	4.1.1	It is pleasing that suspected radicular pain / sciatica is included in this update, but diagnosed radicular pain may be perceived to form a specific pathology and so no longer be within the scope of these guidelines. Given that patients move between having back pain and radicular pain we recommend that both pathways have the same start time. It is important that there is a seamless pathway.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms. There will be a glossary within the final guideline clearly defining all terms that are used.

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					A clear distinction between recurrent back/radicular pain and persisting back pain-related disability would be helpful. Therefore definitions of radicular, radiculopathy, somatic referred pain and mechanical nociceptive pain should be clearly made to avoid confusion and ensure national common use of terms, e.g. Bogduk (2009) in *Pain*. We suggest a strengthening of the idea of separating different types of leg pain from spinal origin. Some patients with somatic referral of leg pain may respond differently to treatment to those patients with neuropathic pain, and that patients with neuropathic pain plus neurological deficit may also respond differently to treatment. It may be that it is possible to distinguish two distinct groups present with radicular pain: 1. Discogenic- most prevalent in the fourth and fifth decades 2. Neurogenic claudication - most prevalent over age 60. With growth of an aging population, demand for treatment would be expected in this age group	The subgroups suggested will be considered by the GDG when determining subgroups for each review question, and those that will be included will be specified in the appropriate review protocols.
109.	SH	Chartered Society of Physiotherapy	12	4.1.1a	We support the inclusion of people between age 65 and 70 for the following reasons: • In the UK the working age is now 68 and planned to extend to age 70. • This means that the pathways for >16 will be the same as adults.	Thank you for your comment. There is no upper limit of age in the scope of the guideline.
110.	SH	Chartered Society of Physiotherapy	13	4.1.1b	Guidance for managing acute back pain is available but the evidence base is less clear. Evidence on the natural history of acute low back pain would suggest an argument for reducing the initial timeframe to 4 weeks, or perhaps 2 weeks to align with the radicular pathway. However, approaches to care would need to take into account the large number of patients who will be symptomatic at 2 weeks but significantly settled at 6 weeks.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms.
111.	SH	Chartered Society of Physiotherapy	14	4.1.1c	The risks for acute Cauda Equina syndrome and the timing of surgery are very different between radicular pain and neurogenic	Thank you for your comment. While the urgent recognition of serious conditions

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					claudication. Suggest sub groups of emergency referrals might be useful here, such as CES and MSCC. There may also be value in specifically addressing people with significant neurological deficit as a separate sub group. We also feel that a sub group addressing people who have exhausted all recommend treatment interventions would be of use	such as cauda equina syndrome will be covered within the scope of the guideline, the subsequent timing of surgery is not within the scope. The subgroups will be considered by the GDG when determining subgroups for each review question, and those that will be included will be specified in the appropriate review protocols. The further management of people with symptoms refractory to treatment is also covered within this scope.
112.	SH	Chartered Society of Physiotherapy	15	4.1.1d	We note that the cut-off point of 12 months has been removed and welcome this; however this will mean that a new body of literature will now become relevant for review by the GDG relating to the management of chronic pain syndromes. Suggest consideration given to whether evidence exists for separating 'chronic unremitting back pain' from 'first presentation' or 'presentation as infrequent relapse' on the other.	Thank you for your comment. As this is a full update of the guideline, all literature will be reviewed again, also accounting for the removal of the 12 month cut-off. How this evidence is stratified will be determined by the GDG when the protocols are drafted.
113.	SH	Chartered Society of Physiotherapy	16	4.1.2a	Radiologically diagnosed grade 1 spondylolisthesis should be included. Suggestion - Grade 1 spondylolysthesis to be included in the non-specific low back pain pathway.	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
114.	SH	Chartered Society	17	4.1.2a	With the exception of the red flags (neoplasm, infection, fracture)	Thank you for your comment. The

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		of Physiotherapy			the inclusion of other pathologies in the initial management pathway would be correct and appropriate. Patients with these specific pathologies might present for investigation as a result of failure to respond to early management. Cauda Equina syndrome is usually due to a primary mechanical failure of the intervertebral disc with secondary neurological consequence (which should be included in this guideline) as opposed to primary intrinsic neurological disorders, which should not be included in the scope of this document. Screening and referral to a spinal on-call service for Cauda Equina Syndrome should be included.	identification of both specific pathologies and serious conditions such as cauda equina syndrome will be covered within the scope of the guideline; however subsequent management will not be covered as it is beyond the remit.
115.	SH	Chartered Society of Physiotherapy	18	4.2	Suggest this is reworded to "all settings in which NHS **funded** care is received". Colleagues who attended the scoping workshop believed this had been agreed. It is important this includes 'NHS funded care' to take into account the implications of commissioning care from 'any qualified provider' to ensure all services providing care are covered by the guideline e.g. private providers for NHS patients.	Thank you for your comment. This wording has been amended accordingly.
116.	SH	Chartered Society of Physiotherapy	19	4.3	We would welcome the guidance recommending a holistic assessment of the patient's condition including risk stratification. We are very pleased to see prognostic factors included – as we believe that the categorisation of acute/sub acute/chronic has proven to be unhelpful and evidence for stratification of patients according to their risk of ongoing disability. There needs to be guidance for the assessment of patients in primary care (including evidence for imaging/screening for prognostic factors etc).The importance of Spinal Triage by appropriately skilled clinicians should be emphasised here. Recommendation - The value of a managed, stratified care pathway is an approach which was not specifically examined in the original 2009 guidance and evidence suggests it should be considered for inclusion.	Thank you for your comment. The topics of risk stratification and duration of therapies will be covered within the scope of the guideline.

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					The issue of timeliness regarding the duration of any therapy and also the expectations of the stage on a pathway that therapies should be provided needs to be considered. Long waits between the steps on a pathway greatly increase the risk of chronicity and disability. There is evidence for particular groups with LBP (i.e. good prognosis, low STarT Back risk score) and opportunity for cost savings where treatment beyond assessment, information and advice does not improve outcome. The key is early identification and clear, timely routes for re-referral if needed. We strongly encourage consideration of the cultural aspects of pain.	
117.	SH	Chartered Society of Physiotherapy	20	4.3	We suggest a stepped approach to care with screening at onset to identify & manage those people at risk of developing chronicity	Thank you for your comment. Appropriate systematic assessment to determine management will be covered by the guideline.
118.	SH	Chartered Society of Physiotherapy	21	4.3.1	An additional area for the GDG to consider is the public education (e.g. Buchbinder et al. 2001, 2004)	Thank you for your comment. Population based interventions do not fall within the remit of this guideline.
119.	SH	Chartered Society of Physiotherapy	22	4.3.1a	A high percentage of back and radicular pain improves with natural history. There needs to be clear guidance for referral thresholds	Thank you for your comment. Referral for specialist treatment will be considered.
120.	SH	Chartered Society of Physiotherapy	23	4.3.1b	Public education and prevention - successful programme that was undertaken in Australia (Buchbinder et al. 2001, 2004) & Scotland. http://www.ncbi.nlm.nih.gov/pubmed/17762817 - this showed significant and measurable reduction in attendances and improvements in attitudes and beliefs about back pain and its appropriate management within the general population. The growing emphasis on self-care means it is important the scope of the guideline includes evidence for the effectiveness of	Thank you for your comment. While population based interventions and prevention of low back pain falls outside the remit of this guideline, individual patient and group education will be covered by this guideline.

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					interventions that educate people with low back pain about active management techniques and strategies (for example, Cochrane, 2007, Interventions to improve adherence to exercise for chronic musculoskeletal pain in adults http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005956.pub2/abstract)	
121.	SH	Chartered Society of Physiotherapy	24	4.3.1b	We suggest careful consideration is given to the evidence to support the implementation of client-centred care for this patient population. It is proposed this approach can act as the framework to bridge the gap between practitioner and patient and create an equal partnership. Blending an active self management approach with interventionist management approaches is proposed to offer a more comprehensive management of low back pain. What is the evidence for general exercise classes for early low back pain? What is the evidence for techniques to help patients learn to self manage in order that they be empowered to manage without turning to healthcare professionals immediately? What is the evidence of effectiveness for functional restoration programmes? We also advise information scientists are aware to take care with key words: 'back school' is outdated; suggest possible use of 'Back Rehabilitation'; 'Back Fitness classes'	Thank you for your comment. Self-management and exercise programmes will be covered within the scope of this guideline. The wording of back schools has been removed.
122.	SH	Chartered Society of Physiotherapy	25	4.3.1b	We suggest that health promotion and health education, simple, clear messages for public health are considered, particularly regarding prognosis, activity / exercise / rest	Thank you for your comment. Lifestyle interventions and self-management strategies will be covered within the scope of this guideline.
123.	SH	Chartered Society of Physiotherapy	26	4.3.1b	We suggest the use of an explicit bio-psychosocial approach to all interventions so for example injections / manual therapies are not 'stand alone' but seen as enabling a rehabilitation pathway; exercise programmes addressing beliefs and attitudes rather than	Thank you for your comments. Interventions will not be assessed in isolation and this will be taken into account when recommendations are

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					a purely mechanical (bio-medical) approach	drafted.
124.	SH	Chartered Society of Physiotherapy	27	4.3.1b	We would encourage the consideration of services that provide early access to rehabilitation with a focus on remaining in / returning to employment / previous level of activity	Thank you for your comment. Return to work interventions are covered within the scope of this guideline, and outcome measures will include return to work and health related quality of life measures that include activities of daily living.
125.	SH	Chartered Society of Physiotherapy	28	4.3.1b	We suggest consideration of the effectiveness of postural advice in self management for people with low back pain	Thank you for your comment. Self-management strategies are included within the scope of the guideline.
126.	SH	Chartered Society of Physiotherapy	29	4.3.1c	The review of pharmacological intervention should include anti-inflammatory opioids, muscle relaxants (including benzodiazepines), antidepressants, anticonvulsant neuromodulators and antibiotics in certain subgroups of LBP (colleagues attending the scoping workshop believe this was agreed). In addition we would highlight the need for the review to include the role of anti-TNF therapies in the management of sciatica.	Thank you for your comment, anti-inflammatory opioids, muscle relaxants (including benzodiazepines), antidepressants, anticonvulsant neuromodulators and antibiotics are included within scope. These are examples of treatments that will be included. Anti-TNF therapies will be considered within injection therapies for sciatica.
127.	SH	Chartered Society of Physiotherapy	30	4.3.1d	"Back schools" are now not a component of modern back pain management	Thank you for your comment. This wording has been removed.
128.	SH	Chartered Society of Physiotherapy	31	4.3.1d	Suggest the GDG considers the paradoxical / competing claims of exercise / manual therapies and self-management: for example, how to encourage patients to take an active not passive approach.	Thank you for your comment. Considerations for treatments will be addressed by the GDG when the evidence is reviewed and recommendations drafted.
129.	SH	Chartered Society of Physiotherapy		4.3.1d.	What is the evidence for effectiveness that addressing lifestyle factors therapeutically (whole –person approach) desensitizes the nervous system and reduces (low back) pain? What is the evidence of effectiveness for a novel treatment called Cognitive Functional Therapy (CFT) for chronic low back pain in reducing pain and disability?	Thank you for your comment. Lifestyle interventions will be included within the scope of the guideline as are psychological interventions, and specific interventions within these headings will be considered when the review questions

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					What is the evidence of effectiveness that changing beliefs about back pain does reduce back pain?	are drafted.
130.	SH	Chartered Society of Physiotherapy	32	4.3.1d	Suggest non-pharmacological interventions include Tai-chi and yoga	Thank you for your comment. The list of non-pharmacological interventions now includes yoga. This list is not all inclusive and if evidence for tai-chi is identified for a relevant review question, it will be included.
131.	SH	Chartered Society of Physiotherapy	33	4.3.1d	Suggest the GDG consider the evidence for the use of complementary therapies for people with low back pain, including Adapted Reflextherapy (www. Adaptedreflextherapy.com)	Thank you for your comment. The list of non-pharmacological interventions is not all-inclusive. The GDG will consider specific interventions when drafting the review questions.
132.	SH	Chartered Society of Physiotherapy	34	4.3.1d	Suggest the GDG considers making recommendations for interventions for the very elderly, such as • Provision of walking aids such as rollaters • Adaptations around the home to make life easier, e.g. a toilet frame fitted and a shower seat.	Thank you for your comment. These areas are beyond the scope of this guideline.
133.	SH	Chartered Society of Physiotherapy	35	4.3.1d	Suggest the GDG considers the evidence for: • Aquatic therapy Group hydrotherapy versus group land-based treatment for chronic low back pain. http://www.ncbi.nlm.nih.gov/pubmed/9408932 Therapeutic aquatic exercise in the treatment of low back pain: a systematic review http://www.ncbi.nlm.nih.gov/pubmed/19114433 • Pilates. Daily Pilates exercise or inactivity for patients with low back pain: a clinical prospective observational study. http://www.ncbi.nlm.nih.gov/pubmed/24104699	Thank you for your comment. Specific types of exercise that will be included will be considered by the GDG when the review protocols are drafted.
134.	SH	Chartered Society of Physiotherapy	36	4.3.1e	We are pleased to see the review including multi-modal or combination therapies as this directly reflects clinical care (with clinicians often utilising packages of care) but can we clarify that the review group will also allow the combination of all packages of care (e.g. combining several types of non-pharmacological or non-	Thank you for your comment. This heading has now been amended for clarity and now reads "combination therapies"

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					pharmacological with pharmacological therapies)	
135.	SH	Chartered Society of Physiotherapy	37	4.3.1f	We recommend consideration of the following: • The cost effectiveness of repeated therapeutic spinal injections • Imaging guided and non-guided injection therapies • Neuro-modulation, including spinal cord stimulators	Thank you for your comment. These topics will be covered within the scope of the guideline.
136.	SH	Chartered Society of Physiotherapy	38	4.3.1g	We see this as one of the 'combination' therapies and wonder why this is considered separately. Clinicians use physical and psychological interventions in combination and for the guidelines to be relevant for clinicians (and hence increase uptake/adoption of the guidance in practice) the guidelines need to reflect this.	Thank you for your comment. The intention is that interventions will be considered as monotherapy, or in combination if evidence is identified. This will be specified within the appropriate review protocols.
137.	SH	Chartered Society of Physiotherapy	39	4.3.1g	This should include the influence of the 'significant others' of those with back pain in relation to their recovery and work participation.	Thank you for your comment. Reviewing evidence for participation of family and carers in the management of low back pain was not highlighted as a priority for inclusion in this guideline by stakeholders. The GDG lay members, however, provide the perspective of patients, family and carers which is vital when drafting recommendations.
138.	SH	Chartered Society of Physiotherapy	40	4.3.1g	We suggest inclusion of "mindfulness"	Thank you for your comment. Psychological interventions are included within the scope, and specific therapies will be considered by the GDG when the protocols for the review questions are drafted.
139.	SH	Chartered Society of Physiotherapy	41	4.3.1h	We query the need for a specific heading for surgery whilst there is no specific section highlighting the need for referral for specialist (not necessarily surgical) opinion. Colleagues attending the scoping workshop felt that this was a key area that needed addressing. We would recommend that the GDG considered a heading: "Indication for onward specialist referral" which allows for referral	Thank you for your comment. After careful consideration, we do not think this should be specifically stated in the scope. Although referral for specialist assessment will be considered, surgery is the only specialist area that will be reviewed to provide recommendation on

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					for opinion from a spinal specialist which may include specialist spinal physiotherapy; imaging / MIR; pain management specialists; as well as specialist surgical opinion. Sleep management should also be included.	type of therapy. We are unable to cover all types of specialist treatment within the scope of this guideline.
140.	SH	Chartered Society of Physiotherapy	42	4.3.1h	Sections "a" to "f" do not begin with the term "Indications for" – we wonder why surgery is phrased differently?	Thank you for your comment. This section has been worded differently to indicate that the GDG will specifically consider both referral for surgery and the type of surgery that should be used.
141.	SH	Chartered Society of Physiotherapy	43	4.3.2	Many of the conditions with specific and uniform pathology that will not be included require diagnostic imaging, so we would welcome guidance on the indications for imaging to be included. Some conditions such as cauda equina and metastatic cord compression may not present as a clear case in the early stages and we would welcome guidance on how clinicians and patients should monitor patients to ensure these cases are identified and present to urgent care appropriately, which may involve providing patient self-monitoring information.	Thank you for your comment. While the diagnosis or identification of these conditions (including cauda equina syndrome) will be covered within the scope of this guideline, the subsequent management will not be.
142.	SH	Chartered Society of Physiotherapy	44	4.4.	We suggest consideration of the following as outcomes: • Return to work / Work ability • Early retirement • Hospital admissions • Patient experience • Keele Start Back (Hill et al., 2008)	Thank you for your comment. The outcomes listed in the scope are intended as examples of the key outcomes for the guideline. The GDG will agree the appropriate specific outcomes per review question which may include addition outcomes. These suggested outcomes will be considered, Return to work has been added to the list of key outcomes.
143.	SH	Department of Health	1	General	Thank you for the opportunity to comment on the draft scope 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 for your comment.
144.	SH	Faculty of Pain Medicine, Royal	1	1	The title is confusing. Why early management? Suggest remove "early"	Thank you for your comment. We agree and have amended the title to:

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		College of Anaesthesia				Low back pain and sciatica: management of non-specific low back pain and sciatica.
145.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	2	4.1.2	The exclusion of those with a well defined diagnosis is likely to disadvantage this group of patients significantly. They will be denied first class symptomatic treatment of their back pain just because they have a diagnosis. Strongly suggest this is addressed – clearly there needs to be a pathway for the treatment of the specific disease but this will often not include first class symptomatic relief.	Thank you for your comment. Unfortunately we are not able to cover all causes of back pain within the scope of this guideline. The assessment and identification of these conditions will be included within this scope and therefore in the pathway, the management is beyond the remit and will not be covered.
146.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	3	General	Psychological factors are very important here and are mentioned in the scope. We would hope that these are given appropriate weight – first class psychology input on panel vital.	Thank you for your comment. We agree and have included a psychologist as a member of the guideline development group.
147.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	4	General	Could the GDG consider which back pain population benefits from which intervention as the non specific back pain population are not homogenous ?	Many thanks for your comment. The GDG will consider heterogeneity in the evidence that is reviewed for all questions, and will endeavour to explore and identify the causes for this heterogeneity, including looking at population differences.
148.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	5	4.4	There is plenty of evidence that there is a strong relationship between being in work and measurable health benefits. Will the health economic analysis factor this in?	Thank you for your comment. The priority areas for new economic evaluation will be decided with the GDG during guideline development. Methods for quantifying health benefits for these analyses will be considered and agreed at this time.
149.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	6	General	The scope of the guideline is wide and the work required to do this should not be underestimated - danger of "broad brush with little depth". However, we recognise that this was acknowledged at the scoping meeting.	Thank you for your comment.
150.	SH	Faculty of Pain Medicine, Royal	7	4.4	Suggest an emphasis (or at least equal weighting) on long term rather than short term benefits if possible.	Thank you for your comment. We agree that long term benefits are important. The

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		College of Anaesthesia				GDG will consider the length of follow up for each review when drafting the protocols.
151.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	8	General	Can there be any specific consideration of "failed back surgery syndrome"?	Thank you for your comment. Failed back surgery syndrome is covered as a population within NICE technology appraisal TA159 (Pain (chronic neuropathic or ischaemic) - spinal cord stimulation). We will cross refer to this guidance.
152.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	9	General	From a patient and public perspective, it would be useful to produce information from the guidelines as to what different therapies do, including aspects such as the difference between an osteopath and a chiropractor. Many will use these guidelines and seek therapy out with the NHS (waiting times etc) so the patient needs this information.	Thank you for your comment and helpful suggestion. At publication, one of the guideline products will be an 'information for the public' version of the guideline. This will include a glossary with terms explained; we will include these definitions within this document.
153.	SH	Faculty of Pain Medicine, Royal College of Anaesthesia	10	General	The Faculty of Pain Medicine welcomes this new approach to the back pain guidelines and commends NICE for taking on the enormous but vital task.	Thank you for your comment.
154.	SH	Grünenthal Ltd	1	3.1 a)	A breakdown of the relative proportion of the £1000 million per year spent on pharmacological therapy vs non-pharmacological therapy vs surgery would highlight the areas to focus on when developing guidance on the treatment of low back pain.	Thank you for your comment. The areas of clinical management to focus on were decided through discussion with stakeholders.
155.	SH	Grünenthal Ltd	2	4.1.1 a)	Reducing the age to 16 years and the duration of symptoms to 2 weeks is welcomed to reflect the patient group who will most benefit from early management guidelines.	Thank you for your comment. The scope has now been amended to cover people from the onset of pain (or first presentation to a healthcare professional).
156.	SH	Grünenthal Ltd	3	4.1.1 b)	The inclusion of suspected radicular pain including sciatica addresses a key, difficult to treat neuropathic component of low back pain.	Thank you for your comment.
157.	SH	Grünenthal Ltd	4	4.3.1 c)	Tapentadol is a centrally acting analgesic combining two	Thank you for this information.

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					mechanisms of action, μ-opioid receptor agonism and noradrenaline reuptake inhibition (MOR – NRI), in a single molecule. This synergistic mode of action with the potential for a reduced reliance on the opioid component, may explain the comparable efficacy to a strong opioid (oxycodone CR)[1], more favourable GI side effect profile[1], lower rates of withdrawal[1] and no evidence of acquired tolerance over 1 year[2]. During the 24 months following its introduction in the US, population-based rates of abuse and diversion for tapentadol were clearly lower than rates for oxycodone and hydrocodone[3]. These attributes suggest a more favourable risk benefit profile than existing strong opioids, supporting its role in the management of persistent non-specific low back pain. [1] Buynak,R. et al. (2010) Efficacy and safety of tapentadol extended release for the management of chronic low back pain: results of a prospective, randomized, double-blind, placebo- and active-controlled Phase III study. Expert. Opin. Pharmacother., 11, 1787-804. [2] Wild J.E. et al. Long-term Safety and Tolerability of Tapentadol Extended Release for the Management of Chronic Low Back Pain or Osteoarthritis Pain. Pain Pract. 2010; 10(5): 416-427 [3] Dart R.C. et al. Assessment of the abuse of tapentadol immediate release: The first 24 months. J. Opioid Management 2012; 8(6): 395-402	
158.	SH	Grünenthal Ltd	4	4.3.1 c)	Since the identification of additional tapentadol studies during the review consultation:- A second phase IIIb study has been published, demonstrating the efficacy of tapentadol prolonged-release in chronic low back pain	Thank you for this information.

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					patients responding to WHO step III opioids but tolerating treatment poorly. Gálvez et al. Tapentadol Prolonged Release Versus Strong Opioids for Severe, Chronic Low Back Pain: Results of an Open-label phase 3b Study. A study of tapentadol vs a combination of tapentadol and pregabalin has demonstrated that mono-therapy with tapentadol is a viable treatment option in patients with severe low back pain with a neuropathic component.  Baron R et al KF58 Pregabalin Tap v Tap  Steigerwald I et al Topline KF58 Pregab .	
159.	SH	Grünenthal Ltd	5	General	Grünenthal welcomes Dr Mark Baker's comments at the scoping workshop regarding the institutes need to move away from the reliance on RCTs and to look at study designs appropriate to the clinical question. By failing to consider anything other than RCTs, the GDG have little or no evidence on: • The long-term efficacy of treatments, which for ethical reasons tend to be collected in open-label extension studies and • The relative risk of tolerance, dependency and abuse of treatments Failure to consider these factors has the potential to put patients' safety at risk.	Thank you for your comment. Development of the guideline will follow the methodology in the NICE guidelines manual, and studies other than RCTs will be considered where appropriate as determined by the GDG and evidence identified.
160.	SH	Medtronic UK	1	3.1 d) Epidemiology section	Comment on 'surgery may occasionally be performed if specifically indicated' – consider appendices 1 & 2 for referral pathway with red and yellow flags outlined by the recent low back pain commissioning guideline.	Thank you for your comment and useful suggestion.
161.	SH	Medtronic UK	2	3.2 b) Current Practice section	If pain persists invasive procedures may be offered – timeline with respect to persistant pain would be very useful	Thank you for your comment. This introductory section is for background information only and is not intended to

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						pre-judge the evidence that will be reviewed, therefore we do not think it is appropriate to add a timeline in this section.
162.	SH	Medtronic UK	3	3.2 c) Current Practice section	'In cases where progressive neurological deficit is diagnosed, urgent surgical treatment is needed' – qualify clinical indicators for progressive neurological deficit & timing of referral (within 24 hrs)	Thank you for your comment. This area of the scope is intended to provide background information only.
163.	SH	Medtronic UK	4	4.3.1.Management; section (h) Surgery	We recommend that Spinal Cord Stimulation (SCS) is included as a key example within section (h) Surgery; Surgical Interventions. SCS has been approved by NICE as a cost-effective intervention (NICE TAG 159) and represents an efficient use of healthcare resources. Indications for SCS referral in alignment with the NICE TAG 159 should also be incorporated in this section.	Thank you for your comment. This guideline will cross refer to TA 159 within the list of related NICE guidance.
164.	SH	Merck Sharp & Dohme Ltd. (MSD)	1	4.3.1.c	The draft scope lists "analgesics" as one of the pharmacological treatments that will be covered by the guideline update. We would like to request clarification that COX-2 inhibitors will be considered as part of this group.	Thank you for your comment. COX-2 inhibitors will be considered within analgesics.
165.	SH	Merck Sharp & Dohme Ltd. (MSD)	2	4.3.1.e	"Multimodal therapies" is listed as a key issue to be covered by the guideline update. We would like to request that clarification be added to the final scope to further describe this term.	Thank you for your comment. The wording here has now been changed to "Combination therapies"
166.	SH	Merck Sharp & Dohme Ltd. (MSD)	3	4.4.c	EuroQol is mentioned an example of a health related quality of life measure. To avoid confusion, we suggest that EuroQol should be replaced by "EQ-5D" which is the actual health related quality of life measure (overseen by EuroQol).	Thank you for your comment. This has been amended.
167.	SH	Merck Sharp & Dohme Ltd. (MSD)	4	4.5	The section on economic aspects currently states that costs considered will usually be only from an NHS and personal social services (PSS) perspective. We suggest that absenteeism could pose a significant issue when considering the topic of low back pain, and consequently, the indirect costs associated with absenteeism should be also be covered in the scope of the guideline update.	Thank you for your comment. The guideline will be developed in accordance with the current NICE reference case, which states that an NHS and PSS perspective should be taken.
168.	SH	NAPP	1	General	We welcome the update to these guidelines and have no specific	Thank you for your comment.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Pharmaceuticals			comments on the scope of the guideline at this stage.	
169.	SH	National Council for Osteopathic Research	1	3.1d)	Bullet point: manual therapies (for example, massage and joint manipulation) This implies massage and joint manipulation are single monotherapies. It would be more accurate to state manual therapy (interventions that may include for example massage and joint manipulation).	Thank you for your comment. This list is intended to be an example of possible therapies. We do not agree that this indicates that these should be delivered as monotherapies.
170.	SH	National Council for Osteopathic Research	2	3.1d)	Acupuncture or dry needling is not explicitly listed and it was one of the core therapies in the current NICE non-specific low back pain clinical guideline. It is included in invasive therapies under the current practice section (3.2).	Thank you for your comment. This list is intended to be an example of possible therapies, and not all inclusive.
171.	SH	National Council for Osteopathic Research	3	3.2b)	The management section currently implies that the stepped approach for the early stages includes conventional treatments such as physiotherapy. This would be more properly termed physical therapy. Physical therapy may include manual therapy which appears to be seen as distinct from the use of manual therapy if pain persists in the section below. European guidelines and RCGP guidelines (now withdrawn) for early stages of back pain include recommendations about manipulation. It would be better if the language focussed on the interventions or packages of care rather than identified professional groups.	Thank you for your comment. This has been amended to say physical therapy as suggested.
172.	SH	National Council for Osteopathic Research	4	4.1.1a)	It would be preferable to keep the population to 18 years and over.	Thank you, after careful consideration, it has been decided that the lower age limit remain at 16 years as this was felt to be most appropriate clinically.
173.	SH	National Council for Osteopathic Research	5	4.1.1a)	It would be helpful to look at the role of good triaging delivered by multi-skilled manual therapy clinicians of any discipline and not necessarily GPs for patients at 2 weeks. This may give better direction to patients to prevent them reaching a sub-acute or chronic status. This would also help to avoid adding an additional burden to an existing heavy workload for GPs, and inappropriate	Thank you for your comment. The guideline will indicate the skills required by the clinician to deliver interventions, rather than their profession.

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					referrals. A good model of this exists with Gurry et al. Journal of Orthopaedic Medicine 2004;26(1):13-18.	
174.	SH	National Council for Osteopathic Research	6	4.1.2b)	This should include individuals under 18 years of age.	Thank you, after careful consideration, it has been decided that the lower age limit remain at 16 years as this was felt to be most appropriate clinically.
175.	SH	National Council for Osteopathic Research	7	4.3.1	The scope is very large and this gives concern if it is to include a review of ANY prognostic factors that could guide management. This would appear to mean reviewing all available prospective cohort studies. The scope then mentions clinical examination and then includes some items as examples. This should be clarified as to whether this relates to clinical prediction rules or risk based prediction rules etc. It is unclear how the large scope will be managed for the interventions listed. It is implied that multimodal therapies will be evaluated as well as specific interventions. There is overlap between the specific interventions and the therapies. Physiotherapy may use acupuncture exercise and manual therapy. It would be better if interventions were chosen or packages of care rather than therapies per se.	Thank you for your comment. We agree that the scope is very large and will develop the workplan for this guideline with this in mind. 'Combined therapies' has now been added to the scope to clarify that these will be included.
176.	SH	National Council for Osteopathic Research	8	4.4	Patient satisfaction/satisfaction with care/patient experience should be included as outcomes. This is important in its own right but also due to its effect on outcomes of care.	Thank you for your comment. The list of outcomes provided are those that are considered to be the key outcomes for the guideline as a whole. It is not intended to be all inclusive, and additional outcomes may be included by the GDG when developing the review protocols.
177.	SH	National Council for Osteopathic Research	9	4.4b)	A range of outcome measures are given as examples. This should be examples only and not limited to the measures listed, some of which are validated for secondary care use only.	Thank you for your comment. This is indeed the intention of this list. Outcomes will be defined within each review protocol and may not be limited to these

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						examples.
178.	SH	National Council for Osteopathic Research	10	General	It is unclear whether spinal stenosis is included or excluded.	Thank you for your comment. Spinal stenosis is covered within the scope of this guideline within sciatica.
179.	SH	National Council for Osteopathic Research	11	General	It would be helpful to look at the literature on the implementation of guidelines as these guidelines have not been well implemented throughout the NHS.	Thank you for your comment, Consideration has been given to why the guideline was not widely implemented and the poor implementation was a factor in the decision to update this guideline.
180.	SH	National Spinal TaskForce	1	1	The title needs expansion to include radicular pain	Thank you for your comment, the title has been reworded to: Low back pain and sciatica: management of non-specific low back pain and sciatica.
181.	SH	National Spinal TaskForce	2	3.1a	Access rates for patients with back pain per 100,000 of the population rose from 231-295 between 2005/6 and 2009/10. If this rate of increase continues it will present a major financial and economic crisis in health care	Thank you for your comment and this information.
182.	SH	National Spinal TaskForce	3	3.1b	Low back pain is the leading cause of disability in the world and a major cause of medical problems including depression and substance misuse	Thank you for your comment.
183.	SH	National Spinal TaskForce	4	3.1c	Delays in treatment only lead to the risk of chronicity and a third of patients with chronic low back pain i.e.> 12 weeks duration have predominantly neuropathic pain	Thank you for your comment.
184.	SH	National Spinal TaskForce	5	3.1d	There were over 70,000 procedures for low back pain in England in 2010/11 with around 67,000 of these being facet joint injections. The Spinal TaskForce Report http://www.nationalspinaltaskforce.co.uk/pdfs/NHSSpinalReport_vis7%2030.01.13.pdf contains useful HES data analysis on back pain and radicular pain.	Thank you for this useful information.
185.	SH	National Spinal TaskForce	6	3.1d and 3.1e	Approval for separating low back and radicular pain treatment.	Thank you for your comment.
186.	SH	National Spinal TaskForce	7	3.1d	Need to include the benefits of public education. This has been successfully achieved in Australia and Scotland using 'conventional' media. Perhaps new social networking may be used	Thank you for your comment. This will be considered within self-management strategies including education and

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					to make an even bigger difference.	advice.
187.	SH	National Spinal TaskForce	8	3.1d	Removal of the time range means that the scope should include chronic pain management treatments such as spinal cord stimulators.	Thank you for your comment. These are included within the scope of the guideline.
188.	SH	National Spinal TaskForce	9	3.1e	Access rates for those with radicular pain have risen from 74 to121 per 100,000 of the population between 2005/6 and 2009/10	Thank you for this information.
189.	SH	National Spinal TaskForce	10	3.2a	Natural history is needed for both acute low back pain and radicular pain. How many settle without active intervention and how quickly. This is important for cost-effectiveness of treatments.	Thank you for your comment.
190.	SH	National Spinal TaskForce	11	3.2b	Initial assessment must include a full history and examination to exclude referred pain, red and yellow flag symptoms and signs, in particular those indicative of long term chronicity. Management must include reassurance, encouragement to stay active, early managed return to work , with simple analgesia, avoiding opiates, and accompanied by patient information literature. Where there is a perceived delay in treatment due to good natural history, this should be explained in the patient information If pain persists stratify the level of chronicity using the STarT Back tool. This should include the ability to access manual therapies, exercise, and or manipulation/acupuncture. All these can be provided by a physiotherapy dept but also by chiropractors and osteopaths. Those at high risk should be able to be referred to a low intensity CPPP with links to psychology services. The widespread development of these services must now be undertaken.	Thank you for your comment. The GDG will consider these factors when reviewing the evidence.
191.	SH	National Spinal TaskForce	12	3.2e	Diagnostic nerve root injections should be considered. I think this is the subject of an NIHR study.	Thank you for your comment. This will be considered as part of injection therapies for sciatic pain.
192.	SH	National Spinal TaskForce	13	4.1.1a	The teenage population needs careful management as they do not always conform or behave in the way in which an adult would, and the pathology may be very different. This area therefore needs careful attention	Thank you for your comment. Consideration will be given to those aged 16-18 if there is evidence that this differs from those aged over 18.

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193.	SH	National Spinal TaskForce	14	4.1.1b	An early review and reassessment at 2 weeks will allow better risk assessment of long term chronicity but also identify those with serious underlying pathology whose condition has not responded to initial advice, and/or deteriorated. It is important to identify that those with radicular pain, including femoral/ sciatic pain, have demonstrable severe limitation of hip extension/ straight leg pain, including cross over pain, and a neurological deficit/reflex change. Increasing severity of pain and deficit, despite adequate initial treatment, are significant factors which should lead to urgent referral and investigation	Thank you for your comment. The scope has been amended to include people from the onset of pain (or first presentation to a healthcare professional). We recognise the importance of early identification.
194.	SH	National Spinal TaskForce	15	4.1.1a-d	We support the increased age range and the lifting of the time	Thank you for your comment.
195.	SH	National Spinal TaskForce	16	4.1.1a-d	There needs to be a definition of back pain and radicular pain. Options include words such as 'disabling' or 'non-tolerable'. Many patients have mild back pain for some time and then it deteriorates or they develop radicular pain. Having a time of 2 weeks from onset largely gets around the issue of when did it start but level of disability is very important when considering management options. Perhaps timing of onset should be defined as the date of onset of non-tolerable pain?	Thank you for your comment. Definitions of all terms used will be provided in a glossary when the full guideline is developed.
196.	SH	National Spinal TaskForce	17	4.1.2a	It is important that these pathologies are excluded by a full history, examination and review. Missed spinal infection and its' consequences is responsible for the largest payments made by the NHSLA in compensation	Thank you for your comment.
197.	SH	National Spinal TaskForce	18	4.1.2a	Spondylolisthesis and spondylolysis should be included. These patients present with back pain and/or radicular pain and this is a common enough clinical scenario to be included. This should include all types of spondylolisthesis (especially lytic and degenerative).	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside of the

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						scope.
198.	SH	National Spinal TaskForce	19	4.1.2a	This is a good opportunity to tackle the issue of cauda equina syndrome and should not be avoided. This must be included. The definition of incomplete cauda equina syndrome is controversial and the British Association of Spine Surgeons is currently running a National Audit on this condition through the British Spine Registry.	Thank you for your comment. While the urgent recognition of serious conditions such as cauda equina syndrome will be covered within the scope of the guideline and will be covered, the management is beyond the remit.
199.	SH	National Spinal TaskForce	20	4.2	This is essential and AQPs should be considered	Thank you for your comment.
200.	SH	National Spinal TaskForce	21	4.3.1c	The specific avoidance of Opiates in the initial management of non-specific low back pain must be re- enforced. They are a source of significant co-morbidity and require careful monitoring	Thank you for your comment. Opiates will be covered by this guidance within analgesics.
201.	SH	National Spinal TaskForce	22	4.3.1d	This should include a review of diet and over the counter medication eg glucosamine	Thank you for your comment. Lifestyle interventions will be included. The specific over the counter medications that will be covered by the guideline will be determined by the GDG when the review protocols are developed..
202.	SH	National Spinal TaskForce	23	4.3.1f	There is no place for epidural injection in the management of non-specific low back pain. Injections should be avoided in patients with low back pain of less than 12 months duration and especially those with a coagulopathy or moderate to severe depression. All injections should be carried out under radiological control. Those with Low back pain of > 12 months duration who have failed treatment should be referred to an MDT and pain management service. There is limited evidence for facet joint injections in the management of non-specific low back pain but fair to good evidence that lumbar facet joint nerve blocks may be effective for the short and long term treatment of chronic facet joint pain. Radiofrequency denervation of lumbar facet joints should only be undertaken after a successful lumbar facet joint nerve block and as part of a MDT managed programme of care.	Thank you for your comment. These topics will be reviewed within the guideline and recommendations drafted as appropriate based on the evidence.
203.	SH	National Spinal TaskForce	24	4.3.1h	When managing radicular pain, nerve roots are decompressed. There remains controversy as to when instrumented or un-	Thank you for your comment. Spinal fusion is included within the scope of the

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					instrumented fusion should be performed to prevent subsequent root compression and/or back pain. This should be included.	guideline. The GDG will specify the types to consider in the review protocols.
204.	SH	National Spinal TaskForce	25	4.3.1h	The use of bone graft substitutes is now widespread and the evidence for these should be reviewed. This has the potential to save the NHS a lot of money	Thank you for your comment; however this is beyond the scope of this guideline.
205.	SH	National Spinal TaskForce	26	4.3.1h	Timing of surgery is important as early surgery may result in operating on patients who may still resolve whilst if too late may result in chronic pain	Thank you for your comment. This will be considered when the evidence is reviewed.
206.	SH	National Spinal TaskForce	27	4.3.1g	Combined Physical and Psychological Programmes should be specifically identified as recommended by the National Spinal Taskforce 2013, " Commissioning Spinal Services- Getting the Service Back on Track. http://www.nationalspinaltaskforce.co.uk/	Thank you for your comment. These will be considered when combined therapies are reviewed.
207.	SH	National Spinal TaskForce	28	4.3.1h	Surgery may be considered for some patients where no other cause can be found and where a high intensity CPPP has failed to produce a significant improvement. Yellow flags should be identified and managed as their presence may rule out surgery. Patients should be informed that the decision to have surgery can be a dynamic process and a decision not to undergo surgery does not exclude them from surgery at a future time. Surgery may include one or two level fusion either anterior, posterior or combined. Lumbar disc replacement should be recommended with prudence and commissioned from a specialist centre. Those with a cauda equine syndrome may require an osteotomy of the lamina to gain access to a large central disc prolapse.	Thank you for your comments.
208.	SH	National Spinal TaskForce	29	4.3.2a	As above, spondylolisthesis should be included. Scoliosis should be excluded but should be recognised as a potential review in its own right. CES should be included (see above)	Thank you for your comment. The diagnosis of back pain due to specific aetiology (including spondylolisthesis), and the recognition of serious conditions (including CES) will be covered within the scope of this guideline, however, the subsequent management of these conditions will not be covered.

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209.	SH	National Spinal TaskForce	30	4.4	There should be recognition of work done by ICHOM (http://ichom.org/#&panel1-2). Care should be taken in separating outcome measures for back pain and for radicular pain. It may be concluded that they are the same?	Thank you for your comment, outcomes for each condition will be determined per review question in the protocols. These outcomes are the key ones that will be considered across the guideline and are not all-inclusive.
210.	SH	National Spinal TaskForce	31	4.4	Outcomes in addition to those in the scope return to work should be an explicit outcome. In addition the standardised activity rate, average length of stay, day-case rate, and short-stay rate should be measured.	Thank you for your comment. The outcomes listed in the scope are intended as broad headings. The GDG will agree the appropriate specific outcomes per review question. These suggested outcomes will be considered, Return to work has been added as an example, and will be included for appropriate review questions.
211.	SH	National Spinal TaskForce	32	4.4	Where it is thought that national data collection would be beneficial, the British Spine Registry would be happy to incorporate additional data collection forms and fields into its existing system and recommend data collection.	Thank you for your comment and offer of support.
212.	SH	National Spinal TaskForce	33	4.4d	Adverse events should also include 7/30 day re-admission rates, re-operation rates within 30 days and in-hospital mortality rates.	Thank you for your comment; this will be considered when outcomes are agreed for each review protocol.
213.	SH	National Spinal TaskForce	34	General	The composition of the committee should be as broad as that used by the National Spinal Taskforce. It should include representation from: Public Health General Practice Neurosurgery Orthopaedic surgery Spinal surgery Clinical psychology Pain medicine Rheumatology Manual therapists (Physiotherapist/ osteopathy, chiropractor) Spinal and interventional radiology	Thank you for your comment. The majority of these disciplines are represented by those recruited as full GDG members or co-optees. The GDG will have the option of co-opting additional members if they feel additional expertise is required for particular review questions.

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					Pharmacist Epidemiologist/ Statistical advice DOH administration	
214.	SH	Neuromodulation Society of the United Kingdom and Ireland (NSUKI)	1	4.3.1	There is some evidence on the use of neuromodulation for LBP. Could we kindly include this on the therapies considered	Thank you for your comment. Neuromodulation will be considered in this guideline under the heading 'electrotherapy'.
215.	SH	Neuromodulation Society of the United Kingdom and Ireland (NSUKI)	2	4.3.1	There is plenty of evidence on the use of neuromodulation for neuropathic pain (TAG 0159). As the current document covers sciatica, this should be included in the current document as it is a very important cost effective therapy	Thank you for your comment. Relevant technology appraisals will be referred to in this guideline where appropriate.
216.	SH	Neuromodulation Society of the United Kingdom and Ireland (NSUKI)	3		There is a role for neuromodulation in the management of LBP and should be considered as a treatment modality in the guidance and treatment algorithm.	Thank you for your comment. The clinical and cost effectiveness of neuromodulation will be covered within the scope of this guideline.
217.	SH	Neuromodulation Society of the United Kingdom and Ireland (NSUKI)	4		There are several modalities of neuromodulation techniques used depending on the aetiology of the back pain with varying degrees of evidence on efficacy, safety and cost-effectiveness.	Thank you for your comment. The specific neuromodulation techniques that will be included will be defined by the GDG when the protocol for this review question is developed.
218.	SH	NHS Direct	1	general	No comments on the updated scope.	Thank you for your comment.
219.	SH	NHS England	1	1 Title	The Title has not been updated. Suggestion is :- Lumbar Spine Disorders: Management of Low back Pain and Radicular Pain	Thank you for your comment, the title has been reworded as: Low back pain and sciatica: management of non-specific low back pain and sciatica.
220.	SH	NHS England	2	3.1 d	Why is surgery treated differently ? All treatments are only performed if specifically indicated. There are good randomised trials to support surgery, unlike for many therapies mentioned. It conveys a suggestion of bias before the GDG has even met	Thank you for your comment. We have amended this accordingly
221.	SH	NHS England	3	3.1 d	Combined Physical and Psychological Programme should be specifically mentioned – it was one of the major recommendations	Thank you for your comment. Whilst we recognise this as a treatment option, and

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					of G88	it will be included in the guideline, this list is not intended to be all inclusive.
222.	SH	NHS England	4	3.1 f	Although disc prolapse is the commonest cause in the fourth and fifth decade, spinal stenosis, either central or lateral recess, is much more common in older patients. As there is no upper age limit proposed it is important that this group is specifically identified as there is an increasing demand for treatment.	Thank you for your comment. Evidence in all people aged 16 or older will be considered in this guideline. When the recommendations are drafted, if particular considerations are required for specific age groups the GDG may either make specific recommendations, or note this in the 'linking evidence to recommendations' section of the guideline. Subgroups are only pre-specified in populations in whom it is expected that treatment effects may differ.
223.	SH	NHS England	5	3.2 b	Clarity in the first bullet would be improved by adding "e.g. Cauda Equina Syndrome and other Red Flags". Cauda Equina is the largest single expense in spinal litigation for the NHSLA.	Thank you for your comment. This has been added as suggested.
224.	SH	NHS England	6	3.2 b	Second Bullet. It is better that specific specialities are not referred to and to emphasise that treatments may be provided by a number of different practitioners thus physiotherapy would be better replaced with manual therapy, which could be moved from the third bullet.	Thank you for your comment, we agree and have amended this section accordingly.
225.	SH	NHS England	7	3.2 b	Third Bullet. Despite poor provision, Combined Physical and Psychological Programmes are available in some areas and used before surgical intervention. The CPPP was a main recommendation of G88 and should be specifically included.	Thank you for your comment. As CPPP is only available in some areas, we do not believe it should be specifically included here.
226.	SH	NHS England	8	3.2 c	The quality of the evidence reviewed is poor. A non-peer reviewed research undertaken three years ago does not provide the strength of evidence that would be looked for. Manual Therapy (including Spinal manipulation) would almost certainly have been available as all physiotherapy departments, and many Physiotherapists deliver acupuncture. They might not, however, be separately identified. It would be pertinent also to identify how many care organisations provided the high intensity CPPP	Thank you for your comment. This section of the scope is to provide some background information to stakeholders and developers during the scoping process. References used in this section are not always peer reviewed and will not be used to inform the guideline recommendations. The Pulse survey was

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					(combined physical and psychological programme).	based on information obtained through a Freedom of Information request sent to all Primary Care Trusts and is legitimate background information. We have also now included a reference to a recent abstract which also highlights that the guidance has not been implemented in primary care.
227.	SH	NHS England	9	3.2 d	It is true that radicular pain can be difficult to distinguish from referred pain, and indeed from neuropathic pain. There is often little agreement in the literature and in many studies the definition used is not explicitly stated. Commonly held beliefs are often incorrect, for example in one study 40 % of patients with non specific back pain had referred pain radiating below the knee (European Spine J;18 Supp.4:S403, 2009). However if the Guidance now deals with radicular pain as well as non specific back pain, then it will be necessary to discriminate between the two. Some clinicians define radicular pain as pain in a dermatomal pattern WITH neurological deficit, referred pain as pain in a dermatomal pattern WITHOUT neurological deficit and neuropathic pain as pain generated within the nerve or CNS with no compression. Others appear to use the terms radicular and neuropathic inter-changeably. The GDG should consider how to address this.	Thank you for your comment. We will include within the guideline how low back pain and sciatica are defined and differentiated for the purposes of the guideline. The guideline will also include a glossary in which all definitions will be provided.
228.	SH	NHS England	10	3.2 d	Spinal stenosis is much more common in the older population and if there is no upper age limit then will require separate consideration. This is a large population and a very large body of evidence exists. The alternative would be to consider disc prolapse alone.	Thank you for your comment. We will consider subgroups of populations if there is evidence of a different treatment effect. Increased prevalence in this group is not an indication alone that the evidence needs to be reviewed separately from younger populations. The GDG will define subgroups per-review question accordingly.

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					Clearly there are also many other causes of radicular pain from mono neuritis to metastatic disease. It is important these are identified but it should be considered whether the Guidance can specifically look at the treatment of all of these.	Thank you for your comment. We have now included sciatica in 4.1.2 to detail the causes that are excluded from the scope of this guideline (in line with the excluded causes of low back pain).
229.	SH	NHS England	11	3.2 e	Timeliness of treatment is a vital consideration. There is evidence that the results of surgical discetomy decline with duration of symptoms and it is likely that the same will apply to other therapies. For employed patients loss of time at work is critical, and increased duration of sick leave is directly associated with long term loss of employment.	Thank you for your comment. We acknowledge the importance of timeliness of treatment. This will be considered when evidence is reviewed and recommendations are drafted.
230.	SH	NHS England	12	4.1.1 a	The vast majority of studies available have been undertaken in a study population aged between 18 and 65. It is certainly important that management of patients over 65 and also the management of patients for example from 16 to 18 should be considered, but a lack of evidence may make firm recommendations difficult. Argument might be made for extending evidence from the adult population into late teenagers but it is less clear that simple extension of results into the elderly would be appropriate (although not addressed in G88). A stratified approach to age above 65 may be indicated: the degree of degenerative change in the older age group is markedly different and it is not clear that non specific back pain has the same incidence or behaviour in the elderly. This is particularly relevant to radicular pain (see comment 4).The addition of radicular pain, which is supported, will undoubtedly markedly increase the work required and it should be considered whether the age group over 65 should be excluded.	Thank you for your comment. The guideline will not exclude people aged over 65. Evidence for older people is frequently less prevalent in RCTs and trial data, but where available it will be included within the reviews. If evidence from older populations are lacking, the GDG will consider per review whether separate considerations are required and how this should be addressed.
231.	SH	NHS England	13	4.1.1 a	Guidance for acute back pain is available but the evidence base is not quite so clear. There is an argument to be made for reducing the initial time limit to 4 weeks or even perhaps two weeks to align with the radicular pathway. However, care would be required to take into account the large number of patients who will still be symptomatic at two weeks who would not be symptomatic at six	Thank you for your comment. The restriction of pain that has persisted for 6 weeks has now been removed from the scope.

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					weeks. The cost effectiveness of treatments in a situation where spontaneous recovery is likely requires careful evaluation.	
232.	SH	NHS England	14	4.1.1 b	The inclusion of radicular pain is supported.	Thank you for your comment.
233.	SH	NHS England	15	4.1.1 c	There is some merit in considering the over 65 age group to be separate. The incidence and behaviour of non specific low back pain is not known to be the same as adults between 18 and 65, and the increasing degenerative changes in the over 65 age group may have a substantial impact on the cause of symptoms and response to treatment. For example exercises in the elderly will be very different. In addition radicular symptoms are very different, often presenting as neurogenic claudication and secondary to spinal stenosis, either lateral recess or central. The management of stenosis is quite different to prolapsed disc and follows a different time line.	Thank you for your comment. We will consider subgroups of populations if there is evidence of a different treatment effect. Increased prevalence in this group is not an indication alone that the evidence needs to be reviewed separately from younger populations. The GDG will define subgroups per-review question accordingly. Reasons for heterogeneity will be explored if identified.
234.	SH	NHS England	16	4.1.1 c	It is suggested that specific consideration could be given to people of working age rendered incapable of work in consequence of their symptoms. In the same way that members of the armed services are afforded special consideration it is suggested that for macro economic reasons it is important to minimise the number of people who are avoidably off work	Thank you for your comment. The guideline will be developed in accordance with the NICE Social Value Judgements report. In line with this people of working age are not treated differently to other population groups.
235.	SH	NHS England	17	4.1.1 d	The removal of the cut off at 12 months is supported. It is suggested, however, that consideration might be given as to whether evidence exists for the separation of chronic unremitting back pain on the one hand and "first" presentation or presentation as infrequent relapse on the other.	Thank you for your comment. Heterogeneity in the evidence reviewed will be explored, if identified.
236.	SH	NHS England	18	4.1.2 a	Cauda Equina Syndrome IS a radicular pain, of the most severe kind. CES accounts for the largest single cost to NHSLA for spinal disorders, and the most catastrophic consequences for patients. If radicular pain is to be included, then CES should be included.	Thank you for your comment. We acknowledge that cauda equina is a radicular pain. However we are unable to cover all types of radicular pain; and the management of cauda equina is beyond the remit of this guideline.

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237.	SH	NHS England	19	4.3.1	An additional area where there was a serious omission from the earlier guidance is the matter of public education and information to match the positive results obtained by study groups such as the study in Australia and the experience in Scotland.	Thank you for your comment. Patient education and advice is included within the scope of this guideline.
238.	SH	NHS England	20	4.3.1	The value of a managed care pathway, for example a "Triage and Treat Practitioner" (ref), is another area which was not specifically examined in the original guidance and is one that should seriously be considered for inclusion. PPE feedback consistently identifies the lack of an identifiable clinician in charge of their treatment as being one of their major concerns. (1. Department of Health, Organising Quality and Effective Spinal Services for Patients: A report for local health communities by the Spinal Taskforce, 2010).	Thank you for your comment. Determining the specifics of who delivers treatment is beyond the scope of this guideline, although it is the intension to include guidance on a care pathway.
239.	SH	NHS England	21	4.3.1	The issue of timeliness should be considered. This would be both in relation to the duration of any therapy but also the expectations of the stage on a pathway that therapies should be provided. Long waits between the steps on a pathway greatly increase the risk of chronicity.	Thank you for your comment. This will be considered within each review question.
240.	SH	NHS England	22	4.3.1	Neuro-modulation such as spinal cord stimulation is a strong candidate for inclusion as the 12 month upper limit has been removed.	Thank you for your comment. Neuro-modulation is included within the scope (within 4.3.1.d). However, spinal cord stimulation is covered by NICE TA 159 (Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin). This update will cross refer to this TA.
241.	SH	NHS England	23	4.3.1	There is evidence with some groups of LBP that treatment (beyond assessment and advice) does not improve the outcome; i.e. good prognosis, low STarT Back score etc. Cost savings by early discharge are a significant opportunity here. Early identification and clear routes for re-referral should the need arise would then be essential.	Thank you for your comment. The scope of the guideline includes assessment and identifying prognostic factors in recognition of the fact that early identification and referral, if necessary, are key factors to consider.
242.	SH	NHS England	24	4.3.1	The high intensity combined physical and psychological programme (CPPP) which formed one of the recommendations of the original review has only limited availability. In view of this, it suggested that this should be explicitly identified as a treatment option. A synopsis of the content of the high intensity CPPP is	Thank you for your comment. This will be included when combined therapies are reviewed.

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					available as appendix III of the Department of Health Document "Organising quality and effective spinal services for patients". There is frequent confusion between the elements that a high intensity CPPP provides and the elements of pain management programme provided by pain services. The effectiveness and cost effectiveness of this programme might be further explored.	
243.	SH	NHS England	25	4.3.1 a	It is essential that radicular pain is clearly defined. Although there are as alluded to in 3.2D other causes of radiculopathy, herniated intervertebral discs is the most common in the 4th and 5th decades. Many surgeons would suggest that to make a diagnosis of radicular pain a neurological deficit, i.e., a motor deficit or loss of a reflex, is required. The rationale for this is that it is well recognised, e.g. McNab's rule of five, that the results of surgical discectomy are more satisfactory in cases where neurological deficit or substantial restriction of straight leg raise is present. It has been reported that up to 40 percent of patients with mechanical or non-specific low back pain have a referred pain which radiates below the knee (European Spine J;18 Supp.4:S403, 2009). It is also known that some 25 percent of asymptomatic subjects subjected to MRI scanning demonstrate a radiological intervertebral disc prolapse. Clearly the coincidental appearance of an asymptomatic disc prolapse with a referred leg pain on the same side has the potential to lead to inappropriate invasive therapy. Many patients in the over 65 age group will present with neurogenic claudication caused normally by a stenotic process engendered by degenerative change. These patients, however, may be symptom free and without demonstrable neurological deficits while at rest. It would be important to distinguish these cases from a neuropathic pain which some clinicians understand to be pain generated either within the nerve root itself or higher in the cord, perhaps due to failure to recover from substantial compression, intra neural scarring etc. Clearly this type of pain would not be	Thank you for your comment and useful information. Sciatica will be defined in the guideline and the GDG will specify inclusions and exclusions in the protocol per review question explicitly.

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					managed in a typical radicular pain pathway.	
244.	SH	NHS England	26	4.3.1 a	In view of its increasing use the STarT Back score should be specifically included.	Thank you for your comment, the STarT back score will be included within the review of assessment methods.
245.	SH	NHS England	27	4.3.1 h	Laminectomy is not a useful term here. For treatment of spinal stenosis decompression is the preferred term. Interspinous spacers have been used in stenosis, especially in the over 65 age group, but evidence of sustained effectiveness is poor.	Thank you for your comment. We have reworded this to 'laminectomy/decompression surgery'. This will also be considered in developing the search strategies.
246.	SH	NHS England	28	4.3.2 a	There is a contradiction between the ability to separate out groups such as spondylolisthesis and the recommendation that imaging should not be undertaken in all patients. With the exception of the cauda equine syndrome and red flags (neoplasm, infection, fracture) the inclusion of other pathologies in the initial management pathway would be correct. Patients with these specific pathologies might present for investigation as a result of failure to respond to early management. It is suggested that Grade 1 spondylolisthesis might continue to be included in the non-specific low back pain pathway.	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
247.	SH	NHS England	29	4.3.2 a	Cauda Equina Syndrome IS a radicular pain, of the most severe kind. CES accounts for the largest single cost to NHSLA for spinal disorders, and the most catastrophic consequences for patients. If radicular pain is to be included, then CES should be included	Thank you for your comment. We acknowledge that cauda equina is a radicular pain. However we are unable to cover all types of radicular pain; and the management of cauda equina is excluded as it is a surgical emergency.
248.	SH	NHS England	30	4.4	It is suggested that return to work should be an explicit outcome measure. This is reported in many studies and provides an effective measurement of re-integration and particularly addresses occupational health issues. There is a real concern that management and rehabilitation pathways stop short of true rehabilitation i.e. return to work/occupation/social re-integration	Thank you for your comment. We have included this in the list of outcome measures.

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					and this needs to be addressed.	
249.	SH	NHS England	31	4.4	If the preferred unit of effectiveness is the QALY, then the EQ5D or one of its variants is essential.	Thank you for your comment. EQ5D will be included.
250.	SH	NHS England	32	4.5	Duration of effect is important. For example, the data from the Swedish Spine Registry in several thousand cases indicates that fusion surgery conveys a benefit of 0.3 QALY sustained for at least 5 years.	Thank you for your comment. Duration of effect will be considered in the analysis.
251.	SH	Pain Concern	1	4.1.2	How would the guidelines cover those who experience episodic pain? If one experiences bouts of week-long LBP over a period of time, how can they be assessed? We stress the need for this to be considered.	Thank you for your comment. In developing the guideline the GDG will consider whether there are subgroups of the low back pain population that require special consideration.
252.	SH	Pain Concern	2	4.1.2	Management of pain, which can be a frightening experience, from first presentation is crucial to the patient. Patients must understand how to get the best out of analgesics. GPs should also assess for unusual levels of anxiety and fear in the patient. Essentially, good management of LBP is important and this requires education of primary care staff.	Thank you for this information.
253.	SH	Pain Concern	3	4.3.1	We also strongly support the development of a return-to-work intervention programme. Is there the possibility of developing employer education? Most employers are aware of the losses LBP can cause, but a greater understanding of the processes of diagnosis, treatment and recovery could be beneficial. For employers to be involved in the treatment process could be highly beneficial, which corresponds to the 'Tackling Musculoskeletal Problems' report, published by the Stationary office in 2009.	Thank you for your comment. When the guideline is published, implementation support tools will be created to accompany the guideline. However, making recommendations for non-NHS staff or organisations falls outside of the mandate of NICE guidance.
254.	SH	Pain Concern	4	4.3.1	There remains an issue regarding the treatment of 16/17 year olds: are these aforementioned treatments suitable? A lack of research on people this age suggests this is a grey area and requires clarity.	Thank you for your comment. This will be considered by the GDG when the evidence is reviewed.
255.	SH	Pain Concern	5	4.3.1	In terms of age, is there the possibility to include education to	Thank you for your comment. After

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					those of a younger age, even 14/15 year olds, to avoid developing habitual behaviour that could lead to LBP in the future?	consideration, it was agreed it would not be appropriate to extend the guideline to include younger ages.
256.	SH	Pain Concern	6	General	People not mentioned and potentially marginalised in this draft include the elderly, whose treatment may need to differ significantly from other patients. Similarly, people with learning difficulties may require alternative methods of delivery when it comes to some forms of treatment. Pain Concern would like assurances that this guidance will be equally applicable to minority/potentially excluded groups such as the aforementioned elderly, the learning disabled and adolescents.	Thank you for your comment. NICE is committed to eliminating discrimination, advancing equality of opportunity as required by the Equality Act 2010. The effect of recommendations on each protected characteristic will be considered at each stage of development.
257.	SH	Pain Concern	7	4.4	We wish to demonstrate our belief that outcomes A-E are interdependent in nature, and must remain so to fully benefit the patient.	Thank you for your comment. The GDG will agree critical and important outcomes in detailing the protocol for each review question.
258.	SH	Pain Concern	8	General	We feel that a timeline for treatment and referral to secondary care is necessary to develop a clearer image of the process for patients and organisations alike.	The guideline development groups frequently develop algorithms as part of the NICE guideline and this will be considered for this guideline. The final guideline will also be incorporated into the NICE pathway linking with other related NICE guidance
259.	SH	Pain Concern	9	General	We feel there needs to be a greater emphasis placed upon the importance of primary care in the consultation, in terms of educating all primary care (GPs, nurses etc) staff.	Thank you for your comment. We agree that this is an important issue. The guideline will apply in settings in which NHS funded healthcare is delivered. Consideration will be given to the importance of primary care. When the guideline is published, implementation tools will also be produced, which may include specific tools for primary care.
260.	SH	Pfizer Ltd	1	4.1.1	Pfizer welcome the inclusion if patients with suspected radicular	Thank you for your comment and this

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				(Population)	pain in the draft scope as many patients with low back pain suffer from neuropathic pain. An estimated 16%-37% of low back pain patients have predominantly neuropathic pain. Low back pain patients with neuropathic pain also report higher ratings of pain intensity, with more (and more severe) co-morbidities such as depression, panic/anxiety and sleep disorders[1, 2]. It is also estimated that 25% of UK low back pain* patients have mixed pain, that is low back pain with both a nociceptive and neuropathic pain component[1]. We request that the scope also consider this group of patients (with mixed nociceptive and neuropathic pain) in terms of identification, and that patients with a neuropathic component to their back pain are signposted to the appropriate NICE clinical guidelines including "Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings" * Assumption made that the patient group who presented with a mixture of symptoms leading to an unclear classification experienced mixed pain	information. People with mixed pain, will be considered if evidence is identified. The guideline will cross refer to other relevant NICE guidance when necessary.
261.	SH	Pfizer Ltd	2	4.3.1c (Management)	The draft scope states that "Guideline recommendations will normally fall within licensed indications; exceptionally and only if clearly supported by evidence, use outside a licensed indication ('off-label use') may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients." We would like to note that the updated GMC guidance[3] published in January 2013 states that 'you may prescribe unlicensed medicines where, on the basis of an assessment of the individual	Thank you for your comment and this information. At the present time, this is the standard process followed by all NICE guidance. It does not conflict with the GMC guidance as it does allow for off-label medications to be recommended if clearly supported by the evidence. We therefore do not think this statement requires amendment in the scope.

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					patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient'; and that 'prescribing unlicensed medicines may be necessary where there is no suitably licensed medicine that will meet the patient's need'. The guidance uses the term 'unlicensed medicine' to describe medicines that are used outside the terms of their UK licence. We request that the NICE guideline process should align with GMC guidance on the use of unlicensed medicines	
262.	SH	Pfizer Ltd	3	4.1.1 (Population)	Groups to be covered include people who are 16 or older. In order that treatments can be assessed within their licensed indication we request that under 18s are assed as a separate group to the patients who are aged 18 years or over	Thank you for your comment. The GDG will decide on how to appropriately stratify or subgroup the evidence when agreeing each review protocol.
263.	SH	Pfizer Ltd	4		References 1. Beith et al. Pain. 2011; 152(7): 1511-1516 2. FreynhagenR, et al. CurrMed Res Opin. 2006;22(10):1911-20 3. Good medical practice (2013). http://www.gmc-uk.org/guidance/good_medical_practice.asp Last acessed November 2013	Thank you for this information.
264.	SH	RCGP	1	3.1.d	? use of TENS mentioned here – not recommended in previous guidelines	Thank you for your comment. TENS is included within the scope of this guideline and will be considered when the evidence is reviewed.
265.	SH	RCGP	2	4.3.1	Culturally sensitive/ relevant information and self – management programmes tailored to and available for, and in, different communities	Thank you for your comment. Promoting equality is key in the development of NICE guidance and any equalities issues surrounding interventions are addressed throughout the development process.

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266.	SH	RCGP	3	4.4	Culturally sensitive measures of pain, quality of life, disability scores	Thank you for your comment. Promoting equality is key in the development of NICE guidance and any equalities issues surrounding interventions are addressed throughout the development process.
267.	SH	Royal College of Chiropractors	1	1	Guideline title: The title of the revised guideline should be changed to reflect its full scope, i.e. should make reference to sciatica.	Thank you for your comment. We agree and have reworded the title as: Low back pain and sciatica: management of non-specific low back pain and sciatica.
268.	SH	Royal College of Chiropractors	2	1.1	Short title: The short title should also include reference to sciatica.	Thank you for your comment. We agree and have reworded the short title as: Low back pain and sciatica.
269.	SH	Royal College of Chiropractors	3	3.1d	The bullet on manual therapies should be changed to include a more accurate definition. We suggest: • manual therapies (for example massage, mobilisation and joint manipulation) as undertaken by chiropractors, manipulative physiotherapists and osteopaths.	Thank you for your comment. This section of the scope is intended to give an overview of the broad range of therapeutic modalities available rather than specific detail of each therapy.
270.	SH	Royal College of Chiropractors	4	3.2a	This paragraph should be changed so that it better reflects current practice. We suggest: a) People with low back pain may go to their GP or other primary health care practitioners for initial treatment and consequently, in most cases, their care will be managed in a primary care setting.	Thank you for your comment this has been amended accordingly.
271.	SH	Royal College of Chiropractors	5	3.2b	In the bullet on *initial assessment*, the term 'red flags' should be added. In the *management* bullet, the term physiotherapy should be replaced with 'advice to remain active and self-care advice' as this is commonly given *prior* to referral for manual therapy. In the *if pain persists* bullet, the term 'psychologically-informed therapies' should be used in place of psychological therapies.	Thank you for your comment. As the purpose of this section is for background information in the scoping process only, the current wording is considered to be sufficiently specific.
272.	SH	Royal College of	6	3.2e	The term *spontaneously* within the sentence 'resolve	Thank you for your comment. This has

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		Chiropractors			spontaneously with conventional management' should be removed as spontaneously implies no causal link with conventional management, and this has not been established.	been amended in the scope.
273.	SH	Royal College of Chiropractors	7	4.3.1d	Non-pharmacological interventions: The definition of manual therapies should read: 'Manual therapies including spinal manipulation, mobilisation and massage' The term *acupuncture* should be changed to read: 'medical acupuncture/dry-needling'	Thank you for your comment. As stated in the scope, this list is not all inclusive; therefore we do not agree that this needs to be reworded.
274.	SH	Royal College of Chiropractors	8	4.3.2a	Management of: We suggest the guideline should include spondylolisthesis and scoliosis.	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
275.	SH	Royal College of Chiropractors	9	4.4	Main outcomes: The RCC would like to see the inclusion of a condition-specific validated biopsychosocial outcome measure for back pain. We suggest the Bournemouth Questionnaire (BQ) be included as this has been used in primary care settings within the NHS that utilise a multi-professional service delivery (see http://healthandcare.dh.gov.uk/back-and-neck-pain-services/) and is currently included in within the Any Qualified Provider back and neck pain service specification (https://www.supply2health.nhs.uk/AQPResourceCentre/AQPServices/PTP/Pages/BackNeckPain.aspx). Further details of the BQ can be found here	Thank you for your comment. The questionnaires stated are examples of those that will be included. Others will also be included if identified in the literature.

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					http://www.aecc.ac.uk/research/bu-study.aspx and Bolton JE and Breen AC (1999) The Bournemouth Questionnaire: a short-form comprehensive outcome measure. I. Psychometric properties in back pain patients. Journal of Manipulative and Physiological Therapeutics 22: 503-510 Bolton JE and Humphreys BK (2002) The Bournemouth Questionnaire: a short-form comprehensive outcome measure. II. Psychometric properties in neck pain patients. Journal of Manipulative and Physiological Therapeutics 25: 141-148 Hurst H and Bolton J (2004) Assessing the clinical significance of change scores recorded on subjective outcome measures. Journal of Manipulative and Physiological Therapeutics 27: 26-35	
276.	SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to update this guideline. It is timely.	Thank you for your comment.
277.	SH	Royal College of Nursing	2	3.1 (d)	Epidemiology - Discussion on therapeutic and rehabilitation strategy mentions orthotic and appliances and gives examples of support and traction - we thought traction was not recommended?	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and is a discussion of current practice rather than the previous recommendations.
278.	SH	Royal College of Nursing	3	3.1 (d)	Add – physiotherapy	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and is not intended to be all inclusive.
279.	SH	Royal College of Nursing	4	3.2 (b)	Current practice - Stepped approach to management - whilst this is very relevant it does not identify that this part can be very time consuming. It is noted that in some cases there has been poor implementation of recommended practice but this can in some	Thank you for your comment and this information.

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					cases be due to lack of time for proper appointment. This type of care cannot be given in a 10 minute appointment.	
280.	SH	Royal College of Nursing	5	4.3 (b)	Management - In discussing lifestyle interventions, 'return to work interventions' is mentioned. The Department of Work and Pensions has specific advisors in Job Centres to provide extra support in this matter if a claimant is on Sick Pay they can be given help via Employment Support Work Coach, and if they are on Job Seekers Benefit but with a disability can be seen by Disability Employment Advisor. Could specific recommendations to link to such staff be included?	Thank you for your comment. When the guideline is published, implementation support tools will be created to accompany the guideline. However, making recommendations for non-NHS staff or organisations falls outside of the mandate of NICE guidance.
281.	SH	Royal College of Nursing	6	4.1.1d	"The cut-off point of 12 months specified in NICE clinical guideline 88 has been removed for the update of the guideline. There will be no restriction on duration of chronic low back pain." The Guideline title needs to be altered. The word "early" needs to be deleted.	Thank you for your comment. The title of the guideline has now been amended to: Low back pain and sciatica: management of non-specific low back pain and sciatica.
282.	SH	Royal College of Nursing	7	4.4	Psychological measures needs to be included. Measures of mood and pain should be included under an additional section 'Psychological measures'.	Thank you for your comment. This list of outcome measures is not intended to be all inclusive. Outcome measures will be determined by the GDG for each review protocol, with additional outcomes if deemed appropriate by the GDG. These may include psychological outcome measures.
283.	SH	Royal College of Nursing	9	Page 4 Workshop notes	Specific subgroups - comment is made in this section of those with high psychosocial co-morbidities and this is often the group who are more time consuming. The reality is for some they have already had 'multiple explanations' so to progress, one needs to unpick that 'knowledge' and re focus or re educate, this is not easy to accomplish and is time consuming.	Thank you for this information.
284.	SH	Royal College of Nursing	10	Page 6 Workshop notes	Comment is made on the efficacy of "Health Trainer". It is accepted practice that low back pain management is best done with a multidisciplinary team (MDT) approach so the point should be made that providing support/intervention can be done by staff, from a varied professional background, that have knowledge/ability to inspire patients to alter lifestyle behaviour.	Thank you for your comment. The guideline will indicate the skills required by the clinician to deliver interventions, rather than their profession.

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285.	SH	Royal College of Paediatrics and Child Health	1	General	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the low back pain draft scope. We have not received any responses for this consultation	Thank you for your comment.
286.	SH	Royal Pharmaceutical Society	1	General	The Royal Pharmaceutical Society welcomes an update to the NICE clinical guidelines for low back pain. We would like to recommend that NICE considers how healthcare professionals might support patients with low back pain and include this within the guidance. There is a brief reference to management of low back pain in a primary care setting under section 3.2; however it would be useful to specify how each healthcare professional might be involved at each stage in the care pathway and also how they might work together to improve patient outcomes. As experts in medicines, pharmacists provide advice on how to take medicines, adverse effects, possible interactions and cautions, to raise patients' awareness and increase their understanding of their condition and therapy, which will encourage medicines adherence and empower self-care. Pharmacists and pharmacy support teams are ideally placed to offer initial and ongoing advice to patients with low back pain. They are able to identify when patients should be referred to their GP e.g. when alarm symptoms are present; provide advice about over-the counter treatments for low back pain (analgesics and anti-inflammatories); and provide appropriate lifestyle advice to help patients manage their symptoms. The accessible and inviting environment of community pharmacies allow patients to seek advice and have conversations about their symptoms at a time that is convenient for them without having to make an appointment.	Thank you for your comment. The guideline will specify skills required by clinician involved in management rather than their profession.
287.	SH	Society for Back Pain Research	1	General	the guidelines should either consider either 1) RCTs only or 2) RCTs, all other sorts of study and expert consensus. Last time it	Thank you for your comment. The guideline will be developed as per the

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					was a hybrid of RCTs + consensus, which was somewhat flawed.	NICE guidelines manual 2012, using the best available evidence where available.
288.	SH	Society for Back Pain Research	2	3.1.d	Firstly the previous BG88 (2009) clearly coined the phrase "combined physical and psychological" programmes, which has been widely adopted, and which describes the main evidence based approach to CLBP. I think this should be adopted universally now, and this applies also to 3.2.b	Thank you for your comment. CPPP will be covered within the scope of this guideline when combined therapies are reviewed.
289.	SH	Society for Back Pain Research	3	3.1.d	Secondly there is an increasing awareness of, and evidence to support "packages of care" rather than monotherapy and this should be a key focus in this update	Thank you for your comment. The wording of heading 4.3.1 (e) has now been changed to "combined therapies"
290.	SH	Society for Back Pain Research	4	3.2.c	One factor that has contribute to poor uptake of the guidance surrounding acupuncture is that the two NHS groups that practice acupuncture are general practitioners and physiotherapists. For the latter this is only available as a post-graduate qualification, and the funding for such training has been reduced.	Thank you for this information.
291.	SH	Society for Back Pain Research	5	4.1.1 a & b	It seems illogical to set 2 weeks as the lower cut off for the guidelines. I think opening the upper limit is very sensible, but to leave the need for a separate guideline for back and leg pain of less than two weeks, when it is likely that the majority of the evidence in early management will cover before and after this watershed seems wrong	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms.
292.	SH	Society for Back Pain Research	6	4.1.b	I am very supportive of the inclusion of radicular pain in this guideline	Thank you for your comment.
293.	SH	Society for Back Pain Research	7	4.3.1	one of the key issues surrounding exercise group interventions is the duration. From the European literature, interventions have been shown to be effective with around 18-20 hours of intervention. Sadly, many back to fitness style programmes within the NHS, offer up to six 1 -1.5 hour classes only. Therefore it is vital that the intensity of interventions is considered when the efficacy of these interventions is reported.	Thank you for your comment, This will be considered when the evidence is reviewed.
294.	SH	Society for Back Pain Research	8	4.3.1.b	Please consider the possibility of including significant others in treatment delivered in both the clinic and workplace. The rationale for this would be based on existing empirical evidence that family members or significant others have been shown to have an influence on an individual's pain behaviour and disability, (both	Thank you for your comment. Reviewing evidence for participation of family and carers in the management of low back pain was not highlighted as a priority for inclusion in this guideline by

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					positive and negative) and also from recent carer surveys and data from the last Census which report on the negative impact on carer health and work participation as a result of looking after someone with a long-term condition/disability. This problem is likely to grow as a result of the ageing population and workforce. Therefore, an intervention including or focused on significant others to aid recovery and return to work would have relevance for both healthcare utilisation and sickness absence/work disability due to back pain	stakeholders. The GDG lay members, however, provide the perspective of patients, family and carers which is vital when drafting recommendations.
295.	SH	Society for Back Pain Research	9	4.3.1.e	Mulitimodal therapies may cover the packages of care I refer to above, but this is emerging as a key part of the way forwards in managing back pain and should be a focus fr the guidelines	Thank you for your comment. This will be covered within the scope of the guideline.
296.	SH	Society for Back Pain Research	10	4.3.1.g	The previous guideline clearly established the term CPP as above and I think this is the only treatment approach which is likely to make a significant long term change in this condition, so I would adopt this as a separate category and main focus	Thank you for your comment. This will be considered under the heading "combination therapies"
297.	SH	Society for Back Pain Research	11	4.4	These outcomes are of very limited importance. I believe that return to work should migrate to being the most important outcome in patients with CLBP, and this is gradually appearing in commissioning guidelines. Time to return to function is also important	Thank you for your comment. Return to work will be included for appropriate review questions.
298.	SH	Society Of British Neurological Surgeons (SBNS)	1	1	The title should specify that the guidance relates to LBP due to **degenerative** conditions of the lumbar spine.	Thank you for your comment. The guideline relates to non-specific low back pain and radicular pain. The title has been reworded to: Low back pain and sciatica: management of non-specific low back pain and sciatica.
299.	SH	Society Of British Neurological Surgeons (SBNS)	2	4.1.2 (a)	In the early phase of the clinical pathway for LBP the possibility that the symptom may be due to **non-degenerative conditions** has to be indicated within the guidance to ensure that the primary and secondary care clinicians will be informed as to how the management and referral process are affected.	Thank you for your comment. The correct identification of non-specific back pain (to include the exclusion of all other aetiologies) will be covered within the scope of this guideline.
300.	SH	Society Of British Neurological	3	4.1.2 (a)	Radicular pain (bilateral or unilateral) is present in virtually all patients with Cauda Equina Syndrome (CES). Also, radicular pain	Thank you for your comment. While the urgent recognition of serious conditions

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		Surgeons (SBNS)			is present in virtually all patients referred/admitted as suspected CES. The evolution of the condition has a wide variation and in clinical practice many patients are referred with suspected CES who do not have the typical or classical clinical features. The primary and secondary care clinicians will benefit from the guidance dealing with the referral indications for this condition. There is a significant volume of clinical negligence cases around the delay in referral for CES which can be reduced with appropriate guidance. We are of the view that the guidance should include the most severe and emergency form of Radiculopathy (CES). If so, the title should indicate that the guidance includes the early management of suspected CES. A separate guidance on CES could be an addendum/supplementary to the LBP guidance. Including CES in the guidance would enhance patient safety in the overall management of patients with LBP.	such as cauda equina syndrome will be covered within the scope of the guideline, the management is beyond the remit and will not be covered.
301.	SH	Society of Teachers of the Alexander Technique (STAT)	1	1	In order to more accurately reflect the population in question, we would propose that the title should be amended to include recurrent (episodic), as well as 'persistent' non-specific low back pain	Thank you for your comment, the title has been amended to: Low back pain and sciatica : management of non specific low back pain and sciatica.
302.	SH	Society of Teachers of the Alexander Technique (STAT)	2	4.1	We agree that the population scope of the LBP guidelines should remain as ≥18 years. However, we suggest that NICE should at some point consider devising separate paediatric LBP guidelines, particularly as there appears to be an increasing incidence of LBP in children. Similarly, we would suggest that guidelines are also needed for non-specific chronic upper back and neck pain as these are significant problems that are not included in any current NICE guidelines.	Thank you for your comment and suggestion. The scope includes people aged 16 and older.
303.	SH	Society of Teachers of the Alexander Technique (STAT)	3	4.2	'All settings in which NHS care is received' should be amended to 'All settings in which NHS-funded care is received' in order to cover service provision, commissioned by the NHS, which is conducted in independent settings.	Thank you for your comment. This has been amended.
304.	SH	Society of	4	4.3.1	We are very pleased to see the inclusion in the draft scope of	Thank you for your comment. Many of

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		Teachers of the Alexander Technique (STAT)			Alexander Technique lessons as one of the interventions being evaluated. We appreciate the efforts to find an appropriate category descriptor that would encompass this intervention and would suggest that 'postural and movement re-education' would be a more accurate description than the current 'postural therapy'. We further propose that it would be more appropriate for 'Alexander Technique lessons' to be moved from the 'Non-pharmacological interventions' section to form part of a new section on 'Self-management strategies' (currently self-management strategies are a sub-section of 'Lifestyle interventions'). The Alexander Technique is inherently a taught self-management method.	the therapies included in the scope are difficult to define under broader headings, therefore they are placed as deemed appropriate at present. This does not reflect how they will be reviewed. After consideration, we do not agree that the alexander technique should be within self-management therapies as these are intended to relate to specific self-management programmes, rather than activities that can be practiced at home. Many exercise regimes could also be considered as self-management if defined in this way, but we propose to also keep this separate.
305.	SH	Society of Teachers of the Alexander Technique (STAT)	5	4.3.1	The 2009 NICE guidelines are unusual in having considered the findings of a large randomised controlled trial (the ATEAM trial, Little et al, 2008; *BMJ* 2008; 337: a884.) without making any recommendations on the main intervention the trial was designed to evaluate (Alexander Technique lessons). Current NICE recommendations based on this trial cover exercise but make no reference to the Alexander lessons intervention and we, therefore, propose that this trial should be reconsidered during the update process as (effectively) new evidence.	Thank you for your comment. All trials relevant to the review questions will be reconsidered and reanalysed during the update of this guideline.
306.	SH	Society of Teachers of the Alexander Technique (STAT)	6	4.3.1	We would like to take this opportunity of indicating that we believe that additional supporting evidence on the effectiveness of Alexander Technique lessons for people with LBP is likely to be forthcoming in time for the current update. The ASPEN trial is a small RCT (N=120), evaluating the effect of Alexander Technique lessons vs group physiotherapy vs Alexander lessons plus group physiotherapy vs usual care. We hope that that the findings of this trial will be published in time for the appraisal; alternatively it may be possible to submit key data in confidence. We would be pleased to submit other supporting (non-RCT) evidence in the	Thank you for this information. This will be noted as a trial to search for when the literature searches are carried out. Please note that literature searches are updated during the development of the guideline. The final searches are run 6-8 weeks before submission of the draft guideline to NICE. Any relevant papers published up to this point will be considered for inclusion in the guideline.

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					form of service evaluations/audits which have recently become available and which may be appropriate for consideration.	
307.	SH	Society of Teachers of the Alexander Technique (STAT)	7	4.4	We suggest that pain frequency should be included as a main outcome in addition to pain severity, as both are important to patients. Different measures of pain frequency have been used in recent trials, including median number of days in pain in the last 4 weeks, or in the last 2 weeks – we suggest that either would be appropriate.	Thank you for your comment. The outcomes that are listed are the key outcomes that will be considered and are not all-inclusive. The GDG will define outcomes per review question and may include additional outcomes for reviews as considered appropriate.
308.	SH	Society of Teachers of the Alexander Technique (STAT)	8	4.4	We believe that pain severity and function measures should not be limited to those listed in the current draft scope but that the definition should be widened to include all relevant measures that have been validated for use in the LBP population. Otherwise, it is conceivable that large randomised controlled trials could be excluded from consideration simply because they have used outcome measures that do not feature in the current limited list, albeit that they are validated and widely accepted.	Thank you for your comment. As stated above, this list is not intended to be all inclusive, and other measures may be added to the protocols if considered appropriate by the guideline development group.
309.	SH	Society of Teachers of the Alexander Technique (STAT)	9	4.5	When the GDG comes to consider evidence on the cost-effectiveness of different interventions, we would request that they re-evaluate the cost-effectiveness data from the ATEAM trial, and take into account the conclusion that 'A combination of six lessons in Alexander Technique followed by exercise was the most effective and cost effective option' (Hollinghurst et al, 2008; *BMJ* 2008;337:a2656. doi: 10.1136/bmj.a2656). In considering the evidence, it is important to note that the ATEAM economic evaluation did not perform any analysis of the cost effectiveness of 24 Alexander Technique lessons compared with either usual GP care or GP advice to take exercise. It evaluated 6 Alexander Technique lessons compared with usual GP care, but 24 Alexander lessons *compared with 6 lessons*. We would also like to mention here that additional cost effectiveness data may become available from the ASPEN randomised, controlled trial (see comment 6 above) in time for consideration by the GDG.	Thank you for your comment. A review of the economic literature will be undertaken for all areas of the guideline.

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310.	SH	The British Pain Society	1	General	We recommend that the guideline scope should include a very clear exposition and definition of terms. There is a lot of confusion about the nomenclature/taxonomy of back pain and, this is evident in the draft scope. For example, in 3.2 (d) lumbosacral radiculopathy (pathology) is equated to sciatica (symptom). Descriptors such as 'mechanical' and 'non-specific' are also problematic and are often misinterpreted.	Thank you for your comments. We agree that terms need to be clearly and carefully defined. The final guideline will include a glossary of terms to ensure this.
311.	SH	The British Pain Society	2	General	The draft scope proposes to exclude patients with acute back pain which is defined as "less than 2 weeks' duration". The scope does not provide a justification for this. There is a widely held view that temporal classifications of pain are best avoided so we suggest that the scope should give a clear explanation for the 2 week criterion or else it should be removed.	Thank you for your comment. The scope has now been amended to include people from onset of pain.
312.	SH	The British Pain Society	3	3.1b	"*social isolation because of disability*" We suggest: "social isolation because of disability, low mood and reduced self confidence"	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
313.	SH	The British Pain Society	4	3.2e	"*The effectiveness of injection treatments and surgery for radicular pain, certainly in the longer term, is not without dispute*" The meaning behind this sentence is unclear. We wonder whether it would it be better to simply state: "The long-term effectiveness of injection treatments and surgery for radicular pain appears weak and inconsistent, though short term benefit from injection therapy may be useful."	Thank you for your comment. This section of the scope is intended for background information in the scoping process only and will not be included in the final guideline.
314.	SH	The British Pain Society	5	4.1.1d	"*The cut-off point of 12 months specified in NICE clinical guideline 88 has been removed for the update of the guideline. There will be no restriction on duration of chronic low back pain.*" The Guideline title needs to be changed and the word "early" removed.	Thank you for your comment. The title of the guideline has been amended to: Low back pain and sciatica: management of non -specific low back pain and sciatica.
315.	SH	The British Pain Society	6	4.3.1	We suggest a small modification: *"Using a systematic assessment to identify 'non-specific' low back pain and radicular pain and any prognostic factors that could*	Thank you for your comment. Although we recognise the importance of the patient's understanding and beliefs about

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					guide management. This would include relevant clinical examination and assessment (for example imaging, physiological testing and psychosocial assessment including an assessment of the patient's understanding and beliefs about low back pain)."	low back pain, we do not agree that this needs to be specifically stated in the scope.
316.	SH	The British Pain Society	7	4.4	Psychological outcome measures are widely used but are omitted here. We propose that you add 'Psychological measures (e.g. of mood, catastrophising and impact of pain)'. Sleep deprivation is another key parameter which is not included.	Thank you for your comment. This list of outcome measures is not intended to be all inclusive. Outcome measures will be determined by the GDG for each review protocol, with additional outcomes if deemed appropriate by the GDG. These may include psychological outcome measures.
317.	SH	The British Pain Society	8	5.1.2	We suggest that 'Depression in adults with a chronic physical health problem', NICE clinical guideline 91 (2009), may be more relevant than guideline 90.	Thank you for this information. Both CG 90 and CG91 are now included in the list of related NICE guidance.
318.	SH	The General Council for Massage Therapies (GCMT)	1	General	The GCMT is the body that represents soft tissue therapists in the UK. It is responsible for setting the minimum education standards for soft tissue therapy qualifications. It currently has 11 member associations representing around 15,000 soft tissue therapists. GCMT member associations also act as verifying organisations for registration with the voluntary regulator, the Complementary and Natural Healthcare Council (CNHC). All members of the Professional Associations forming the GCMT would have met or exceeded the required minimum education standards.	Thank you for this information.
319.	SH	The General Council for Massage Therapies (GCMT)	2	General	The GCMT was disappointed that in the original guidance on low-back pain you did not specifically recognise Soft Tissue Therapists as a group who could deliver the manual therapies you recommend. We work very closely with other professions such as Physiotherapists, Osteopaths and Chiropractors particularly in the private sector, and although we recognise the superb work they do most of them have minimal training in soft tissue work. For example most Physiotherapy degrees incorporate as little as one or two days training in soft tissue techniques.	Thank you for your comment. The guidance is not intended to inform which healthcare professional should deliver the recommended interventions. The scope is written to indicate the therapies and interventions that will be considered, rather than specifying the profession who delivers the intervention so as not to favour one over another.
320.	SH	The General Council for	3	3.2a	You state that most people attend primary care for initial treatment, but this hides the fact that a substantial number of	Thank you for your comment. The remit for these guidelines is any setting in

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		Massage Therapies (GCMT)			people present for initial treatment at a private sector Physiotherapist, Osteopath, Soft Tissue therapist or Chiropractor. A large number of people with low back pain are treated effectively by this community and therefore never come to the attention of primary care.	which NHS funded care is received. We acknowledge that some people do not present to their GP at first, and therefore have reworded this section to say 'GP, or other healthcare provider'.
321.	SH	The General Council for Massage Therapies (GCMT)	4	3.2b last bullet	Refers to acupuncture. Many soft tissue therapists perform 'dry needling', which is a variant of acupuncture that is informed by clinical evidence rather than esoteric Chinese wisdom. Suggest you broaden the scope to include dry needling provided by Soft Tissue Therapist, Physiotherapists, Osteopaths and others.	Thank you for your comment. The scope is not intended to specify all types of treatment that will be considered. This will be defined when the GDG draft the review protocol.
322.	SH	The General Council for Massage Therapies (GCMT)	5	4.1.1b	We welcome the addition of clients with radicular pain and sciatica	Thank you for your comment.
323.	SH	The General Council for Massage Therapies (GCMT)	6	4.2	The suggested choice of setting has some obvious limitations. Given the numbers of people who are seen by professionals in the private sector either instead of, as an adjunct to, or (all too often) as a result of the failure of the NHS. It would seem sensible to extend the setting to services where NHS services could be commissioned, and probably WOULD be commissioned if the evidence base made it clear that this was a cost effective way to address LBP.	Thank you for your comment. The wording has been amended to state 'all settings in which NHS funded care is received.
324.	SH	The General Council for Massage Therapies (GCMT)	7	4.3.1d second bullet	We do not find massage to be a useful term when talking about manual therapies for something like LBP. 'Massage' is a blanket term that covers everything from the relaxation treatment provided by beauticians in salons (which would probably not help low back pain) through to the highly specialised techniques that are practiced by the soft tissue therapists who work with elite sportsmen and women to improve their performance and help them to manage their injuries (which probably would). Soft Tissue Therapists were invited to work at the 2012 Games (we provided 250 therapists) and operate at every level of professional and amateur sport as well as treating non-sporting	Thank you for this information. We will incorporate these terms when undertaking the relevant literature searches.

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					members of the public. At the very least, search terms for 'massage' need to include the key techniques provided by soft tissue therapists – Muscle Energy Technique, Neuromuscular Technique, Soft Tissue Release, Active Isolated Stretching, Myofascial release etc.	
325.	SH	The General Council for Massage Therapies (GCMT)	8	4.3.1d last bullet	Expand to include dry needling.	Thank you for your comment. The scope is not intended to specify all types of treatment that will be considered. This will be defined when the GDG draft the review protocol. Dry needling is not intended to be excluded from the scope.
326.	SH	The General Council for Massage Therapies (GCMT)	9	General	Could we ask you to consider including a Soft Tissue Therapist in your Guideline Development Group—all other relevant groups currently have potential representation apart from this key constituency.	Thank you for your comment. In the update of this guideline, the position we advertised for was 'therapist with an interest in spinal manipulation' as that was considered most appropriate to the draft scope. It does not restrict to the type of manual therapist that would be considered if applications were received. During the development of the guideline, the GDG will have the option to co-opt experts if expertise is required in a particular area. This will be considered depending on the experience and expertise of the GDG members who are appointed.
327.	SH	The National Ankylosing Spondylitis Society (NASS)	1	4.2 (d)	It is sensible to remove the restriction on duration of lower back pain.	Thank you for your comment.
328.	SH	The National Ankylosing Spondylitis Society (NASS)		4.2.2 (a)	If conditions of a non-mechanical nature, such as inflammatory causes of back pain including ankylosing spondylitis, are to be specifically excluded from this guideline on low back pain it is absolutely essential that they are included in another clinical	Thank you for your comment. The identification of back pain of specific aetiology will be included in the scope of this guideline. You are correct, however,

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					guideline as soon as is practically possible. NASS is delighted to have had assurances from Professor Mark Baker at NICE that the process of developing a clinical guideline on Spondyloarthritis (SpA), including AS, will be started early in the new year. It is important that this guideline is published as soon as possible so that those people with AS, who are specifically excluded from this guideline, will have access to appropriate guidelines for their condition. Currently a huge issue is that people with AS present with lower back pain and the fact that it is inflammatory is NOT diagnosed. Inflammatory Back Pain (IBP) can often go unrecognised and patients may wait many years before being referred to rheumatology. In fact, over 20% of patients with axSpA have a delay of 10 years or more between symptom onset and diagnosis.[1] Currently many primary healthcare professionals are not confident in identifying what is mechanical and what is inflammatory back pain and as a result the average delay in diagnosis currently faced by people with ankylosing spondylitis remains at a shocking 8.5 years. During this time these people are often told that the problem is mechanical, and they would therefore incorrectly be included in this guideline. It is therefore essential that clinical guidelines are developed to help health care professionals properly identify inflammatory back pain. The clinical guidelines on lower back pain will only be truly effective for the group that they are meant to help if people with lower back pain which is actually inflammatory are identified early and there is are another clinical guidelines covering appropriate care and treatment for these people. 1. Hamilton L, et al. *Rheumatology* 2011;50:1991–1998.	in noting that the treatment of inflammatory back pain will not be covered in this guideline.

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329.	SH	The National Ankylosing Spondylitis Society (NASS)	3	4.3.1	Assessments of low back pain to identify 'non-specific' low back pain must be able to identify, and therefore exclude, low back pain which is inflammatory. Currently this is often not the case and on average people with IBP are waiting for 8.5 years before getting a diagnosis. Any relevant clinical examination and assessment must ask the right questions in order to identify IBP. Once IPB is identified there must be relevant alternative clinical guidelines to cover these people. NASS has developed a Back Pain Seminar Initiative which aims to: • Improve understanding and recognition of inflammatory back pain (IBP) versus mechanical back pain • Support appropriate referral of patients from primary care to specialists • Provide an overview of the evaluation, investigation and management of patients with back pain. Information from these back pain seminars, which have been very well received around the UK, could be adapted to create clinical guidelines which would cover people with inflammatory back pain.	Thank you for your comment. The identification of inflammatory back pain is covered by the scope of this guideline, however, the subsequent management will not be. While, in the absence of clinical evidence, the GDG's expert knowledge and experience is sought – including experience of use of other guidance – the direct adaptation of non-validated clinical guidelines is not currently accepted in the development of NICE guidelines.
330.	SH	The National Ankylosing Spondylitis Society (NASS)	4	4.4	One of the main outcomes should be that people with inflammatory back pain are correctly identified early on so that they are dealt with by the most relevant clinical guideline. It is therefore crucial that the clinical guideline on SpA is developed as soon as possible.	Thank you for your comment. This section of the scope specifically refers to outcomes that will be searched for in the literature.
331.	SH	The Royal College of	1	3.2(c)	I noted that the CG88 had had very poor uptake. A suggested route for improving this would be to stipulate that one of the GDG	Thank you for your suggestion. The guideline development groups frequently

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		Radiologists		& General	aims of this update process would be to produce a generic, evidence-based, easily-applied protocol/flow diagram that can be instantly recognisable and used, so all stakeholders in the relevant diagnostic and treatment pathways recognise their role and responsibilities facilitating required timely input. (I have attached a pathway, sent as a pack to GPs, which was used with some recognised beneficial impact, within Greater Glasgow which the GDG could perhaps review along with other similar ones, update and modify to apply to requirements).	develop algorithms as part of the NICE guideline and this will be considered for this guideline. The final guideline will also be incorporated into the NICE pathway linking with other related NICE guidance.
332.	SH	The Royal College of Radiologists	2	4.1.1 (a)	Age 12-18 likely developing bad habits w.r.t. carrying, sitting uncomfortably for long periods (school, pc/xbox games, heavy satchels of poor design w.r.t. distribution of weight etc). This group can be targeted easily via schools and colleges and preventative work commenced to avoid continuing into their adulthood with back problems later on. This area would be important w.r.t equality of opportunity for the <18 age group whilst also having potential impact on the adult age groups.	Thank you for your comment. The prevention of low back pain falls outside the remit of this guideline which is focussed on diagnosis and management.
333.	SH	The Royal College of Radiologists	3	4.1.1 (c)	Suggest stipulate 'active GP management (regular analgesia; 1st line, 2nd line etc, Muscle relaxants (short term -1 week max), psychosocial,symptomatic,advice – avoid bedrest, stay active etc)) for 2 weeks' or similar as many patients who come to GP may have had their symptoms for some time, having done nothing and therefore it wouldn't make a huge amount of sense to delay intervention for a further 2 weeks.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms, or first presentation to a healthcare provider.
334.	SH	The Royal College of Radiologists	4	4.1.1. (d)	There probably are a few subgroups that should be identified; e.g. psychosocial, learning difficulties, occupational risks (NHS, Emergency services, GPO workers, deprivation, non-English speaking – and then addressing equality of opportunity in these groups would be recognised as there may be a range of specific challenges from late presentation to frequent attenders with the same problems.	Thank you for your comment. This area of the scope aims to identify subgroups that will respond differently to all therapies and so should be analysed separately throughout the guideline. Specific subgroups will be specified per review as appropriate. Any issues of equality involving protected characteristics will be considered for each intervention/therapy covered.

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335.	SH	The Royal College of Radiologists	5	4.1.2	*'Groups that will not be covered'* These groups should be covered because, practically, one has to tease out and exclude the redflags, cancers, sepsis, fractures, acute and chronic inflammatory spondyloarthropathies, radiculopathies etc before the patient is labelled with 'non-specific back pain' as that is what happens in reality. As our table at the recent stakeholder meeting noted, there will be some flux between various subgroups of these patients (e.g. LBP only, Radicular pain only, Both LBP and radicular pain). Patient access to timely, referral for imaging following appropriate, skilled, clinical assessment is essential for this, hence giving all subgroups an equality of opportunity for high level triaging and appropriate and relevant treatment. 4.1.2 (b) Should be included as the first presentation could be when the cancer is diagnosed !	Thank you for your comments. The assessment of the patient with back pain and/or sciatica forms part of this scope (see 4.3.1a). The identification of the conditions you mention is a key issue and will be covered. The subsequent management of these conditions, once identified, falls outside the guideline scope.
336.	SH	The Royal College of Radiologists	6	4.3.1 (d)	*Use of invasive procedures:* Suggest that image-guided procedures and non-image guided procedures be separated here.	Thank you for your comment. The GDG will consider separating the types of procedures when developing the review protocol.
337.	SH	The Royal College of Radiologists	7	4.3.1 (b)	*Use of antibiotics for back pain (cf. Modic type I endplate changes on MRI scans of the spine)* At present there is little evidence and care should be taken how reference is made in this final document. Large scale, high dose antibiotic treatment of chronic back pain in the community intuitively feels misguided, until proven otherwise, as the impact could be significantly detrimental.	Thank you for your comment. The quality of the evidence is considered as part of all reviews within NICE guidance, and in drafting the recommendations accordingly.
338.	SH	The Royal College of Radiologists	8	4.3.1 (g)	*Indications for surgery:* This should probably read Indications for surgical referral or indications for specialist opinion.	Thank you for your comment. This section specifically relates to surgery, and therefore we think the existing wording is adequate to cover what is intended.
339.	SH	The Royal	9	4.4	*Main outcomes:*	Thank you for your comment. These

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		College of Radiologists			Extremely important to get this nailed down early on. Discussion needed on a spinal registry/Work function database to record (simply and easily) the bio, social and physical data w.r.t benefits and outcomes of the interventions used. The management of back pain can then continually improve with the analysis of this important data. This would then feed into future guideline updates. Follow up time would need to be agreed on (e.g. ?upto 12 months)	factors will be considered by the guideline development group early in the process when the protocols are agreed.
340.	SH	The Society and College of Radiographers	1	General	The guideline target to a 2 week wait seems appropriate and acceptable. It should be noted that this will greatly impact the availability of MRI and subsequent reporting thereof. As such other qualified practitioners, such as the advanced and consultant radiographers, need to be considered as well as radiologists in providing this service.	Thank you for your comments. The 2 week cut-off has now been removed from the scope so as to include people from the first presentation. The impact of these changes will be considered in the development of the guideline.
341.	SH	The Society and College of Radiographers	2	General	There is no mention of any imaging pathways or guidelines for the best modality. We would have expected to see some guidelines as when to image and how so that individuals are not inappropriately being sent for imaging.	Thank you for your comment. Imaging is included as one of the key issues that will be covered as stated with in section 4.3.1 a)
342.	SH	The Society and College of Radiographers	3	General	Early assessment and intervention should be the standard as this would allow more rapid progress to be made in the treatment pathway so that people can return to active lives.	Thank you for your comment.
343.	SH	UK Clinical Pharmacy Association	1	General	Thank you for the opportunity to respond to this consultation. We have no further comments to add.	Thank you for your comment.
344.	SH	United Chiropractic Association	1	3.2b – Current Practice	The following one year study 'Treatment- and Cost-Effectiveness of Early Intervention for Acute Low-Back Pain Patients' clearly demonstrated the treatment and cost-effectiveness of an early intervention program for acute LBP patients Journal of Occupational Rehabilitation March 2003, Vol 13, issue 1, pp 1-9: Treatment and Cost-Effectiveness of Early Intervention for Acute Low-Back Pain Patients: A One-year Study	Thank you for this useful information.

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345.	SH	United Chiropractic Association	2	General, 3.2 Current Practice	With the financial burden on the NHS increasing the inclusion of evidence-based healthcare approaches such as Chiropractic care within emerging value-based health plans represents a significant advancement in cost and clinical effectiveness of LBP. Research documented in 'A Hospital Based Standardized Spine Care Pathway: report of a Multidisciplinary, Evidence-Based process' confirms this perspective. According to the study, those 402 low back pain patients treated exclusively by Chiropractors at the low back pain program implemented at Jordan Hospital, Plymouth, Massachusetts achieved successful clinical outcomes in an average of 5.2 visits at the low cost of $302 (£193) per case, whilst maintaining satisfaction rates above 95%. In addition, self reported pain and disability scores were reduced by about 70% over the course of a few weeks. These studies show the enormous power and benefits of 2 things: 1. The utilisation of Chiropractic in a primary care setting; and 2. The magnitude of successful outcomes, both clinical and cost, that can be achieved when all members of the health sciences work together as a team for the betterment of the patient putting aside all professional rivalries. The NHS current practice follows a stepped approach, largely managed by the GP in the primary care setting, progressing from initial assessment and conventional management with pharmacological/ exercise therapies to more vigorous interventions such as manual/ psychological therapies and invasive procedures. It appears that the general consensus among clinical experts at the Scoping Workshop of 3 October 2013 fully supported early and accurate assessment/ diagnosis and targeting patients for timely/ critical access to the most clinically-relevant management pathway. Journal of Manipulative and Physiological Therapeutics (JMPT)	Thank you for your comment and for the useful information

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					2011 Feb;34 (2) -98-106: A hospital-based standardized spine care pathway: report of a multidisciplinary, evidence-based process.	
346.	SH	United Chiropractic Association	3	General & 4.5 Economic Evidence	The Mercer Report published in peer-review literature in October 2009 further enhances the cost-effectiveness of Chiropractic. Prepared by two distinguished medical researchers using EU figures and extrapolated to USA utilisation their findings were: 1. Chiropractic care is widely used with almost half of all patients with persistent back pain seeking out this form of treatment 2. Chiropractic care for 'low back and neck pain is highly cost effective, represents a good value in comparison to medical physician care and to widely accepted cost effectiveness thresholds" Choudry N, Milstein A, -2009 Mercer Report: Do Chiropractic Physician Services for Treatment of Low Back and Neck Pain Improve the Value of Health Benefit Plans	Thank you for your comment and this useful information.
347.	SH	United Chiropractic Association	3	General & 4.5 Economic Evidence	In recent years, numerous independent researchers and various government agencies have conducted studies which focus on the efficacy, appropriateness and cost effectiveness of Chiropractic care for LBP: • **The Manga Report** – In 1993, the Ontario Ministry of Health commissioned and funded a study to examine the effectiveness and cost-effectiveness of Chiropractic management of LBP. The report concluded that: *"There would be highly significant cost savings if more management of low-back pain was transferred from physicians to Chiroprctors.....Users of Chiropractic care have substantially lower health care costs, than those who use medical care only"* • **Victorian Work Care Scheme** - This workers' compensation study published in the Chiropractic Journal of Australia compared Chiropractic and medical	Thank you for your comment and this useful information

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					management of 1,996 cases of work-related mechanical LBP. The number of compensation days (paid days off work) taken by claimants was found to be significantly lower with Chiropractic care (an average of 6.26 days for Chiropractic patients and 25.56 days for medical patients) The average cost of Chiropractic care was $392 and for medical management $1,569 , four times greater than Chiropractic management. There was also a significantly lower incidence of progression to a chronic low back pain status in those patients who received Chiropractic care, thereby making a significant impact on reducing the costs associated with long-term disability and social ramifications. • **UK Beam Trail** – This study of multi-disciplinary physical therapy for LBP shows convincingly that both manipulation alone and manipulation followed by exercise provide cost effective additions to care in general practice. The study authors stated: *"Indeed as we trained practice teams in the best care of back pain, we may have under estimated the benefit of physical therapy (spinal manipulation) when compared with 'usual care' in general practice"* The detailed clinical outcomes report reinforces these positive findings by showing that the improvements in health status reported by patients reflect statistically significant improvements in function, disability, pain, physical and mental aspects of life quality and beliefs about back pain. The Manga Report (1993) " A study to Examine the Effectiveness & Cost Effectiveness of Chiropractic Management of Low-Back pain Mechanical Low Back Pain: A comparison of Medical and Chiropractic Management within the Victorian Work Care Scheme. Ebrail, PS. Chiropractic Journal of Australia -	

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					1992; 22:47 -5 UK Beam Trial – British Medical Journal 2004 (Dec 11); 329 (7479): 1381	
348.	SH	United Chiropractic Association	4	3.2(b) & (e)	Chiropractic should be considered earlier in the stepped approach to manage people with LBP. In a randomised comparison of four treatment types by Dutch medical researchers on patients who suffered from persistent back pain they found that spinal manipulation provided greater improvement of symptoms compared with physical therapy. The patients receiving spinal manipulation had better physical function and less pain at 12 months than those receiving physiotherapy Per 3.2 (e), "The effectiveness of injection treatments and surgery for radicular pain, certainly in the longer term, is not without dispute. The gain of potential faster recovery with invasive interventions needs to be considered against the increased cost and complication rate of these procedures." Chiropractic is demonstrated to be conservative, clinically and cost-effective as an intermediary step. Randomised Clinical Trial of Manipulative Therapy and Physiotherapy for Persistent Back and Neck complaints: Results of One Year Follow Up. Koes, B.W. et al. British Medical Journal – 1992;304: 601 -605	Thank you for your comment and useful information.
349.	SH	United Chiropractic Association	5	4.3.1 (b) through (h)	From the Stakeholders Scoping Workshop of 3 October 2013 to the Draft Scope for Consultation of 23 October 2013, it appears there is an omission/ deletion of 'spinal manipulation' specifically from this list of interventions for LBP management. With respect, the above-referenced evidence for both clinical and cost-effectiveness of chiropractic care in primary care, managed care, multi-disciplinary/ hospital settings and with respect to occupational applications necessitates reinstating 'spinal manipulation' and/or 'chiropractic treatment' in this section of scope, as 'manual therapies' is neither specific nor definitive.	Thank you for your comment. Spinal manipulation is included within the broader heading of 'manual therapies' and will be included within the scope of this guideline. We are unable to specify all of the specific treatments that will be covered, which is the same approach used for the list of pharmacological treatments.
350.	SH	United	6	4.3.1 (h)	Again, from the Stakeholders Scoping Workshop of 3 October	Thank you for your comment. Referral for

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		Chiropractic Association			2013, there was some consensus regarding opening the scope from 'referral to surgery' to the broader 'referral to a secondary management pathway'. It was felt that this broader scope would allow for GP/ Primary Care setting to access a more timely, more clinically-relevant/ successful, and ultimately a more cost-effective patient management strategy.	specialist assessment will be included within the scope of the guideline.
351.	SH	United Chiropractic Association	7	General	With respect to the RCT being considered the 'gold standard' when it comes to evaluating evidence of objective clinical efficacy of a particular health care intervention, using a methodology that is a less-than-ideal model to evaluate the appropriateness of hands-on intervention must be considered by the NCC in addition to RCT evidence. The conclusions of a systematic review of randomised controlled trials clearly highlights that the adoption of interventions evaluated by only observational data is of benefit. BMJ 2003;327:1459: Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials	Thank you for your comment. The guideline will be developed as per the NICE guidelines manual 2012, using the best available evidence where available. This is not limited to RCTs if none are available.
352.	SH	United Chiropractic Association	8	4.5 Economic Evidence	In addition to the multiple specific citations above, we respectfully draw the committee's attention to the possible limitations of utilising the QALY as the 'preferred unit of effectiveness'.	Thank you for your comment. The QALY is NICE's preferred outcome measure and although it has limitations, so do all alternative health outcome measures.
353.	SH	United Kingdom Spine Societies Board (UKSSB)	1	General	**Composition of GDG** We recommend focusing on clinical experience and competence of GDG clinicians rather than which profession they belong to. The composition of the group should be reflective of NHS services who see: o The highest volume of back pain patients o Primary care pharmacology is not represented o Spinal Triage is not represented o Low intensity `CPP is not represented o Diagnostic radiologists are not represented	Thank you for your comment. The membership of the GDG was determined to provide the expertise relevant to the scope. The GDG members will have the opportunity to co-opt additional members during development for specific areas if it is felt that additional expertise is required.

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					○ Low volume/high cost procedures ○ High intensity CPPP is not represented ○ Interventional radiology is not represented. ○ Neuromodulation ○ Spinal instrumentation ○ Perhaps clinicians could be co-opted for the relevant parts of the guidance. There is over representation on the current GDG composition to pain services. The clinical nurse specialists should have experience of back pain management rather than general pain management. To allow a greater spread of representation, perhaps one GP would be appropriate.	
354.	SH	United Kingdom Spine Societies Board (UKSSB)	2	General	**Rank Issues in the Scope in order of importance:** 1. Management of Radicular Pain 2. Barriers to implementation of CPPP 3. Cost effectiveness of screening (Red Flags) 4. Cost effectiveness and morbidity of imaging 5. Prevention of LBP related disability 6. Antibiotics for LBP with modic change	Thank you for your comment.
355.	SH	United Kingdom Spine Societies Board (UKSSB)	3	General	Consistency of terms throughout the scoping document e.g. sciatica/radicular/ lumbrosacral radiculopathy.	Thank you for your comment. Please see our response below regarding use of such terms. When the full guidance is developed, terms will be clearly defined according to their use in the guideline.
356.	SH	United Kingdom Spine Societies Board (UKSSB)	4	General	The term Sciatica should be avoided as this is not applicable to higher lumbar levels and there is much unhelpful literature related to sciatica in the public domain.	Thank you for your comment. While there is, unfortunately, no consensus on the correct terminology for leg pain secondary to nerve root compression/pathology, 'sciatica' (to mean leg pain secondary to lumbar nerve

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						root compression/pathology) is widely used by both patients and clinicians and is the prevalent term used in the literature.
357.	SH	United Kingdom Spine Societies Board (UKSSB)	5	General	The same review principles of should be applied to all treatments reviewed.	Thank you for your comment. The guideline will be developed as per the NICE guidelines manual 2012, using the best available evidence where available for all review questions.
358.	SH	United Kingdom Spine Societies Board (UKSSB)	6	General	There is concern related to the level of evidence that will be applied. Level 1 evidence is recommended.	Thank you for your comment. The guideline will be developed as per the NICE guidelines manual 2012, using the best available evidence where available.
359.	SH	United Kingdom Spine Societies Board (UKSSB)	7	General	Review areas that were not covered in CG88 rather than re-interpret given the recent update found no new evidence that would change the recommendations.	Thank you for your comment. All areas included in the final scope will be re-reviewed in full.
360.	SH	United Kingdom Spine Societies Board (UKSSB)	8	General	A high percentage of back and radicular pain improves with natural history. There needs to be clear guidance for referral thresholds	Thank you for your comment. Referral for specialist assessment will be considered within the guideline.
361.	SH	United Kingdom Spine Societies Board (UKSSB)	9	General	It is important to differentiate between what is normal aging (degeneration), and what we know from the prevalence of imaging findings in asymptomatic populations.	Thank you for your comment. In developing recommendations for diagnostic procedures, the GDG will always consider the clinical benefit balanced against the harms.
362.	SH	United Kingdom Spine Societies Board (UKSSB)	10	1	Suggested Title: Pain of Lumbar Origin: Management of Non-Specific Low Back Pain and Radicular Pain.	Thank you for your comment. We agree that the title needed to be amended and have changed it to: Low back pain and sciatica: management of non-specific low back pain and sciatica.
363.	SH	United Kingdom Spine Societies Board (UKSSB)	11	1.1	**Suggested Short Title:** Pain of Lumbar Origin	Thank you for your comment. We agree that the title needed to be amended and have changed it to: Low back pain and Sciatica
364.	SH	United Kingdom	12	3.1.e	Why is surgery singled out. The same principles should be	Thank you for your comment. This

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		Spine Societies Board (UKSSB)			consistently applied to all interventions.	section has been worded differently to indicate that the GDG will specifically consider both referral for surgery and the type of surgery that should be used.
365.	SH	United Kingdom Spine Societies Board (UKSSB)	13	3.1 g	Radicular pain of discogenic origin most prevalent between 40 and 60. Neurogenic claudication most prevalent over age 60. With an aging population growth in demand for treatment.	Thank you for this information.
366.	SH	United Kingdom Spine Societies Board (UKSSB)	14	3.2 b	Non-Specific Low Back pain is a diagnosis of exclusion. Essentially, once the risk of specific pathologies (Tumour, infection, fracture, inflammatory disease) has been considered, the diagnosis of non-specific LBP is made.	Thank you for your comment.
367.	SH	United Kingdom Spine Societies Board (UKSSB)	15	3.2 b	Because there is overlap between professions delivering services/interventions we recommend focusing on the intervention rather than the professional group delivering it.	Thank you for your comment. We agree, the final guideline will indicate the skills required by the clinician to deliver interventions, rather than their profession.
368.	SH	United Kingdom Spine Societies Board (UKSSB)	16	3.2 c	The quality of the evidence used here is unacceptable. PULSE is not peer reviewed. GD88 recommends manual therapy **including** manipulation. Manual Therapy is widely available in NHS physiotherapy departments. If clinically appropriate many physiotherapists can manipulate. Acupuncture is commonly available in NHS physiotherapy departments. In some areas however commissioning groups have put out Lavender Statements, which discourage the delivery of acupuncture. High intensity CPPP (combined physical and psychological programme) is an umbrella term and applies to intensive pain programmes such as Functional Restoration through to Pain Management programmes. There is considerable variation in the content of programmes, even with the same name. There is patchy availability across the country and as far as we are aware there have been no new programmes introduced since GD88.	Thank you for your comment. The function of this section of the scope is to provide some background information to stakeholders and developers during the scoping process. References used in this section are not always peer reviewed and will not be used to inform the guideline recommendations. We have also now included a reference to a recent abstract which also highlights that the guidance has not been implemented in primary care.
369.	SH	United Kingdom	17	4.1.1 a	The age group studies in current research is typically age 18 to	Thank you for your comment.

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		Spine Societies Board (UKSSB)			65.	
370.	SH	United Kingdom Spine Societies Board (UKSSB)	18	4.1.1 a	We support the inclusion of people between age 16 and 18 for the following reasons: • In NHS services the age cut off for Paediatric/Adult is age 16. • They may also be in work • They may also have child-care difficulties. • Age related to licensing of drugs should be considered.	Thank you for your comment.
371.	SH	United Kingdom Spine Societies Board (UKSSB)	19	4.1.1 a	We support the inclusion of people between age 65 and 70 for the following reasons: • In the UK the working age is now 68 and planned to extend to age 70. • This means that the pathways for >16 will be the same as adults.	Thank you for your comment.
372.	SH	United Kingdom Spine Societies Board (UKSSB)	20	4.1.1. a & b & c	The acute back pain guidelines would benefit from review. Many people do not present to health care before 2 weeks.	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of symptoms.
373.	SH	United Kingdom Spine Societies Board (UKSSB)	21	4.1.1. a & b & c	Given that patients move between having back pain and radicular pain we recommend that both pathways have the same start time. It is important that there is a seamless pathway.	Thank you for your comment. The scope of the guideline has been amended accordingly with the pathways for both populations starting at onset of symptoms.
374.	SH	United Kingdom Spine Societies Board (UKSSB)	22	4.1.1. b	The principles of screening and management of acute and persisting LBP have many similarities.	Thank you for your comment.
375.	SH	United Kingdom Spine Societies Board (UKSSB)	23	4.1.1 c	There needs to be a clear distinction between Radicular pain of discogenic origin, neurogenic claudication and neuropathic pain.	Thank you for your comment. We note the need for a distinction between these conditions, and the GDG will consider this when drafting the relevant review protocols.
376.	SH	United Kingdom Spine Societies Board (UKSSB)	24	4.1.1 c	The risks for acute Cauda Equina syndrome and the timing of surgery are very different between radicular pain and neurogenic claudication.	Thank you for your comment. We agree, while the identification of cauda equina is covered within the scope of this guideline, its subsequent (including

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						surgical) management will not be covered. Different considerations for sciatica and neurogenic claudication will be considered when the evidence is reviewed and recommendations drafted.
377.	SH	United Kingdom Spine Societies Board (UKSSB)	25	4.1.1 c	There needs to be clear guidance on the management of radicular, neurological weakness	Thank you for your comment.
378.	SH	United Kingdom Spine Societies Board (UKSSB)	26	4.1.1.d	Psychosocial co-morbidities should be taken account of.	Thank you for your comment. The GDG will decide whether particular subgroups require special attention per review question protocol. Management of comorbidities is outside of the scope for this guideline however.
379.	SH	United Kingdom Spine Societies Board (UKSSB)	27	4.1.1 e	We support removing the cut off at 12 months is supported.	Thank you for your comment.
380.	SH	United Kingdom Spine Societies Board (UKSSB)	28	4.1.1 e	There is a clear need for guidance on the management of patients with persisting symptoms who have exhausted the treatment options in GD88.	Thank you for your comment. The management of patients with symptoms refractory to treatment is covered within the scope of this guideline.
381.	SH	United Kingdom Spine Societies Board (UKSSB)	29	4.1.1 e	There needs to be a clear distinction between recurrent back/radicular pain and persisting back pain related disability	Thank you for your comment. Specific subgroups will be defined per review protocol. Heterogeneity within populations will be explored within each review questions, including reasons for these differences. If appropriate, recommendations will be drafted accordingly.
382.	SH	United Kingdom Spine Societies Board (UKSSB)	30	4.1.2 a	Cauda Equina syndrome is usually due to a primary mechanical failure of the intervertebral disc with secondary neurological consequence (which should be included in this guideline) as opposed to primary intrinsic neurological disorders, which should not be included in the scope of this document. Screening and	Thank you for your comment. Identification of cauda equine syndrome is within the scope of this guideline and will be included.

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					referral to a spinal on-call service for Cauda Equina Syndrome should be included.	
383.	SH	United Kingdom Spine Societies Board (UKSSB)	31	4.1.2 a	Radiologically diagnosed grade 1 spondylolisthesis should be included.	Thank you for your comment. Spondylolisthesis and spondylolysis are diagnoses made radiologically. Prior to radiological diagnosis, the early management of these patients is usually the same as for non-specific low back pain/radicular pain and the therapies/interventions proposed in the scope would apply. Once diagnosed, the detailed management of these conditions (often surgical) would be outside the current scope.
384.	SH	United Kingdom Spine Societies Board (UKSSB)	32	4.1.2 a	High grade (2 or above) spondylolisthesis should be excluded.	Thank you for your comment. We agree, this population is excluded from the scope of this guideline.
385.	SH	United Kingdom Spine Societies Board (UKSSB)	33	4.1.2 a	The timing of imaging for suspected high grade spondylolistheis is likely to arise from the fact that there has been insufficient response to the recommended interventions.	Thank you for your comment.
386.	SH	United Kingdom Spine Societies Board (UKSSB)	34	4.1.2 d	This should align with the earlier scope.	Thank you for your comment. The scope has now been amended to include both patients with suspected non-specific back pain and suspected lumbosacral radiculopathy from onset of symptoms.
387.	SH	United Kingdom Spine Societies Board (UKSSB)	35	4.3.1 b	We recommend the inclusion of the following: • Antibiotics for modic change	Thank you for your comment. Antibiotics are included within 4.3.1 c.
388.	SH	United Kingdom Spine Societies Board (UKSSB)	36	4.3.1 c	We recommend the inclusion of the following: • Media campaigns • Public information • Patient preference • Packages of care based on protocols/guidelines • Stratified care/targeted treatments. • Combined treatments.	Thank you for your comment. While most of these topics will be covered within the scope of this guideline, media campaigns and public information are population-based interventions usually covered by public health guidance, and patient preference is an issue across the board

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					• Weight management, smoking, inactivity. • Timing of interventions • Orthotics and appliances • Spinal Triage	and not specific to management of low back pain. Therefore, these issues will not be covered.
389.	SH	United Kingdom Spine Societies Board (UKSSB)	37	4.3.1 d	We recommend the inclusion of the following: • The cost effectiveness of repeated therapeutic spinal injections • Spinal Surgery • Neuro-modulation, including spinal cord stimulators.	Thank you for your comment. The clinical and cost effectiveness of spinal injections, spinal surgery and spinal cord stimulators are all covered within the scope of this guideline
390.	SH	United Kingdom Spine Societies Board (UKSSB)	38	4.3.1.e	• CPPP specifically for back pain. • The cost effectiveness of MDT Pain management programmes	Thank you for your comment. The clinical and cost effectiveness of combined therapies (including CPPP and pain management programmes) is covered within the scope of this guideline within combined therapies.
391.	SH	United Kingdom Spine Societies Board (UKSSB)	39	4.3.1	Identification of groups where the prognosis is good and intervention will not add value.	Thank you for your comment. Stratification of care according to prognostic indicators is covered within the scope of the guideline (Section 4.3.1 a)
392.	SH	United Kingdom Spine Societies Board (UKSSB)	40	4.3.1	The clinical importance of intensity and duration of recommended interventions.	Thank you for your comment. The GDG will consider intensity and duration of interventions, if evidence is available, when developing recommendations.
393.	SH	United Kingdom Spine Societies Board (UKSSB)	41	4.3.1	Referral thresholds	Thank you for your comment. Referral for specialist assessment will be covered by the scope of this guideline.
394.	SH	United Kingdom Spine Societies Board (UKSSB)	42	4.3.1	Impact of waiting times on disability and healthcare costs	Thank you for your comment. Waiting times are not within the scope for this guideline however.
395.	SH	United Kingdom Spine Societies Board (UKSSB)	43	4.3.1	The morbidity of Imaging should also be addressed.	Thank you for your comment. Adverse effects of diagnostic tests are always considered when developing recommendations.
396.	SH	United Kingdom	44	4.3.1, f	Back schools are no longer commonplace in the UK.	Thank you for your comment. This

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		Spine Societies Board (UKSSB)				wording has been removed.
397.	SH	United Kingdom Spine Societies Board (UKSSB)	45	4.3.1	The cost effectiveness of: • MDT assessments	Thank you for your comment. The cost effectiveness of all interventions included will be considered.
398.	SH	United Kingdom Spine Societies Board (UKSSB)	46	4.3.1 e	The influence of the 'significant others' of those with back pain in relation to their recovery and work participation.	Thank you for your comment. Reviewing evidence for participation of family and carers in the management of low back pain was not highlighted as a priority for inclusion in this guideline by stakeholders. The GDG lay members, however, provide the perspective of patients, family and carers which is vital when drafting recommendations.
399.	SH	United Kingdom Spine Societies Board (UKSSB)	47	4.3.1 g	There should be consistency applied to all interventions. ○ Sections "a" to "f" do not begin with the term "Indications for", why is surgery different.	Thank you for your comment. This section has been worded differently to indicate that the GDG will specifically consider both referral for surgery and the type of surgery that should be used.
400.	SH	United Kingdom Spine Societies Board (UKSSB)	48	4.4	• Spine registraries. • Work ability • Healthcare utilisation • Hospital admissions. • Independence in managing recurrence. • Self efficacy	Thank you for your comment. The GDG will specify appropriate outcomes per review question. This list is intended as key outcomes and is not all-inclusive.
401.	SH	University Hospitals Birmingham (UHB) NHS Foundation Trust.	1	4.1.2a)	It is requested that there is further clarification of "Groups that will not be covered" although it is recognised that this is not an exhaustive list. The Emergency Department request that patients presenting with vascular conditions, genito-urinary, renal or gynaecological conditions are added within the section "conditions of a non-mechanical nature".	Thank you for your comment. These conditions will indeed be considered as "conditions of a non-mechanical nature" but will not be individually specified in the scope.
402.	SH	University Hospitals Birmingham (UHB) NHS	2	4.3.1a) and 4.3.2	4.3.1a is the only section where imaging is included. As this is a significant component to the assessment and management for this patient group, at least in secondary care, consideration of a separate section including further criteria to guide appropriate	Thank you for your comment. The areas included in the scope are those highlighted by stakeholders as priority areas that will add most value. Further

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		Foundation Trust.			imaging is requested e.g. MRI, plain x-ray. It is also requested that the GDG consider other investigations/ screening tools to assist differential diagnosis and enable identification of other conditions excluded from the guideline e.g. blood testing, vascular assessment.	imaging in secondary care was not identified as a priority. The GDG will decide, in detailing the protocols around diagnosis will agree on the most appropriate comparators.
403.	SH	University Hospitals Birmingham (UHB) NHS Foundation Trust.	3	4.3.1b)	It is requested that "weight control" and "smoking" are included within "lifestyle interventions". In addition, incorporating negotiated goals and patient expectations within this section is requested, as engaging the patient in the proposed management plan is always important and impacts on outcomes.	Thank you for your comment. These will be taken into consideration by the GDG when agreeing comparators for the review protocol.
404.	SH	University Hospitals Birmingham (UHB) NHS Foundation Trust.	4	4.3.1d) and e)	The current CG88 has been interpreted literally within this Trust to meet requirements for AQP/ NHSLA. Within physiotherapy this has led to delivery of single modality treatments in sequence (i.e. manual therapy or exercise or acupuncture), although such management is a deviation from national practice and restricts treatment selection based on clinical examination and reasoning. This alteration in practice has, in turn, led to substantial staff retraining and service reorganisation and these changes are ongoing. Will the GDG review available evidence relating to delivery of multimodal treatment e.g. manual therapy and exercise? In addition, it is requested that the GDG carefully consider phrasing of the revised document to enable clinicians to incorporate evidence into practice whilst retaining autonomous and bespoke treatment selection based on patient assessment.	Thank you for your comment. Combination therapies are included within the scope of this guideline.
405.	SH	University Hospitals Birmingham (UHB) NHS Foundation Trust.	5	4.4	Considering the time and cost for including outcomes measures within clinical practice, what evidence exists that measuring such outcomes on a routine basis improves patient care? Please remember that there is an opportunity cost to mandating routine collection of such outcome data. For individual patient management these tools have very limited clinical utility, in our view. More directly relevant measures e.g. better, worse, same or	Thank you for your comment. The GDG will consider any relevant cost differences between strategies being evaluated for the guideline.

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					return to previous activity/ work would be easier and more relevant in routine practice. Finally, will the GDG consider the licensing and cost implications if specific outcomes measures are recommended?	
406.	SH	University Hospitals Birmingham (UHB) NHS Foundation Trust.	6	General	Development of a sensitive audit tool is requested to underpin the guideline.	Thank you for your comment. The implementation and subsequent monitoring of this guideline will be guided by the NICE implementation team and will be developed to accompany the guideline when it is published. Appropriate implementation tools will be considered by the implementation team in collaboration with the guideline development group members at this time.
407.	SH	University of York	1	general	Acupuncture is a complex intervention that is commonly used in everyday practice to address multi-symptom problems, such as low back pain and depression. Evidence on acupuncture as an intervention for depression comes from a recently published trial in PLoS Medicine (MacPherson H, Richmond S, Bland, Brealey S, Gabe R, et al. (2013)Acupuncture and Counselling for Depression in Primary Care: A randomised Controlled Trial. PLoS Med 10(9): e1001518). There is an opportunity for NICE to consider recommending the offer of acupuncture for such mixed condition problems in order to avoid referrals for a parallel psychological intervention.	Thank you for your comment and useful information. The management of comorbidities such as depression are beyond the scope of this guideline however.
408.	SH	University of York	2	general	With regard to the comparator when evaluating clinical and cost-effectiveness, it should be noted that sham or placebo comparators are not appropriate controls for complex interventions such as acupuncture. With regard to establishing cost-effectiveness, a sham comparator will not provide meaningful data, as it is an artificial comparator that is not provided in settings in which NHS care is received (see Settings, page 6). The relevant comparator should be some form of standard or usual NHS care.	Thank you for your comment. We acknowledge the issues around selecting the appropriate comparator for acupuncture studies. The GDG will consider the appropriate comparators, and study designs for each review question when developing the protocols.

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409.	SH	University of York	3	general	When comparing non-pharmacological interventions, the same or equivalent comparators should be used throughout, so that there is a fair comparison across all interventions. The implication is that it would not be a fair comparison to use a sham/placebo comparator of one intervention and a standard or usual care comparator for another, as effect sizes will depend to a considerable extent on the nature of the comparator.	Thank you for your comment. The guideline will be developed as per the NICE guidelines manual 2012, using the best available evidence where available.
410.	SH	University of York	4	general	It might be helpful for a specialist in acupuncture research be involved in the interpretation of the evidence on acupuncture.	Thank you for your comment. An acupuncture specialist was included within the list of co-optees for the guideline development group with the intention that they will be involved in the relevant review questions.
411.	SH	University of York	5	7	It is appropriate that acupuncture will be considered as a non-pharmacological intervention rather than an invasive procedure	Thank you for your comment.
412.	SH	Warwick Clinical Trials Unit	1	General	The scope for this revised guideline is substantially larger than for its predecessor. There is a substantial risk here that it will not be possible to cover the scope satisfactorily within the available resources. A previous scoping review for NICE has shown that, for much of the material covered in the previous iteration of the guidance, there is not a substantial new evidence base that would change the conclusions of the previous GDG. Extending the time limit for duration to which the guidance applies should not cause a problem in the interpretation of data for those areas where there is insufficient new evidence to affect conclusions. In reality the previous guideline included data from this population with long standing chronic back pain. Thus, these data can be easily integrated into a revised pathway relevant to this scope. On the other hand a new search across all modalities will be needed to advise on the management of low back pain lasting for 2-6 weeks; i.e. all studies of treatment for acute low back pain/radicular pain. This has the potential to be a major task with little reward. The addition of radicular pain will generate a burden of reviewing work similar to that of the previous guideline, particularly as a greater degree of detail is sought on surgical	Thank you for your comment. After careful consideration of all stakeholder responses it was agreed that providing guidance on this group (acute LBP) would add value. The scope of the guideline has, therefore, been amended to include people from onset of symptoms.

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					interventions. An overwhelming need to look at the management of acute back pain has not been presented. Since, even for this group, the prognosis is generally excellent it is not clear why this is a priority for inclusion in the guideline. It may be better to keep the original lower limit for duration of six weeks.	
413.	SH	Warwick Clinical Trials Unit	2	General	The title ' early management of persistent non-specific low back pain' need revising to reflect the changed scope	Thank you for your comment. We agree and have reworded the title as: Low back pain and sciatica : management of non-specific low back pain and sciatica.
414.	SH	Warwick Clinical Trials Unit	3	General	Stratified care is not mentioned. This is an important topic that should be addressed. The use of sub-grouping to inform care is being introduced. It would be good to formally assess stratified care, and the use of clinical prediction rules more widely.	Thank you for your comment. Stratified care is included within the scope of this guideline under the heading of systematic assessment.
415.	SH	Warwick Clinical Trials Unit	4	General	It is disappointing that the patient perspective has not been more explicitly integrated into the scope. Whilst this is to some extent covered by generic working practices and the NICE social values document there are some specific areas that it may be worth considering. Specifically, what are the roles of patient preferences and choices in considering treatment choices? How might shared informed decision making fit into the pathway? Might it be that integrating these explicitly into the care pathway might improve outcomes?	Thank you for your comment. Patient choice is something that should be considered across medical practice and therapeutic modalities. It is not an issue specific to low back pain and radiculopathy. The guideline will also cross refer to the NICE guideline CG138 Patient experience in adult NHS services, where these issues are addressed.
416.	SH	Warwick Clinical Trials Unit	5	3.1.b	A minor point. Those unable to work because of persistent low back pain will not be in receipt of sickness benefits. They will, currently, receive Employment Support Allowance. For many the problem will be that they are in receipt of job seeker's allowance and unable to find work because of their back pain. Suggest 'reliance on state benefits' as better wording	Thank you for your comment. This has now been removed from the scope.
417.	SH	Warwick Clinical Trials Unit	6	3.2.b	It is of note that the stepped approach suggested as current practice does not match current NICE back pain guidance. If there is some evidence that this is current practice then this discord is part of the justification for a revision and needs to be in the background. If there is no evidence for this might it be better here to reflect current NICE guidance for persistent low back pain.	Thank you for your comment. We disagree, and feel that CG88 very much reflects a stepped approach.

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					It may also be appropriate to note any differences in the current care pathway for people with radicular pain	
418.	SH	Warwick Clinical Trials Unit	7	3.2.d	There is nothing simple about non-specific low back pain. Suggest omit 'simple'	Agreed.
419.	SH	Warwick Clinical Trials Unit	8	3.2.d	Is there evidence that the majority of either, or both, of referred pain and radicular pain, are caused by disc prolapse?	Thank you for your comment. The intention was to express that sciatica is most commonly caused by a herniated disc, while those with non-specific low back pain who have referred leg pain may present in a similar way to those with sciatica, and so the diagnosis is often difficult.
420.	SH	Warwick Clinical Trials Unit	9	3.2.e	The penultimate sentence of this paragraph implies (without actually stating) that the short term effectiveness of injection treatments and surgery for radicular pain is without dispute. The evidence on this point may not be clear and it might be worth dropping 'certainly in the longer term' from this paragraph. The final sentence may be better if it started; ' The potential gain from faster recovery…'	Thank you for your comment. This section has now been reworded to: "The potential for faster recovery with invasive interventions for sciatic pain should be considered as well as the cost-effectiveness and increased complication rates of these procedures."
421.	SH	Warwick Clinical Trials Unit	10	4.1.1.b	It would be nice to have some evidence adduced for the reason for choosing two weeks as duration for entry to guideline rather than the more conventional six weeks. There is not here an objection to including the 2-5 week group (unlike for 4.1.1.a) rather it is not clear where the justification comes from. Might it be more efficient to start all of the guidance (LBP and radicular pain) from six weeks	Thank you for your comment. The scope of the guideline has now been amended to include people from onset of pain or first presentation to a healthcare professional as stakeholder comments have indicated that treatment will not differ according to whether the person has been in pain for 2 or 6 weeks, or at their first presentation.
422.	SH	Warwick Clinical Trials Unit	11	4.1.1.d	Might it be better to include this subhead, along with lowering of age range, in parentheses in 4.1.1.a to match style of 4.1.1.b	Thank you for your comment, The age range is explicitly stated in 4.1.1.a and b as suggested. The removal of the 6 week cut-off has also been added to 4.1.1.d.
423.	SH	Warwick Clinical Trials Unit	12	4.1.2.a	With inclusion of 16 and 17 year olds should adolescent scoliosis be added as a specific exclusion in the specific spinal disorders? It is covered in 4.3.2.a but may also merit a mention here	Thank you for your comment. We agree and have now added adolescent scoliosis to the areas that will not be

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						covered.
424.	SH	Warwick Clinical Trials Unit	13	4.3.1.a	It is suggested here that prognostic factors that guide management will be sought. Prognostic factors identify those who will do well, irrespective of treatment choice. What is more important in guiding treatment choice is being able to identify factors that moderate treatment effects. Suggest this is clarified to make it clear that it is moderating factors that are of interest rather than prognostic factors. This links to the general comment about stratified care and clinical prediction rules	Thank you for your comment. It is the intention that moderating factors will be included within the review when assessment is considered. However, we do not believe that the section of the scope should be reworded.
425.	SH	Warwick Clinical Trials Unit	14	4.3.1.b	Return to work interventions are included here. Return to work is not included as an outcome of interest in section 4.4. If return to work interventions are to be considered then it would seem sensible to have return to work in the outcome set. Since costs are only usually considered from NHS and personal social services perspective any return to work data are unlikely to inform any economic models. It may be that workplace interventions and return to work interventions are not going to contribute greatly to the guidance as these are not focussed primarily on the outcomes of interest. This may be an area that can be safely dropped to keep the workload manageable	Thank you for your comment. Return to work has been retained in the scope because these interventions are likely to be of great importance to people with low back pain. The outcome list covers key outcome measures for the guideline but additional outcome measures specific to individual reviews will be considered by the GDG during the development of the review protocols and so may include return to work for appropriate review questions as it could be considered as an important outcome for people with low back pain.
426.	SH	Warwick Clinical Trials Unit	15	4.3.1.c	Is there any particular reason why NSAIDs are not included in this list?	Thank you for your comment, NSAIDs will be considered within analgesics.
427.	SH	Warwick Clinical Trials Unit	16	4.3.1.d	Is there a reason why Alexander technique is the only treatment approach that is named? Either leave as a general exercise/postural bullet of add other common approaches, e.g. Yoga, Tai Chi, Qigong, Pilates, core stability…	Thank you for your comment. The intention is that other exercise / postural therapies will be included if agreed by the GDG when formulating protocols for the review questions, and if evidence is identified. However, Alexander technique has been specifically stated as this was an area that had been highlighted in the review decision to update this guideline.

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						Yoga has also now been added specifically to this list.
428.	SH	Warwick Clinical Trials Unit	17	4.3.1.e	Need to explain what is meant by multimodal therapies. Is this combined physical and psychological treatment as defined in previous iteration of the guideline or is this addition of any two treatment approaches e.g. facet joint injections plus exercise?	Thank you for your comment. This wording has now been changed to 'Combined therapies' intending to reflect any combination of therapies that are included within the scope of this guideline.
429.	SH	Warwick Clinical Trials Unit	18	4.3.1.g	If specific psychological approaches are to be named considering adding other approaches such as mindfulness as examples.	Thank you for your comment. The intention is that other psychological therapies will be considered if evidence identified. Cognitive behavioural pain management has been stated specifically as an example as it was an area that was raised during the stakeholder workshop.
430.	SH	Warwick Clinical Trials Unit	19	4.4	The EuroQol is not a measure of health related quality of life. The EQ-5D from which it is derived can be interpreted as a quality of life measure.	Thank you for your comment. This has been amended.
431.	SH	Warwick Clinical Trials Unit	20	4.4	It may be worth considering the inclusion of psychological distress or improved mental wellbeing as an outcome. An intervention that improves mental health in a population with chronic pain and disability might be worth considering even if it does not affect pain, or pain related disability.	Thank you for your comment, outcomes for each condition will be determined per review question in the protocols. The outcomes listed in the scope are the key ones that will be considered across the guideline and are not all-inclusive.
432.	SH	Yoga for Healthy Lower Backs	1	1 and General	Title wording 'early management' needs to be addressed specifically and appropriately, i.e.:- 1. the patient will most usually present to a GP and so there should be good CGC representation of GPs and Primary Care professionals, and especially community-based health professionals, (whereas it currently seems to be Secondary Care 'heavy') and 2. This title reflects the urgent need to find less costly, but also more 'pro-active' early interventions, not only for patient satisfaction but in order to prevent development of long-term chronic conditions. A good example of this could be provision of a	Thank you for your comments. We have amended the title to: Low back pain and sciatica: management of non-specific low back pain and sciatica

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					gentle evidence-based yoga programme offered as a first-line, multi-modal combination treatment option once serious pathology has been ruled out by triage or GP.	
433.	SH	Yoga for Healthy Lower Backs	2	3.1	It is important to note that 75% of patients presenting to their GP with lbp re-present within 12 months, i.e. there is an urgent need to get appropriate treatment options for patients. Self-management options with proven long-term outcomes should be preferred treatments (especially as we have been asked to consider cost implications).	Thank you for your comment. Self-management strategies will be covered within the scope of this guideline (see section 4.3.1 b).
434.	SH	Yoga for Healthy Lower Backs	3	3.1.b	- mental health conditions also associated with lbp, e.g. especially depression, but also anxiety. Please consider adding this.	Thank you for your comment. This has been added to the scope.
435.	SH	Yoga for Healthy Lower Backs	4	3.1.c	The Scope says currently:- 'Interventions and therapies are used to help people manage their low back pain and cope with daily life. They also aim to help people to remain in – or return to work and minimise the risk of recurrence.' There was talk at the draft scope workshop meeting about the importance of language used by professionals (this is backed up by Back Pain Revolution book written by back pain specialists Dr. Kim Burton and Prof. Jennifer Klaber-Moffett). Currently, it sounds as if a person presenting with lbp is likely to 'suffer' forever and will have to learn to 'cope' and 'manage'. More positive language, which in turn might be more likely to have better outcomes, would be to put the following wording instead: '**Interventions and therapies are used to help people to manage and improve their back condition and to lessen the intensity, recurrence and/or duration of back pain episodes**.' The second sentence confuses, as it is not just those who are in work who wish to minimise the risk of recurrence. The second sentence could read (aiming also not to stigmatize or depress those who are out of work). '**They aim to help people to remain more physically and socially active in their daily lives and to reduce absenteeism from work**.'	Thank you for your comment. We agree with your suggestion and have amended the scope accordingly.
436.	SH	Yoga for Healthy	5	3.1.d	Please add '**Specialized yoga'** or 'Appropriate yoga' to this list.	Thank you for your comment. This list is

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		Lower Backs			Refs. to RCT trials by Helen Tilbrook et al (*Annals of Internal Medicine* 2011) and Karen Sherman et al, and to systematic reviews and meta-analysis on yoga as an effective treatment for back pain by Eric Groessl, H. Cramer, Arthritis Research UK CAD Review, plus more, and the University of York Trials Unit's cost-effectiveness paper L-H Chuang et al (*Spine* journal 2012) showing that offering a 12-week group yoga class 'would be likely to be cost-effective if offered within an NHS setting'. A once-off yoga course (such as the generalizable and available 12-week *Yoga for Healthy Lower Backs* course developed for the Arthritis Research UK / University of York RCT - H. Tilbrook and L-H Chuang RCT published papers) offers a multi-modal, primary care, group treatment option that combines physical, mental, psychosocial, back education, behavioural/lifestyle change, postural awareness, relaxation technique approaches that could potentially save the NHS (and Councils) money, by offering a long-term multi-dimensional treatment option. Please mention 'specialized yoga' specifically in the guideline. Yoga has been recommended treatment for low back pain in the US since 2008 due to research previous to this University of York RCT, because it has good outcomes, patient satisfaction is high, and because it can save costs.	not intended to be all-inclusive and we are unable to mention all possible treatments specifically.
437.	SH	Yoga for Healthy Lower Backs	6	3.2.b	Under the second bullet point 'Management', **'Specialized yoga'** (or 'Appropriate yoga') should be mentioned, as it offers a non-invasive, gentle combined/multimodal approach to long-term physical and mental health. It aims to care for the holistic and lifestyle needs of the patient and does not just address the lbp. 'Specialized yoga' should be mentioned as a suggested first-line treatment option, as it offers considerable self-management skills education with long-term positive outcomes potential.	Thank you for your comment. This is a broad summary of management options and is not intended to list specific management options.
438.	SH	Yoga for Healthy Lower Backs	7	3.2.f	In order to improve quality of life for patients, it is helpful to involve them in their treatment by informing them about choices available. It is also preferable and advantageous to give them self-management tools (rather than the unsustainable option of them 'relying on' health professionals for the long-term).	Thank you for your comment. We agree. Patient involvement is an important principal of all NICE guideline development and ensuring that recommendations are drafted from a

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					Primary Care health professionals have a fundamental experiential understanding of the importance of this way of prescribing treatment options for a biopsychosocial condition such as lbp. Lbp has the potential to become disabling for the long-term, which can subsequently lead to, or contribute to worsening of, other co-morbidities.	patient focus. The guideline will also cross refer to the NICE guideline CG138 Patient experience in adult NHS services, in which patient choice is a key focus of the recommendations.
439.	SH	Yoga for Healthy Lower Backs	8	4.3.1.d	Please add '**For example, a specialized yoga programme'** after mentioning 'Multimodal therapies'. (See above for refs and reviews.)	Thank you for your comment. We have added yoga as an example within 4.3.1 d.
440.	SH	Yoga for Healthy Lower Backs	9	4.4 General	Due to the nature of the condition of lbp, it is important to measure more than just physical outcomes, e.g. mental health.	Thank you for your comment. We agree that mental health is an area that should be considered within the outcomes. These are the key outcomes that will be considered, but are not all inclusive, and other outcomes may be added to specific review questions as appropriate when the GDG draft the review protocols.
441.	SH	Yoga for Healthy Lower Backs	10	4.5 and General	Please make sure the University of York's L-H Chuang et al (Aug 2012, *Spine* journal linked to the *Annals of Internal Medicine* Nov 2011 paper) published paper is considered, as this specifically mentions that a 12-week specialized group yoga course would be cost-effective if offered within an NHS setting compared to what is currently offered. Thank you. We can send through a copy of the full paper which considers QALYS, economic data, and the fact that it is a dominant treatment for society and from an economic perspective. Significantly, in this RCT with 313 participants and good statistical power, those offered a 12-week yoga course ('intention to treat' model) had on average 3.83 days off work over the 12 months studied compared to 12.29 in the non-yoga 'usual care' control group.	Thank you for this information. A full and detailed literature search will be carried out for all review questions. Any studies relevant to the protocol will be included. However, it is helpful to be of informed of potential papers in advance and we make a note of this for consideration when we undertake the relevant review question.
442.	SH	Yoga for Healthy Lower Backs	11	General	It is noted that antibiotics were mentioned as something to be considered – this 2013 research involved this relatively new treatment option for low back pain with 100 patients being offered antibiotics.	Thank you for your comment. As stated above yoga has been added as an example within 4.3.1 d of therapies that will be considered.

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					The University of York, Department of Health Sciences, York Trials Unit (Arthritis Research UK funded) yoga research trialling the 12-week 'Yoga for Healthy Lower Backs' fully-resourced, generalizable yoga programme intervention was offered to 156 participants and patients were followed up over the same 12 month period showing yoga had good outcomes on the RMDQ and other measures compared to the 157 in the control group. Yoga is not a new treatment modality, as it has been available and anecdotally efficacious for long-term holistic outcomes for centuries (although of course the research from 2011 and 2012 is relatively new). Please therefore mention 'specialized yoga' (and possibly also 'appropriate yoga') in the guidelines.	
443.	SH	Yoga for Healthy Lower Backs	12	General	There is a Department of Health call for the nation to become more physically active and this guideline should reflect this. There is evidence that for improving lbp, and associated osteoarthritis and depression, one must emphasize maintenance of fitness and activity levels. Giving people the tools to gently return to exercise when they have lost confidence to do this, and their movements have become restricted, is important. Suggesting they go to the gym or to sports centre exercise classes may not be appropriate, whereas a gentle, gradually-progressing, professionally-guided approach addressing the individual needs of the person, such as 'Yoga for Healthy Lower Backs' course, would be a good evidence-based programme to offer as a treatment option.	Thank you for your comment. The guideline scope includes exercise therapies and yoga and guidance will be based on the best evidence available for physical activity, and will include consideration for people who may not be able to visit a gym or have impaired mobility.
444.	SH	Yoga for Healthy Lower Backs	13		'Comments below from 'British Council for Yoga Therapy' Chairperson (CNHC's specialty body for yoga) who is also a 'Yoga for Healthy Lower Backs' teacher. "After attending the NICE Scope meeting on behalf of 'Yoga for Healthy Lower Backs' (and thinking about it afterwards), one of the big things that concerns me is that the NICE Guidelines are being rewritten without understanding why the previous ones weren't implemented and without looking at all the reasons for this, e.g. – lack of funds?; lack of available low cost treatment	Thank you for your comment, the decision to update the guideline was based upon a review of the existing guidance undertaken by the Centre for Clinical Practice at NICE. During this process, they did take into consideration why the original guideline was not implemented. It is our intention to address these issues in the update of the guideline.

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					options?; *lack of joined up multi-disciplinary team-working?;* GPs' lack of knowledge, or understanding, of the Guidelines?; assessment by the GP that the patients lbp may resolve itself over a couple of weeks?; etc. I did not get the impression that we got a 'feel' for what actually happens nationally at the GP initial consultation phase regarding lbp." A visit to the GP is the beginning of the care pathway – relevant questions are 'What do patients expect/want?' and 'What does the GP expect/believe?'. With 80% of people experiencing lbp within their lifetime, it is crucial that the beginning stages are dealt with appropriately and that 'these frequently-returning, heart-sink patients do not just fall inappropriately into the pain clinics for lack of other good available options'. (Quote from GP who supports use of specialized yoga, after seeing his patients' positive results from The University of York's yoga RCT). Although different localities and regions may have different needs, perhaps a best practice for the initial phase would be GP lbp specialist triage service. This recommendation should be considered as good practice by the Pathfinder care pathway for commissioning team.	

These organisations were approached but did not respond:

Aintree University Hospital NHS Foundation Trust

Allocate Software PLC

Association of NHS Occupational Physicians

Association of Anaesthetists of Great Britain and Ireland

Association of Catholic Nurses of England and Wales

Association of Chartered Physiotherapists in Oncology and Palliative Care
Association of Chartered Physiotherapists in Women's Health
Barnsley Hospital NHS Foundation Trust
Bedfordshire Primary Care Trust
Berkshire Healthcare NHS Foundation Trust
Biomet UK Ltd
Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust
Boehringer Ingelheim
Bolton Council
Bolton Hospitals NHS Trust
Bonesupport AB
Boots
Boston Scientific
Brain and Spine Foundation
Brighton and Sussex University Hospital NHS Trust
British Association of Behavioural and Cognitive Psychotherapies
British Association of Prosthetists & Orthotists
British Cardiovascular Society
British Geriatrics Society
British Medical Acupuncture Society
British Medical Association
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Nuclear Medicine Society
British Red Cross

British Society for Paediatric and Adolescent Rheumatology
British Society of Interventional Radiology
British Society of Neuroradiologists
British Society of Rehabilitation Medicine
British Society of Skeletal Radiologists
BSN Medical
BUPA Foundation
Calderdale Primary Care Trust
Calderstones Partnerships NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust
Capsulation PPS
Capsulation PPS
Care Quality Commission (CQC)
Central London Community Health Care NHS Trust
Cephalon UK Ltd
Chartered Physiotherapists in Mental Health
Chronic Pain Policy Coalition
CIS' ters
Clarity Informatics Ltd
College of Emergency Medicine
College of Occupational Therapists
Commission for Social Care Inspection
Complementary and Natural Healthcare Council
County Durham Primary Care Trust
Coventry and Warwickshire Cardiac Network
Croydon Clinical Commissioning Group
Croydon Health Services NHS Trust

Croydon University Hospital
Daiichi Sankyo UK
David Lewis Centre, The
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Derbyshire Mental Health Services NHS Trust
East and North Hertfordshire NHS Trust
East Kent Hospitals University NHS Foundation Trust
East Midlands Spint Ltd
Eastbourne District General Hospital
Economic and Social Research Council
Eli Lilly and Company
Equalities National Council
Ethical Medicines Industry Group
Faculty of Intensive Care Medicine
Faculty of Occupational Medicine
Five Boroughs Partnership NHS Trust
Frimley Park NHS Foundation Trust
GE Healthcare
General Chiropractic Council
General Hypnotherapy Register
General Osteopathic Council
Greater Manchester Neurosciences Network
Greater Manchester West Mental Health NHS Foundation Trust
H & R Healthcare Limited
Hammersmith and Fulham Primary Care Trust
Hampshire Ambulance Service NHS Trust

Harrogate and District NHS Foundation Trust
Health & Social Care Information Centre
Health and Care Professions Council
Health and Safety Executive
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Healthcare Infection Society
Healthwatch East Sussex
Heart of England NHS Foundation Trust
Hermal
Herts Valleys Clinical Commissioning Group
Hillingdon Hospital NHS Trust
Hindu Council UK
Hockley Medical Practice
Hove Polyclinic
Hull and East Yorkshire Hospitals NHS Trust
Humber NHS Foundation Trust
Independent Healthcare Advisory Services
Integrity Care Services Ltd.
Interactive Teaching Method Association - Alexander Technique
Invacare
James Cook University Hospital
Janssen
Johnson & Johnson
Johnson & Johnson Medical Ltd
Keele University

Knowsley Primary Care Trust
Kyphon Inc.
Lancashire Care NHS Foundation Trust
Lanes Health
Leeds Community Healthcare NHS Trust
Leeds North Clinical Commissioning Group
Leeds Primary Care Trust (aka NHS Leeds)
Leeds South and East Clinical Commissioning Group
Leeds Teaching Hospitals NHS Trust
Liverpool Primary Care Trust
Local Government Association
Luton and Dunstable Hospital NHS Trust
Market Access & Reimbursement Solutions Ltd
McKenzie Institute Mechanical Diagnosis and Therapy Practitioners
McTimoney Chiropractic Association
Medicines and Healthcare products Regulatory Agency
Medway Community Centre
Mental Health Act Commission
Mind
Ministry of Defence (MOD)
Musculoskeletal Association of Chartered Physiotherapists
Myeloma UK
National Association of Primary Care
National Deaf Children's Society
National Institute for Health Research Health Technology Assessment Programme
National Osteoporosis Society
National Patient Safety Agency

National Pharmacy Association
National Public Health Service for Wales
Neurocare Europe Ltd
NHS Barnsley Clinical Commissioning Group
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Connecting for Health
NHS County Durham and Darlington
NHS Cumbria Clinical Commissioning Group
NHS Derbyshire County
NHS Greater Manchester Commissioning Support Unit
NHS Halton CCG
NHS Health at Work
NHS Improvement
NHS Kirklees
NHS Medway Clinical Commissioning Group
NHS Pathways
NHS Plus
NHS Plymouth
NHS Sefton
NHS Sheffield
NHS South Cheshire CCG
NHS Southern Derbyshire CCG
NHS Wakefield CCG
NHS Warwickshire North CCG
NLSSM The School of Sports Massage
North Bristol NHS Trust

North of England Commissioning Support
North Tees and Hartlepool NHS Foundation Trust
North West London Hospitals NHS Trust
North Yorkshire & York Primary Care Trust
Northwest Pain Group
Nottingham Back Team
Nottingham City Council
Nottingham City Hospital
Nuffield Orthopaedic Centre
Orthopaedic and Trauma Alliance UK
Ossur UK
Oxford Health NHS Foundation Trust
Oxfordshire Clinical Commissioning Group
Paget's Association
Pain Relief Unit
Pain Solutions
Pain UK
Pancreatic Cancer UK
Patient Assembly
Pelvic Pain Support Network
PERIGON Healthcare Ltd
PHE Alcohol and Drugs, Health & Wellbeing Directorate
Primary Care Musculoskeletal Research Centre
Primary Care Partnerships
Primary Care Pharmacists Association
Primary Care Rheumatology Society
Primrose Bank Medical Centre

ProStrakan Group
Prototype Bioforum Ltd
Public Health Wales NHS Trust
Queen Elizabeth Hospital King's Lynn NHS Trust
Rarer Cancers Foundation
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Rochdale and District Disability Action Group
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health, Gastroenetrology, Hepatology and Nutrition
Royal College of Pathologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Surgeons of England
Royal Free Hospital NHS Foundation Trust
Royal National Hospital for Rheumatic Diseases NHS Foundation Trust
Royal National Orthopaedic Hospital NHS Trust
Royal Society of Medicine
Royal United Hospital Bath NHS Trust
Salford Primary Care Trust
Salford Royal Foundation Hospital
Salisbury NHS Foundation Trust
Sandwell and West Birmingham Hospitals NHS Trust
Sandwell Primary Care Trust
SANOCHEMIA Pharmazeutika AG

Scottish Intercollegiate Guidelines Network
Sheffield Primary Care Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence

Society of Orthopaedic Medicine
South Devon Healthcare NHS Foundation Trust
South London & Maudsley NHS Trust

South West Yorkshire Partnership NHS Foundation Trust
South Western Ambulance Service NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
St Helens and Knowsley Teaching Hospitals NHS Trust
St John Ambulance
St Jude Medical UK Ltd.
St Mary's Hospital
Staffordshire Ambulance Service NHS Trust
Staffordshire and Stoke on Trent Partnership NHS Trust
Stockport Clinical Commissioning Group
Stockport Primary Care Trust
Target Ovarian Cancer
Taunton & Somerset NHS Foundation Trust
Tenscare Ltd
Teva UK
Thames Ambulance Service Ltd
The African Eye Trust
The British Homeopathic Association & Faculty of Homeopathy 131134
The Neurological Alliance

The Patients Association
The Work Foundation
Trinity-Chiesi Pharmaceuticals
United Kingdom Council for Psychotherapy
University College London Hospital NHS Foundation Trust
University of Southampton
Walsall Local Involvement Network
Welsh Government
Welsh Institute of Chiropractic
Welsh Pain Society
West Hertfordshire Primary Care Trust
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Western Sussex Hospitals NHS Trust
Wigan Borough Clinical Commissioning Group
Wirral GP Commissioning Consortium
Wirral Primary Care Trust
York Hospitals NHS Foundation Trust