Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Acupuncture Association of Chartered Physiotherapists	FULL	General	general	The Acupuncture Association of Chartered Physiotherapists (AACP) is extremely disappointed with the advice contained within the new NICE LBP guidelines regarding acupuncture. This is a transformation from the 2009 NICE guidelines which Physiotherapists have attempted to comply with, despite funding issues. The AACP has 6000 members, many of whom are already providing acupuncture for LBP conditions within the NHS as an alternative to patients taking drugs. This is consistent with a holistic approach to patient treatment as noted on Pg 3 of the draft document. The use of acupuncture is consistent with the concept of evidence based medicine utilising clinical expertise in conjunction with patient values and choice as noted on Page 3 of the draft document. The new guidelines will be difficult to implement given that Physiotherapists already use acupuncture for pain relief in conjunction with the other modalities suggested in the guidelines as part of multi modal packages. AACP is now concerned that patients will be denied this treatment and forced to consider either no treatment at all or other more invasive options for pain relief such as surgery or radiofrequency denervation when the suggested treatment strategies have failed.	Thank you for your comment. Although GC88 published in 2009 recommended that a course of acupuncture should be considered, this was poorly implemented and formed part of the decision to update the guideline. In re-reviewing the evidence the GDG do not believe there is sufficient evidence to recommend acupuncture on the NHS due to the lack of evidence for a consistent effect compared to sham / placebo. The evidence reviewed also unfortunately did not support the inclusion of acupuncture of one of the components of a package of treatment, therefore no recommendation was made regarding this option. People with low back pain will be able to consider other treatment options recommended in this guideline, such as exercise, a treatment package of exercise alongside manual therapy and/or psychological therapy, or pharmacological therapy as well as being supported in self-management of their pain before more invasive options are considered.
Acupuncture Association of Chartered Physiotherapists	FULL	General	GENERAL	AACP contend that NICE have failed to properly evaluate the comparison between acupuncture and other treatment modalities. In particular there are issues with research findings regarding sham and placebo interventions which are highly contentious concepts. Whilst it is accepted that the reply comment will note that these comparisons are part of the informed decision making process as described by the NICE policy documents, sham comparisons continue to not be clinically relevant as they are not treatments that can be offered to patients and are not indicative of real life decisions.	Thank you for your comment. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. For all the evidence reviews conducted for this guideline, the protocols, with inclusion criteria for interventions and comparators, were agreed a-priori with the GDG. Where there was any uncertainty regarding the appropriateness of a sham control, usual care or treatment modality this was discussed and confirmed with the GDG.
Acupuncture Association of Chartered Physiotherapists	FULL	General	GENERAL	Other bodies such as the Scottish Intercollegiate Network (Sign 2013) and other European and International bodies including the World Health Organisation continue to support the use of Acupuncture (AP) as an effective treatment. It is disappointing that the previous guidelines for acupuncture and Low Back Pain (LBP) were reviewed based on a perceived lack of compliance with funding based on one specific article. The article (Pulse- 2010) suggested that some commissioners expected "clinical exceptionality" for AP when this is not the threshold for other types of therapies. Failure of commissioners to adequately fund should not be equated to lack of effectiveness in the clinical environment.	Thank you for your comment. The decision to update the review was partially influenced by the lack of implementation of some of the recommendations in CG88, however this has not informed the recommendation making in this update. The updated recommendations are based on a detailed systematic review of the best available evidence for all topics and this has been discussed and considered by the GDG to form recommendations. In considering this evidence the GDG do not believe there is sufficient evidence to recommend acupuncture on the NHS due to there being a lack of a consistent effect demonstrated when compared to sham / placebo.
Acupuncture Association of Chartered Physiotherapists	FULL	General	GENERAL	Placebo is a contentious issue as "sham" interventions (which are perceived as the most effective type of placebo) are not physiologically inert. As a result these can have effects both physically and contextually that can change effect size. Sham or Placebo interventions inform the decision making process (as indicated in NICE processes) but this is not what happens in real life: Testing under controlled conditions indicates poor external generalisability. Any complex intervention, whether it is AP, Physiotherapist led exercise or manual therapy must use the most appropriate control to establish clinical benefit. Research methodology suggests that "a no-acupuncture arm", or "no exercise arm" or "no manual therapy arm" should be utilised therefore sham with minimal insertion is not a useful comparison. It is also important that NICE use equivalent criteria in judging the effectiveness and cost-effectiveness of the different therapies and not use higher thresholds for effect for AP. It is well documented that even sham and its many different versions will be providing a response throughout the neural system which may or may not be modulated at higher	Thank you for your comment. The GDG were mindful that the evidence included a variety of sham controls with a varied capacity to elicit physiological effects, and acupuncture consistently did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams, therefore, the GDG were of the view that the sham comparisons were essentially credible. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to first

Low back pain and sciatica
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24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				levels. The research post-2009 notes a number of trials with semi-blunt needles being used as the sham intervention which would still be facilitating input into brain structures and thus achieving an effect. There is also the possibility of having other tissue effects with AP (fascia releases similar to those of massage) without high levels of time/effort from the practitioner and potentially gaining quicker results. This adds to the possibility of increasing the size of the treatment effect. In the largest LBP trial, sham performed almost twice as well as the guideline based standards of care but these effects were noted as contextual. Clinical relevance should be measured against treatments used in practice or in addition to usual care to reduced bias as there is no clinical relevance to sham interventions. Usual care as part of a pragmatic trial is what actually works in real life rather than sham which is deemed explanatory research. There is an argument that if a drug produced positive results over usual care then there would be no hesitation in recommending it.	demonstrate a treatment effect separate from the non-specific treatment effects. This is consistent across treatments, including the pharmacological treatments which are compared to placebo, which is also known to produce effects, as you highlight in your response.
Acupuncture Association of Chartered Physiotherapists	FULL	General	GEN ERAL	Adequacy of acupuncture dosage is also a further issue related to sham. Minimally invasive AP is still AP but is related to dosage. At no point did any of the sham interventions do better than real AP which may be relevant if context is deemed the greater issue.	Thank you for your comment. The inclusion criteria for the review was agreed with the GDG and a co-opted acupuncturist and it was agreed that all forms of acupuncture should be pooled. The recommendation was made on the basis that there was no consistent benefit observed of acupuncture over sham, rather than because there was evidence that sham produced a meaningful benefit over acupuncture. This is consistent with decision making for all comparators in the guideline where decisions are made based on evidence of clinically important benefit over the comparator, rather than the converse.
Acupuncture Association of Chartered Physiotherapists	FULL	General	GEN ERAL	"Talking therapies" have been recommended. The cost impact on the NHS for this therapy, particularly given the national shortage of clinical psychologists and long waiting lists already (1 year in some areas) then the potential burden of disease would magnify. How do the GDG propose to deal with this? Particularly in light of perceived non-compliance of previous guidelines due to funding issues.	Thank you for your comment. The guideline recommends psychological therapies only if offered as part of a package of treatment with exercise with or without manual therapy. We will pass your comments onto the resource impact team at NICE who will consider the resource impact of all recommendations in the guideline.
Acupuncture Association of Chartered Physiotherapists	FULL	15	GEN ERAL	The treatment algorithm depicts a state where nothing more can be done for the patient leaving a potential long term associated cost burden on society. Despite noting that AP could be considered for those not responding to other treatments, it was deemed inappropriate to consider AP. However, other NICE guidelines advocate that AP can be used when other strategies have proven ineffective prior to offering more invasive treatments with a greater risk of harm (Overactive Bladder Guidelines and CG150- Migraines and Headaches). This appears to be a more consistent approach to the "real world" environment. NICE should reconsider this approach for long term pain clients using AP as part of a multi model package of care in relation to costs associated with DWP social benefits Perhaps the wording of "consider" in these circumstances or do not do routinely would be more appropriate as there is weaker evidence (pg 56, line 26) for AP interventions.	Thank you for your comment. The algorithm depicts the recommendations contained in the guideline in a graphical format. Acupuncture is not recommended as an intervention in this guideline as it was agreed there was insufficient consistent evidence of benefit compared to sham. There was no evidence that it would be more effective after other treatments had been tried. We have now added further clarification for what can be considered if there's an inadequate response to the treatments previously tried at the end of the algorithm.
Acupuncture Association of Chartered Physiotherapists	FULL	496	GEN ERAL	The recommendations appear to justify the GDG decisions for not recommending AP, however there are a number of questionable statements that may reflect opinion rather than evidence. 496- "Other Considerations" • The 1st paragraph uses the terms "thought unlikely" but this is not proven fully with the evidence. • It assumes AP to be acting only on "contextual mechanisms"- but so are most of the other therapies that are still recommended including exercise	Thank you for your comment. When developing recommendations, the GDG used the evidence review to form opinions regarding the clinical effectiveness of interventions, which were discussed at length and captured in detail to give readers a thorough understanding of the decision-making process. The GDG and co-opted acupuncturist took into consideration the conflicting evidence for acupuncture versus sham acupuncture, and as a result decided against recommending acupuncture in a NHS setting to allow the

Low back pain and sciatica
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				• Further explanation of the statement "contextual effects rather than pain reduction" is needed as if context reduces pain then it becomes a valid treatment in terms of the responder. • "Unlikely to have a specific effect"- is not a proven statement therefore constitutes supposition on the part of GDG members. Until it is proven otherwise in terms of scientific research that it definitely does not have an effect then AP should always be considered. • The GDG assume that if there was an effect it was because of pain reduction (which is exactly why AP is used within the NHS) • The potential cost impact was discussed but as it was already noted that there is variable provision following the previous guideline recommendation then logically in terms of finance, the status quo should be maintained. Thus even if AP was recommended there will be no additional costs to this. • The previous guidelines provided a breakdown (and an in-depth powerpoint presentation) as to how recommendations would be funded – this is missing in these guidelines thus citing finances is arbitrary. • The GDG may not have found evidence to support AP when other strategies have failed (although this was not part of the scope), conversely there is none to refute its use either. • The passive nature of acupuncture was discussed and it was noted that WMA is usually integrated as part of a pathway to optimise tissue conditions and promote self management which is all part of multi-modal care provided by Physiotherapists at present. Hence the word "passive" is not indicative of practice and is a subjective opinion of the GDG members. • The "majority view of the group" to state "do not do acupuncture" is open to question. For example, was the group tested for bias initially? If members were against AP prior to review (as noted in various opinionated blogs and social media) then this could have affected the whole outcome. On pg 23 the process dictates that if the GDG member has a biased view then they would withdraw from discussions. According to the minutes there were no withdraws suggesting that the bias may have occurred. • The final statement regarding the "unlikely alteration of conclusions" suggests that the outcome is already a 'fait accompli' even when the interpretation of the evidence levels have thrown up inconsistencies with way that AP was reviewed compared to other modalities. • There is a gap in the process of Guideline development as there is no system of recourse for responses by NICE to the comments provided by Stakeholders, particularly in light of the above statement.	recommendation of other treatments which have showed benefit over placebo/sham. When revisiting the exercise review, the GDG agreed neither of the sham comparisons were true exercise shams and therefore excluded this evidence from the review. As a result, the recommendation formed for the exercise review was focussed on the evidence against usual care. GDG members were withdrawn from discussion regarding evidence if they had conflicts of interests. As this wasn't the case for acupuncture, no GDG member needed to be excluded from discussions regarding this recommendation. There was a co-opted acupuncturist who formed part of the GDG when discussing the evidence but not when writing the recommendation. Acupuncture is already a well-researched area, reflected through the 29 RCTs included in this review, therefore a research recommendation is not warranted and is unlikely to give clarity to the conflicting nature of the evidence against sham. With regards to the funding of acupuncture, if an intervention is found to be not cost effective, it should not be recommended as it represents an inefficient use of NHS resources. The cost impact of interventions is an additional consideration that the GDG should take into account when making recommendations but should not be used in isolation for guiding decision making. Cost impact analyses may be developed at the time of the guideline publication and therefore are not available at this stage.
Acupuncture Now Foundation	Appendices K-Q	161-163	general	SELECTIVE OMISSION In Appendix H, p215 a study is extracted with ID Witt 2006. However, none of the extracted results for pain reduction, quality of life, or healthcare utilisation are presented in the forest plots. An update of this draft must include these results in the analysis.	Thank you for your comment. We apologise for this omission, Witt 2006 has now been fully extracted and included in the evidence review.
Acupuncture Now Foundation	Appendices K-Q	60	Figure 219	DATA MISINTERPRETATION The values used in the plot are different to those in the original study, and different to those extracted in Appendix H, p146. Albert 2012 reports the following: Exercise group VAS: 1.5 (SD=2.1). Sham exercise group VAS: 2.3 (SD=2.7). Thus, the mean difference is -0.80 [-1.52, -0.07]. So the effect of exercise over sham is not clinically significant.	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore, the revised guideline no longer has any evidence for exercise versus sham including the Albert 2012 study, as this was subsequently excluded due to the arm previously labelled as sham comprising of another form of exercise, which does not meet the protocol.
Acupuncture Now Foundation	Appendices K-Q	63	Figure 228	DATA ERROR/REPORTING ERROR Firstly, there is a data error in Goren 2010.	Thank you for your comment. We have checked the data and there are no errors in the data extracted from Goren 2010. This trial has 3 arms; exercise plus ultrasound, exercise plus sham ultrasound and usual care. The 2 arms

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Secondly, the study is testing Exercise + Ultrasound vs Usual Care. The usual care group did not receive ultrasound and thus, this study should be reported in combination therapy, not in exercise vs usual care.	extracted from Goren 2010 for inclusion in the exercise chapter were the exercise plus sham ultrasound and usual care. The comparison between exercise plus ultrasound versus usual care has not been included in the exercise review, it has been included however in the electrotherapy review under the combination of interventions section (chapter 14).
Acupuncture Now Foundation	Appendices K-Q	72	Figure 266	DATA ERROR There is an error in this forest plot. The SD for Kell in the biomechanical exercise group was 2.0, not .2	Thank you for your comment. The SD has been corrected to 2.0 instead of 0.2; we apologise for the error.
Acupuncture Now Foundation	Appendices K-Q	153	Figure 667	DATA ERROR This forest plot contains a number of errors. The data from Brinkhaus 2006A should read: acupuncture mean = 3.45 (SD=2.85), sham mean =4.3 (SD=3.1) The data from Leibing 2002 should read: acupuncture mean = 2.1 (SD 2.2), sham mean = 3.2 (SD 2.2) With the correct values in place, the mean difference of acupuncture over sham is -1.03 [-1.53, -0.54) thus demonstrating a clinically significant reduction in pain of acupuncture vs sham acupuncture.	Thank you for your comment. The studies included in the meta-analysis in figure 667 have been checked again. Brinkhaus 2006 has been amended. Leibing 2002 reports change scores, which have been pooled within the meta-analysis accurately. The revised mean difference for pain is -0.8 which does not reach the clinically important difference between groups agreed by the GDG.
Acupuncture Now Foundation	Appendices K-Q	153	Figure 668	DATA ERROR There is an error in this forest plot. The results for Leibing 2002 according to the original study are acupuncture mean 3.1 (SD 1.8) and sham acupuncture mean 3.5 (SD 2.2). The mean difference with the corrected data is -0.38 (-0.66, -0.11). This result is not considered 'clinically significant' according to the current NICE criteria, but does demonstrate a long-term benefit of acupuncture above minimal/sham acupuncture.	Thank you for your comment. The data meta-analysed in figure 667 have been checked. Leibing 2002 reports change scores, -2.7 (SD 2.2) and -2.1 (2.2) for the acupuncture and sham group respectively, with a mean difference of 0.80. The GDG acknowledged that although the meta-analysis is leaning towards acupuncture, clinical significance has not been achieved and therefore clinical benefit of acupuncture over sham cannot be assumed from this figure.
Acupuncture Now Foundation	Appendices K-Q	155	Figure 678	REPORTING ERROR Figure 678 is mis-labelled - according to the original study, acupuncture outperformed sham in Function in the long-term.	Thank you for your comment. This has been amended.
Acupuncture Now Foundation	Appendix B	17	Stephen Ward	EVIDENCE OF CONFLICT OF INTEREST It is noted that Stephen Ward has declared a personal pecuniary interest and that the action taken has been to 'Declare and participate.' NICE Policy on Conflicts of Interest states that in the case of a specific personal financial conflict of interest, the individual should 'Declare and leave the meeting.' (NICE Policy on Conflicts of Interest, p7). Therefore Stephen Ward's actions have been contrary to NICE policy. It is also noted in the same policy that "The Chairs of advisory committees are in a special position in relation to the work of their committee and so may not have any specific financial or non-financial personal, non-personal or family interests" (Ibid., p4). In Dr Ward's case, there are a further five declared Conflicts of Interest that exclude him from his role as chair. Together, these Conflicts of Interest create a clear mandate for the scrapping of the current draft guidelines on low back pain and sciatica and the creation of a new GDG to re-examine the evidence. Failure to do this calls into question the integrity of the GDG and the robustness of NICE policies.	Thank you for your comment. Because GDG members were recruited in 2013, the DOI policy that was followed for the purposes of this guideline was the 2007 policy (updated October 2008). This was stated in appendix B and has now also been added to section 3.4 of the full guideline for clarity. The Chair and all GDG members were recruited in accordance with this policy. All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and it was agreed that no member unduly influenced the decision of the committee.
Acupuncture Now Foundation	Appendix H	216-217	Group Aerobics versu	DATA ERROR The incorrect results were extracted for VAS. The results shown are for the Resistance Training arm, but they should be for aerobics. So it should be Group 1: 4.8. SD. 0.8. This	Thank you for your comment. The data extraction, forest plots, evidence tables and evidence statements have been corrected using the correct mean and SD for the aerobic arm; we apologise for the error. The amended mean difference is -0.10, which changes the analysis from clinically significant

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			s Usual Care	means that the results in Appendix K, p76, Figure 282 are incorrect. Using the correct data, group aerobic exercise does not outperform usual care.	favouring aerobic exercise (mean difference of -1.13) to no clinically important difference between aerobic exercise and usual care.
Acupuncture Now Foundation	Appendix K	159	Figure 696	REPORTING ERROR Cherkin 2001 compared acupuncture to self-management, as noted by the individual who extracted the data. Erroneously, the results given in this table are for acupuncture versus usual care. This also applies to Figure 701 on page 160.	Thank you for your comment. Cherkin 2001 has been removed from this review as on re-inspection the intervention did not meet the protocol.
Acupuncture Now Foundation	Appendix K-Q	151-156	General	SELECTIVE OMISSION Brinkhaus 2006 reported data on healthcare utilisation that should be included. This study found that those in the verum acupuncture arm had fewer than half as many days taking painkillers as those in the sham arm. This should be included in the updated draft.	Thank you or your comment. The healthcare utilisation data from Brinkhaus 2006 has been now been extracted and the evidence review updated.
Acupuncture Now Foundation	full	General	Benefit to harm	DETAILED COMMENT - Ethics of Benefit to Harm Ratio Whenever a medical treatment is recommended or chosen, this should be done because it is believed that on balance it will help the patient - that is, the advantages outweigh the disadvantages. Once referred to as the "risk-to-benefit ratio" this is now more appropriately called the benefit to harm ratio. If the likelihood of benefit is greater than the likelihood of harm, this is considered a positive benefit to harm ratio and a good recommendation. In this day of "evidence-based medicine", however, there is often a need to compare different therapies to measure their benefit to harm ratio in relation to each other. When comparing therapies for potentially life-threatening conditions, the likelihood of a higher rate of benefit may be worth a greater chance of harm. But when comparing therapies for conditions such as low back pain that are self-limiting and not life threatening and whose severity is gauged by the subjective assessment of the patient, ethics demands that a greater emphasis be placed on reducing potential harms, especially if those harms are more serious than the condition being treated. With an emphasis on the ethics of safety, the strength of recommendations of different therapies should follow this order: 1. Less harm and greater benefit 2. Less harm and equal benefit 3. Less harm and slightly less benefit 4. Equal harm and slightly greater benefit 5. Slightly more harm but significantly greater benefit Therapies that would be the most unethical to recommend follow this order: 1. Greater harm and less benefit 2. Greater harm and equal benefit 3. Equal harm and less benefit The draft guidelines recommend some treatments with a very low benefit to harm ratio and do not recommend acupuncture, which has a very high benefit to harm ratio. This appears to be antithetical to the remit of healthcare guideline development.	Thank you for your comment. The trade-off between benefits and harms is considered by the GDG for each intervention reviewed and the discussion is captured within the 'recommendations and link to evidence' sections in each chapter. In the case of acupuncture the GDG agreed that there was no consistent evidence of benefit compared to sham/placebo, and therefore a recommendation in favour of acupuncture should not be made.
Acupuncture Now Foundation	Full	299	Line 20-22	DATA MISINTERPRETATION "A clinically important benefit of physical and mental quality of life was observed for group aerobic exercise when compared with usual care in people with low back pain without sciatica (2 studies; very low quality; n=109)." The mean differences were 2.26 on a 100 point scale and 3.86 on a 100 point scale, respectively. It is unclear how these results are 'clinically important'.	Thank you for your comment. We have used the published minimal important difference for the SF36 physical component summary and the mental component summary, which is 2 and 3, respectively. The criteria used for determining clinical importance are stated in the methods section of this guideline.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Acupuncture Now Foundation	full	196	24-26	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS "Evidence from 1 study reporting at the longer-term time-point confirmed a benefit of self-management compared to usual care for quality of life in terms of well-being and general health domains of the SF-36." None of these outcomes were clinically significant. Furthermore, for the general health domain, the outcome was not statistically significant. Thus it would appear that results which do not meet NICEs definition of clinical significance are judged able to confirm a benefit in respect of self-management, whilst this is not the case in respect of acupuncture. Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.	Thank you for your comment. The GDG have clarified that the recommendation for self-management is intended to apply as a principal alongside all treatment for people with low back pain and sciatica as part of routine practice. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified. This is further supported by evidence from the combination and MBR reviews where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this.
Acupuncture Now Foundation	full	199	8.6 Recommendations - Trade-off between benefits and harms	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS "The GDG noted that when self-management was compared to usual care, clinical benefit was in most cases observed at the outcomes reported at longer term follow up (greater than 4 months)." It is unclear which outcomes are being referred to here. Self-management did not outperform usual care with any clinical significance for a single outcome according to the Forest plots in Appendix K, pp43-44. Indeed, self-managementfails the criteria applied to acupuncture. Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.	Thank you for your comment. The outcomes showing clinical benefit of self-management over usual care are detailed in the Clinical evidence statements section (8.5.1.1.2). There was evidence of benefit of self-management over usual care for quality of life and healthcare utilisation outcomes, in most cases at the longer term follow-up. The GDG have now edited the recommendation to clarify that self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practice. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified. This is further supported by evidence from the review of multidisciplinary programmes where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this.
Acupuncture Now Foundation	full	199	8.6 Recommendations - Trade-off between benefits and harms	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS "There was evidence that healthcare utilisation (consultation for back pain, hospitalisation, physician visits, physiotherapist visits) was reduced by the use of self-management programmes." None of these results meet the GDG's criteria for clinical significance. For physiotherapy, the outcome crosses the line of no effect. Clinical significance would appear to be applied to some interventions and not others. Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.	Thank you for your comment. The outcomes showing clinical benefit of self-management are detailed in the Clinical evidence statements section (8.5.1.1.2). The outcomes mentioned show clinical benefit of self-management over comparator. Furthermore, the GDG have clarified that the recommendation for self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practise. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified. This is further supported by evidence from the review of multidisciplinary programmes where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this.
Acupuncture Now Foundation	Full	297	27-29	DATA MISINTERPRETATION/INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS Using the correct data from the study, there was no clinical benefit of exercise over sham at either short-term or long-term end-points. Consistent application of the same criteria to exercise as are applied to acupuncture in the draft guidelines would preclude any recommendation of exercise, on the grounds that any clinical benefits over usual care are likely to be due to non-specific/contextual effects, which in the case of acupuncture is found unacceptable (draft guidelines 1, p. 495). Declared criteria have therefore been applied inconsistently to different interventions, which suggests a biased approach.	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore the revised guideline no longer has any evidence for exercise versus sham. The GDG considered the remaining evidence, and concluded that the recommendation would not change. This was based on evidence showing a benefit of exercise when compared to usual care and self-management. The GDG considered that the effect of exercise could be partly due to an imbalance of therapeutic attention, however concluded that that exercise is likely to be of value and therefore made a 'consider' recommendation. Since there were many studies included in chapter 13

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					comparing acupuncture to sham controls, the GDG gave this evidence priority when forming the recommendation (standard methodology, see chapter 4).
Acupuncture Now Foundation	full	349	11-13	ABSENCE OF PARITY BETWEEN DIFFERENT INTERVENTIONS "Manual therapists often combine a range of techniques in their approach and may also include exercise interventions and advice about self-management." This is also true of acupuncturists, particularly traditional acupuncturists, who use a wide range of treatment components in addition to the insertion of needles, including moxibustion, cupping, herbs, exercises, and lifestyle advice. This should be noted in the introduction of the acupuncture section to create parity between acupuncture and manual therapy in this respect. [note; the list of additional treatment components here is derived from STRICTA (Standards of Reporting in Clinical Trials of Acupuncture), the acupuncture-specific annexe to the CONSORT statement which has been providing informed quality control for Clinical trials of acupuncture for the past fifteen years. See http://www.stricta.info/checklist.html for more details, including the 2010 reworking of the checklist.]	Thank you for your comment. Although the GDG recognise that acupuncturists use a blend of interventions, such as lifestyle-management, which are useful to maximise outcomes in service delivery, they recognise that this is difficult to capture and evaluate in research-settings.
Acupuncture Now Foundation	full	349	14-16	ABSENCE OF PARITY BETWEEN DIFFERENT INTERVENTIONS "Research into manual therapy often uses pragmatic trials to determine effectiveness. This reflects the complex nature of the intervention, the inability to blind the practitioner, and the challenges of blinding participants and designing suitable sham or placebo controls." All of these considerations also affect acupuncture, where pragmatic approaches to trial design have been in the ascendant in the past decade of research. Pragmatic models developed by acupuncture researchers have served as something of a blueprint for advances in clinical testing across complementary therapies, For an early iteration, see MacPherson, H. (2004) Pragmatic Clinical Trials. *Complementary Therapies in Medicine* 12: 136-140.	Thank you for your comment. In order to best assess the clinical and cost-effectiveness of interventions, the GDG agreed a priori that the best available evidence will be included within this guideline. In the case of the intervention based reviews such as that conducted for acupuncture, RCT evidence was given priority and non-randomised studies were only considered if there was a lack of/insufficient RCTs available. Since the acupuncture review included 29 RCTs, the GDG agreed no other study designs were needed to inform their decision making. Therefore it is not possible for the GDG to include pragmatic trials such as MacPherson 2004 into this review.
Acupuncture Now Foundation	Full	461	Study name GERAC trial: Haake 2007	SELECTIVE OMISSION Haake reports responder criteria for improvement in pain as 33% improvement or better. This is consistent with the GDGs definition of responder criteria and should be included. The same issue is in place in Figure 690, p157, Appendices K-Q, where Molsberger's responder data which showed acupuncture outperforming sham should also be included.	Thank you for your comment. Responder criteria for Molsberger 2002 has now been added to the acupuncture review. The responder criteria data for Haake 2007 has been reported as pain, as the description best fits this outcome.
Acupuncture Now Foundation	Full	493	13.6 Recommendations and links to evidence; Trade-off between clinical benefi	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS "The GDG first discussed the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects." when considering the evidence base for acupuncture. Such an approach should be applied to the evidence for all interventions in order to provide an unbiased review of the evidence. There is, however, no indication in the draft that the GDG started its discussion of the clinical benefits of any other intervention, including non-pharmacological interventions such as therapy and exercise, in a similar manner. Acupuncture appears to have been singled out and treated differently than every other intervention that the GDG evaluated. It is difficult to see how such an inconsistent approach to evaluating interventions can lead to unbiased guideline development. An updated version of the draft should apply the same performance criteria to every intervention considered.	Thank you for your comment. It was agreed a priori that placebo/sham evidence would be given priority where possible, and has been done consistently across the guideline wherever sham evidence was available. We apologise this wasn't explicit in the guideline, the methods chapter has now been updated to clearly state this.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			ts and harms .		
Acupuncture Now Foundation	Full	494	3rd paragraph	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS "It was noted that 4 of the included studies had a 'waiting list' group as their usual care comparison. It was considered that this may over-estimate the effects of treatment as people may become disheartened in the comparison group whilst waiting to start active treatment . . .It was also noted that people within the control group of many of the usual care studies received management that was not representative of UK primary care practice. It's possible that in some cases this group represents people for whom standard usual care has been insufficient to manage their pain and are receiving more than standard usual care. It is noted this applies to all reviews with usual care comparators and has been taken into account equally across interventions reviewed in this guideline." Firstly: if it is possible that a 'waiting list' control group is receiving more than standard care to manage their pain, this could in fact further strengthen a recommendation of acupuncture shown to outperform standard care in this context. Secondly, it is noted that MBR is recommended even though it did not outperform 'waiting list' control.. Therefore the complications identified with 'waiting list' controls have demonstrably not 'been taken into account equally across interventions reviewed in this guideline'. Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.	Thank you for your comment. Waiting list groups do not receive treatment, and therefore would not receive more than standard care. There is evidence to suggest comparison to waiting list groups can over-inflate the effects seen in the intervention group (in this case acupuncture) not vice versa as you state below. When people may be receiving more than standard care it is possible that this may bias in the opposite direction, however as stated in the LETR, this was considered by the GDG. The recommendation was however based on the lack of evidence of a consistent effect compared to sham, not to usual care or waiting list. Regarding MBR, there was limited evidence of benefit of a 3-element MBR compared to usual care/waiting list. However, there was some evidence of benefit of a 2-element MBR compared to usual care/waiting list. Please see section 17.5.1 (Clinical evidence statements) for details. Although the GDG acknowledged that the evidence for MBR was mixed, the GDG felt that it should be recommended on account of MBR showing benefit over waiting list, single and combined interventions, alongside evidence from single intervention chapters.
Acupuncture Now Foundation	full	495	Trade -off	DETAILED COMMENT – SHAM ACUPUNCTURE IS NOT AN INERT PLACEBO CONTROL "The GDG noted that although comparison of acupuncture with usual care demonstrated improvements in pain, function and quality of life in the short term, comparison with sham acupuncture showed no consistent clinically important effect, leading to the conclusion that the effects of acupuncture were probably the result of non-specific contextual effects." This merits some deconstruction. First of all, the literature demonstrates that verum acupuncture *does* outperform sham acupuncture in the treatment of pain where this comparison is done on a large enough scale to detect differences in effect size (Vickers *et al*, 2012). Next, it should be noted that this detected superiority is 'relatively modest' in size (Vickers *et al*, 2012, p. 1444) because the sham treatments involved are not inert. Furthermore, the GDG is correct to note that acupuncture comprises well-documented non-specific treatment effects (Paterson and Britten, 2001; Linde *et* al, 2010). Sham acupuncture is not an appropriate control for these effects, as a sham acupuncture treatment can contain several components of a true acupuncture treatment and thereby carry some or all of the non-specific treatment effects associated with true acupuncture. Historically, attempts to provide controls which mimic the appearance and experience of the verum treatment have involved the deliberately shallow needling of acupuncture points without stimulation and/or the needling of 'non-points' outside of the agreed network of acupuncture points (see, for eg, Witt *et al*, 2005, where both are in place in a procedure described as 'minimal acupuncture'), and the application of technologically innovative bespoke devices which employ a 'stage dagger' retraction-into-handle mechanism for a non-penetrative delivery (Streitberger and Kleinheintz, 1998; Tan *et al*, 2009; Takakura *et al*, 2011). None of these contrivances can be considered inert. Superficial needling or the application of non-penetrative devices to acupuncture points stimulates these points in a manner that	Thank you for your comment. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. The GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Since a large number of RCTs were identified for this review, the prospective studies mentioned would not be considered.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				could simply equate to a lower dose of the same treatment (Birch, 2006; Itoh and Kitakoji, 2007). Introducing the minimal acupuncture control group in their 2005 RCT on osteoarthritis of the knee, Witt *et al* state that '…the additional no acupuncture waiting list control was included since minimal acupuncture might not be a physiologically inert placebo' (Witt *et al*, 2005, p. 137). The physiological mechanisms by which acupuncture is thought to work include modulation of neural pathways, release of endogenous opiates and endorphins, and alteration of extra-cellular mediators (Lin and Chen, 2008; Napadow *et al*, 2008; Bei *et al*, 2009), but a traditional acupuncture treatment delivered in clinical reality also involves interaction with a practitioner in a manner that carries concomitant physiological and psychological benefits. Because of this, it is inappropriate to consider the physiological effects of needling to be the total effect of the treatment. Sham acupuncture is therefore an inappropriate comparator in a study that seeks to determine effectiveness, because it is a contrivance that bears no relation to what is clinically offered to patients. These arguments have led to the development of pragmatic trial models which assess the effectiveness of acupuncture treatment in ecologically valid settings. The GDG's focus on comparison with sham acupuncture ignores a decade of research in this area (eg; MacPherson *et al*, 2012; MacPherson *et al*, 2013) Mike Cummings of the British Medical Acupuncture Society, who sat on the GDG meetings, has commented: > The comparison of normal and sham acupuncture … underestimates the whole effect attributable to needle acupuncture. Consequently it would be inequitable to place too strong a reliance on the clinical relevance of this difference, but appropriate to focus on this for biological plausibility of the technique, before moving on to consider more pragmatic comparisons with usual care. (Cummings, 2016) References: Bei, L., Qin, W., Liang, J., Tian. J. and Liu, Y. (2009) Spatiotemporal Modulation of Central Neural Pathway Underlying Acupuncture Action: A Systematic Review. *Current Medical Imaging Reviews* 5, 167-173. Birch, S. (2006) A Review and Analysis of Placebo Treatments, Placebo Effects, and Placebo Controls in Trials of Medical Procedures When Sham Is Not Inert. *The Journal of Alternative and Complementary Medicine* 12:3, 303–310. Cummings, M. (2016) Exercise not acupuncture recommended by NICE for low back pain – balanced assessment, bias or error? [online] *Acupuncture in Medicine Blog.* Available at: <http://blogs.bmj.com/aim/2016/03/31/nice-exercise-not-acupuncture/> [last accessed 18th April 2016]. Itoh, K. and Kitakoji, H. (2007) Acupuncture for Chronic Pain in Japan: A Review. *Evidence-Based Complementary and Alternative Medicine* 4:4, 431-438. Kaptchuk, T.J. and Miller, F.G. (2015) Placebo Effects in Medicine. *New England Journal of Medicine* 373: 8-9. Lin, J.G. and Chen, W.L. (2008) Acupuncture Analgesia: A Review of its Mechanisms of Actions. *American Journal of Chinese Medicine* 36:4, 635-645. Linde, K., Niemann, K., Schneider, A. and Meissner, K. (2010) How large are the nonspecific effects of acupuncture? A meta-analysis of randomised controlled trials. *BMC Medicine* 8:75, 1-14. Lund, I., Näslund, J. and Lundeberg, T. (2009) Minimal acupuncture is not a valid placebo control in randomised controlled trials of acupuncture: a physiologist's perspective. *Chinese Medicine* 4:1. MacPherson, H., Tilbrook, H., Bland, J.M., Bloor, K., Brabyn, S., Cox, H., Kang'ombe, A.R., Man, M-S., Stuardi, T., Torgerson, D., Watt, I. and Whorwell, P. (2012) Acupuncture for	

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Irritable Bowel Syndrome: Primary Care Based Pragmatic Randomised Controlled Trial. *BMC Gastroenterology* [online]. Available at: <http://bmcgastroenterol.biomedcentral.com/articles/10.1186/1471-230X-12-150> [last accessed 18th April 2016]. MacPherson, H., Richmond, S., Bland, M., Brealey, S., Gabe, R., Hopton, A., Keding, A., Lansdown, H., Perren, S., Sculpher, M., Spackman, E., Torgerson, D. and Watt, I. (2013) Acupuncture and Counselling for Depression in Primary Care: A Randomised Controlled Trial. *PLoS Medicine* 10:9 [online]. Available at: <http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1001518.PDF> [last accessed 18th April 2016]. Napadow, V., Ahn, A., Longhurst, J., Lao, L., Stener-Victorin, E., Harris, R. and Langevin, H.M. (2008) The Status and Future of Acupuncture Mechanism Research. *The Journal of Alternative and Complementary Medicine* 14:7, pp. 861–869. NICE (2014) Types of evidence NICE uses to answer specific types of question [online]. Available at: <https://www.nice.org.uk/advice/lgb23/chapter/Types-of-evidence-NICE-uses-to-answer-specific-types-of-question> [last accessed 18th April 2016] Paterson, C. and Britten, N. (2004) Acupuncture as a Complex Intervention: A Holistic Model. *The Journal of Alternative and Complementary Medicine* 10:5, 791-801. Streitberger, K. and Kleinheintz, J. (1998) Introducing a Placebo Needle into Acupuncture Research. *Lancet* 352:9125, 364-5. Takakura, N., Takayama, M., Kawase, A. and Yajima, H. (2011) Double Blinding with a new Placebo Needle: A Validation study on Participant Blinding. *Acupuncture in Medicine* 29:3, 203-7. Tan, C-W., Christie, L., St-Georges, V. and Telford, N. (2009) Discrimination of Real and Sham Acupuncture Needles Using the Park Sham Device: A Preliminary Study. *Archives of Physical Medicine and Rehabilitation* 90:12, 2141-2145. Vickers, A.J., Cronin, A.M., Maschino, A.C., Lewith, G., MacPherson, H., Foster, N.E., Sherman, K.J., Witt, C.M. and Linde, K. (2012) Acupuncture for Chronic Pain: Individual Patient Data Meta-analysis. *Archives of Internal Medicine* 172:19, 1444-1453.	
Acupuncture Now Foundation	full	495	Paragraph 2	DETAILED COMMENT - Safety/adverse events 'Although acupuncture was considered a relatively safe intervention, it was acknowledged that lack of detail on the nature of the adverse events as reported by the trials is a concern with regard to interpreting results appropriately' (NICE 2016, p. 495). The authors could perhaps find some assistance with calibrating this problem in the largest-scale survey work to date in the UK on adverse events associated with traditional acupuncture (MacPherson *et al*, 2001). In this prospective survey, no serious adverse events and 43 minor adverse events were reported in 34 407 acupuncture treatments, representing one month's throughput of patients through the clinics of 1/3 of the British Acupuncture Council's membership. This translates to an underlying serious adverse event rate of between 0 and 1.1 per 10 000 treatments. By contrast, non-steroidal anti-inflammatory drugs were causing 'approximately 3500 hospitalisations for and 400 deaths from ulcer bleeding per annum in the UK in those aged 60 years and above' (Hawkey and Langman, 2003, p.600). References: Hawkey, C.J. and Langman, M.J.S. (2003) Non-steroidal anti-inflammatory drugs: overall risks and management. *Gut* 52, 600-608. MacPherson, H., Thomas, K., Walters, S. and Fitter, M. (2001) The York acupuncture safety study: prospective survey of 34 000 treatments by traditional acupuncturists. *British Medical Journal* 323, 486-7.	The GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Since a large number of RCTs were identified for this review, the prospective studies mentioned would not be considered. However the GDG believe that stating that acupuncture is a relatively safe intervention reflects what you report from this study.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Ofman, J.J., MacLean, C.H., Straus, W.L., Morton, S.C., Berger, M.L., Roth, E.A. and Shekelle, P.A. (2002) Metaanalysis of severe upper gastrointestinal complications of nonsteroidal antiinflammatory drugs. *Journal of Rheumatology* 29, 804–812.	
Acupuncture Now Foundation	Full	571	Table 284 - Outcomes	INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS The critically important outcomes listed for psychological therapies are stated as health-related quality of life, pain severity and function. These critical outcomes are repeated on p603 under "Recommendations and link to evidence." Under "Trade-off between clinical benefits and harms" on p602, however, the CDG writes "The primary aim of a cognitive behavioural approach is not to directly improve pain and function, but reduce the fear of pain, thus increasing people's confidence in undertaking physical rehabilitation and therefore the GDG considered it unsurprising that meaningful effects were not seen in these outcomes." The GDG goes on to recommend this therapy as part of a multi-modal treatment package even though it demonstrated no efficacy or effectiveness. If the GDG feels that reducing fear of pain is more important than actually reducing pain in the case of cognitive behavioural approaches, this should have been listed as a critical outcome. It is unclear whether the GDG found any specific evidence that cognitive behavioural approaches actually do reduce fear of pain or increase confidence in physical rehabilitation, or any evidence of a specific effect for cognitive approaches in the MBR literature that was clearly separate from non-specific effects. This would seem crucially important as the recommendation was based on this supposition despite overwhelming evidence that the intervention wasn't effective for any of the critical outcomes. Psychological therapies do not meet the criteria for inclusion applied to acupuncture. It would appear that that different criteria have been used to evaluate different interventions, which is inconsistent with an EBM approach. This occurs repeatedly in these draft guidelines (see further examples above and below), which should be rewritten with a consistent approach to all interventions included. The unequal scrutiny given to acupuncture in these guidelines is redolent of bias, which should not be the case in a NICE publication.	Thank you for your comment. The GDG acknowledged that the evidence from single intervention psychological therapies trials was not convincing. The GDG considered however that CBA would often be offered in combination with other interventions in clinical practice, and that the improvement of pain and function is not the primary aim of this type of interventions, possibly explaining the lack of meaningful effects observed in these outcomes. Evidence from the combination section of the review and the MBR chapter supported the recommendation of psychological therapies to be offered as part of a treatment package including exercise, with or without manual therapy. This is detailed in section 15.7 (Recommendations and link to evidence). When setting the protocols the GDG agreed that the outcomes to be considered should be the same across reviews for consistency of decision making. Although fear of pain was not considered as a separate outcome, psychological distress was an outcome for all reviews, which a priori, the GDG believed would cover the important outcomes for decision making. Regarding the evaluation of non-specific effects in the MBR review, it was not possible to determine how much of the effect of the treatment was specific. Where possible, it was taken into account. This is consistent with the approach in all other intervention reviews in the guideline. This is not inconsistent with the decision making with acupuncture as with psychological therapies there was additional evidence in combination and from the review of 'MBR' interventions which provided enough evidence to warrant this to be considered only as part of a package of treatment. The combinations reviewed did not support the same recommendation to be made for acupuncture. This approach to decision making has been applied consistently across the guideline.
Acupuncture Torbay	Full	457	5	In the UK other forms of Acupuncture which existed pre-Chinese revolution are practiced such as 'Five Element' Acupuncture and 'Integrated' Acupuncture. I practice at least seven forms of Acupuncture.	Thank you for your comment. Our literature searches were not restricted to acupuncture type, therefore any trials which met the review protocol were included.
Acupuncture Torbay	Full	457	6	Conventional Physiology cannot explain everything and so if something is not explained by Conventional Physiology this does not mean that it does not exist or work by some undiscovered mechanism.	Thank you for your comment. The introduction is intended to give context to the review and the area being addressed by the question.
Acupuncture Torbay	Full	457	7	All of the effects of Acupuncture cannot be explained by neurophysiological mechanisms. For instance I have taught 'Western medical Acupuncture' to the British Dental Acupuncture Society. Using Acupuncture to Anaesthetise a patient's jaw for tooth extraction cannot be explained by nerve pathways. But, it can be explained by the Meridian pathway.	Thank you for your comment. The introduction is intended to give context to the review and the area being addressed by the question.
Acupuncture Torbay	Full	457	11	'Needle sensation' or 'De qi' is not always used, in fact I don't try to get this sensation and still get very good results.	Thank you for your comment. The introduction is intended to give context to the review and the area being addressed by the question.
Acupuncture Torbay	Full	457	13	Often Patients will give up if no improvement is felt after one or two treatments. Luckily this is not that often otherwise I would be out of business! Having said that some Patients with Chronic long term problems may need to be treated for much longer than this. An example; One of my Patients was told she would be in a Wheel Chair by 40 because of Chronic Osteo-Arthritis of the neck. It took two years of treatment, at the end she was coming once a month. She is over 40 now and works in a Garden Centre. No signs of any Ostoe-Arthritis of the neck and no wheel chair for her.	Thank you for your comment.
Acupuncture Torbay	Full	457	18	The vast majority of my Back Pain and Sciatica patients have none-specific pain usually because they have not been to a Doctor or if they have the Doctor has not referred them on and just given them Pain Killers. Even if they have been given a specific cause for their pain, the pain causes a chain reaction around the back and legs; it can even affect the neck and	Thank you for your comment. The introduction is intended to give context to the review and the area being addressed by the question.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				shoulders. Therefore I have to break in to this cycle of pain and referred pain. It is unusual for me to see people with something as specific as a slipped disc because if they have gone this far then they have usually taken the GP/specialist route. Sometimes I do get them after this when they have been for many appointments and not got any joy. They usually come in and say something like "you are my last resort". This is because they don't like the idea of needles. Once they get to this stage they are usually ready to commit to treatment and so get good outcomes. I would actually say I spend 50% of my time treating none-specific Backpain or Sciatica and if I did not get good results I would not be as busy as I am. Most of my business is by word of mouth.	
Acupuncture Torbay	Full	457	24	There is no such thing as 'Sham' Acupuncture. Any intervention such as touching Acupuncture points will have an effect hence therapies such as Tuina (Acupressure massage). Placebo…..Almost any Therapy has a placebo effect including just talking to a Doctor or Therapist.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Acupuncture Torbay	Full	458	1	It is impossible to carry out a RCT in to Acupuncture. You either have Acupuncture or you don't. The use of Sham Acupuncture needles is a worthless exercise as they touch the Acupoints and using none points does not work because there is a Meridian system that is similar to blood capillaries and covers the body. If you use Trigger Points or Dry Needling this is often away from the main Meridians but can still work. PLEASE do not be fooled by the so called Systemic Reviews of people such as Professor Edzard Ernst and Dr Adrian White. They are from the 'Department of Complementary Medicine' at Exeter University. I think they are now also associated with Peninsular Medical School. They are part of a group known as 'Sense about Science'. Their places are sponsored by pharmaceutical companies (Please enquire and you will find this to be true). They carry out a form of research called Meta Analysis where they cherry pick other peoples research. They only choose research which fits their narrow criteria and use this to show the outcomes that they want. They have been the bain of Complementary therapies for over twenty years and have caused countless damage to many therapies not just Acupuncture. They are a thoroughly disreputable bunch and any 'evidence' produced by them should be treated as suspect.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. In the development of this guideline, a throughout systematic review of the evidence was undertaken based on a protocol agreed with the GDG including a co-opted acupuncturist. This review included the best available evidence that was identified and a total of 32 studies were identified and assessed. The recommendation was based on the GDG's consideration of this evidence, not on other published systematic reviews.
Acupuncture Torbay	Full	459	Study 1	There are points on the hands and feet that can treat this type of pain. So even this treatment will have some effect plus their will always be some Placebo.	Thank you for your comment. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment for acupuncture, particularly with penetrating shams as described in Brinkhaus 2006. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Acupuncture Torbay	Full	459	Cherkin 2001	How do you know which therapy had an effect?	Thank you for your comment. Cherkin 2001 has now been excluded from the acupuncture review. This is because the acupuncture group also received a range of other interventions which were not included in this guideline, and therefore did not meet our protocol criteria (see Appendix C).
Acupuncture Torbay	Full	459	Cherkin 2009	Acupuncture was applied via the Toothpick! This is a totally unsuitable sham.	Thank you for your comment. The GDG included the sham as defined by the study, however the different applications were noted and discussed when considering the evidence.
Acupuncture Torbay	Full	460	Edelist 1976	Using none points will have a small effect as will electrical stimulation.	Thank you for your comment. Since electrical nerve stimulation was delivered to both the acupuncture and sham groups, we can assume they will equally

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					benefit from any effects of this treatment and the effects of acupuncture can still be determined.
Acupuncture Torbay	Full	460	Cho 2013	Again the points were stimulated in the so called 'Sham'	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Acupuncture Torbay	Full	460	Coan 19980	A small trial but looks like no Acupuncture verses Acupuncture so this would be valid.	Thank you for your comment, this trial has been included in the review however there were no relevant outcomes to analyse.
Acupuncture Torbay	Full	461	GERAC trial: Haake 2007	Still Stimulating the points as a sham	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Acupuncture Torbay	Full	461	Hasegawa 2014	Again the points were stimulated by the needle so the trial is invalid.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Acupuncture Torbay	Full	461	Gunn 1980	Explanation is not good, was it Acupuncture OR Physiotherapy? This would be an interesting comparison but I welcome the use of good Physiotherapy with Acupuncture in normal circumstances.	Thank you for your comment. The group which received acupuncture also received same the treatments as the usual care group. This has been stated in the summary of studies table as well in the clinical evidence table in appendix H for Guinn 1980.
Acupuncture Torbay	Full	461	Grant 1999	Using TENS and Acupuncture. Which gets the results? It should be Acupuncture or Normal treatment.	Thank you for your comment, the study compares acupuncture to TENS, neither group receive both treatments.
Acupuncture Torbay	Full	470	general	I have looked at all the trails and most of them have a very high risk of bias because of the use of Sham. All Sham can have an effect. For instance some Auricular Acupuncture involves taping a seed to an Acupuncture point on the ear. In your trials this would count as a Sham but it is a Therapy. The only true trial would be using Acupuncture on its own verses no treatment or 'usual' treatment. During Tuina I would use my fingers on Acupuncture points on the back, this does not constitute Acupuncture but is used therapeutically. If I use Trigger points they are none-Acupuncture points but they are used therapeutically so most of the trials above are very poorly designed and really none scientific. Also who administered the 'true' Acupuncture? A Physiotherapist who has done several weekends training in Acupuncture is not the same as a professional Acupuncturist with three and a half years training and a degree in the subject. This is why you will not get the same results. This is like me doing a quick Physiotherapy course over a few weeks and calling myself a Physiotherapist, it is unethical. Also which points were used for the 'true' Acupuncture? In my experience as treatment progresses and the Patient's condition improves, you have to change the points and introduce a variety, you also learn which points are having the best effect for that particular Patient. You cannot call this 'Clinical Evidence' because the trial quality is so poor and imprecise.	Thank you for your comment. The inclusion criteria for the review as well as the comparators were agreed with the GDG and co-opted acupuncturist when setting the review protocol. Full details of the types of sham and acupuncture were detailed in the evidence tables and available for the GDG when considering the evidence. Any uncertainty about whether the interventions or comparators met this inclusion criteria was checked with the GDG or co-optee as appropriate. All of the included studies were agreed as relevant. For many of the interventions included in the guideline, levels of training may differ according to the expertise of the practitioner, however this cannot be assessed within the systematic review and it has been assumed that unless otherwise stated, that the people delivering the interventions are trained to do so.
Acupuncture Torbay	Full	479	General	Many of your Psychological results seem skewed but I cannot spot why. Many go completely against the MYMOP trial carried out by Dr Charlotte Patterson that showed the	Thank you for your comment. The data analysed in this review was taken directly from the trials included and has been checked to ensure no errors were made during analysis.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				first thing that improved with any Acupuncture was the "feeling of wellbeing" this almost universally improved. The study was published in the Lancet but I don't have the date sorry.	
Acupuncture Torbay	Full	483	General	I do not discourage the use of NSAIDS for my patients but I do encourage them to slowly lower their intake as their pain disappears. We do it in steps until they are off them all together and then I can get a true idea of the unmasked pain and deal with that.	Thank you for your comment.
Acupuncture Torbay	Full	491	general	Acupuncture should only be applied by a Professional Acupuncturist. It is an invasive therapy and when not applied with full knowledge can cause damage. I found a GP in my town 'dabbling' with Acupuncture (his words) he was using Hypodermic needles instead of Acupuncture needles this is so dangerous. Luckily he listened to me and now dabbles on his NHS Patients using Acupuncture needles. I am going to 'dabble' at being a GP next week! On the cost effective side, the average fee for an hours Acupuncture is £35 that is including premises, materials, CPD, insurance, Etc. How much does a Physiotherapist cost for this time? If I average out the number of treatments I give a person with Back Pain, I would say it is about 6. So the cost is £210. Many people are very pleased to pay this to get rid of the pain.	Thank you for your comment. It is beyond the scope of this review to specify who should deliver an intervention, the review focussed on whether or not acupuncture was clinically and cost-effective and was based on the best available evidence identified according to the review protocol.
Acupuncture Torbay	Full	491	general	Previous trials have shown the occurrence of adverse events from Acupuncture to be very low. There was a large trial carried out by the British Acupuncture Council.	Thank you for your comment. We have stated in the 'linking evidence to recommendation' section that acupuncture was considered to be a relatively safe intervention.
Acupuncture Torbay	Full	492	general	Even these poor quality trials show some improvement with Acupuncture bearing in mind many of them are biased by none existent Sham that actually has an effect. So it is worth recommending people to try Acupuncture especially as it is cost effective and has a low risk.	Thank you for your comment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. The GDG also observed that there was conflicting evidence for the benefit of acupuncture. The GDG therefore concluded that there was no compelling and consistent evidence of a treatment-specific effect for acupuncture
Acupuncture Torbay	Full	495	Summary	A Sham Acupuncture comparison is totally invalid because of the reasons I have stated previously. How can something that can be used therapeutically be used as a Sham? This has biased the results. Unfortunately there is very little good research done on the effects of Acupuncture and the vast majority is carried out by Doctors and Physiotherapists why do not have the qualifications or experience to carry out the trails. Real trials should be carried out by Acupuncturists providing the treatment and medical professional running the trial. I think Hue McPherson did some of this http://www.hughmacpherson.com/journal-articles.html You could also refer to the Acupuncture Research and Resource Council; http://www.acupunctureresearch.org.uk/ here is another resource; http://www.acupuncture.org.uk/category/a-to-z-of-conditions/a-to-z-of-conditions.html	Thank you for your comment. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. For many of the interventions included in the guideline, levels of training may differ according to the expertise of the practitioner, however this cannot be assessed within the systematic review and it has been assumed that unless otherwise stated, that the people delivering the interventions are trained to do so.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Acupuncture Torbay	Full	496	Other considerations	Because a mechanism of operation cannot be discovered as yet (it may be at a Quantum Physical level or may operate through Connective Tissue pathways) this should not rule out the treatment. There are many factors in Medicine as a whole that are not understood. The important factor is, do Patients benefit? I have been an Acupuncturist for 21 years and my Practice is building all the time. I have even treated the family of my GP. There are a lot of hospital Specialists who now say to my Patients "try it". I have Patients why get better and then come for another ailment later. If Acupuncture was not effective the word would get around and I would quietly go out of business but I have to pass Patients on because I often have too many to cope with. I even treat myself and my Partner. To be honest, it makes no difference at all to me if you recommend Acupuncture or not because the treatments will be carried out by poorly trained Physiotherapists who are only allowed to give six ten minute treatments. The reason I have spent three hours writing this is because you would be doing the public a disservice by not recommending the treatment. I have a Scientific background, I am also a HND qualified Electronics Engineer so I am not blinded by some airy Fairy idea of Acupuncture. Some people get no help from it and it seems to be the person rather than the ailment. I wish I knew why. But, on the whole Acupuncture helps many things; I have helped eight women with Infertility problems to have babies. And I do treat people for depression with success. So please, you need some good research carried out by none biased open minded people. At least come to the conclusion that there is not enough evidence to recommend Acupuncture for back pain but there is not enough evidence to disprove it either. Thank you for listening.	Thank you for your comment. The GDG agreed that in order to make a recommendation for a treatment on the NHS, evidence of effect beyond the non-specific treatment effects was required. They did not believe there was consistent evidence of effect for acupuncture in order to base this recommendation on. Although there was conflicting evidence, the GDG agreed it was more appropriate to have a recommendation against using acupuncture in the NHS than making no recommendation because there was sufficient evidence to suggest it may not be effective and therefore would not be a good use of scarce NHS resources.
Arthritis Research UK	Full	General	General	(see also short, general, general) The rationale for using the term non-specific LBP is clear.	Thank you for your comment. The introduction to the guideline has been edited to clarify the use of the term 'non-specific low back pain'. Throughout the guideline and in the title, the guideline now refers to 'low back pain' rather than 'non-specific…' as it was agreed this term is poorly defined and misinterpreted.
Arthritis Research UK	Full	General	General	(see also short, general, general) We are pleased to see that the guidelines have moved away from an emphasis on a restricted duration of back pain (6weeks to 12months in the previous guideline), and have chosen to focus on the assessment and management from first presentation onwards (page 20, line 18-21). Terms such as 'acute' and 'chronic' are difficult to define and operationalise, estimation of duration is variable and unreliable, and the majority of people seeking healthcare for LBP have had previous episodes and / or have long-duration of symptoms (often years). Whilst the conceptual change away from using duration as a key basis for treatment decisions is supported by the literature (Von Korff & Dunn, 2008; Dunn et al, 2008) it is not cited or mentioned in the guideline. We would suggest that some further background or justification of the removal of a duration-based approach is warranted, as clinicians may be more used to categorising patients as acute or chronic, and many previous reviews such as Cochrane reviews use duration as a basis for summarising best available evidence. References: • Von Korff M, Dunn KM (2008) Chronic pain reconsidered. Pain 138: 267–276. • Dunn KM, Croft PR, Main CJ, Von Korff M (2008). A prognostic approach to defining chronic pain: Replication in a UK primary care low back pain population. Pain 135: 48–54.	Thank you for your comment. We agree that defining low back pain in terms of duration can be unhelpful. The GDG agreed that low back pain almost certainly represents a continuum where defining populations at risk of poor outcome, regardless of duration, is more important than defining the population in terms of duration alone. The introduction has been amended to reflect this view.
Arthritis Research UK	Full	General	General	There is an impressive volume of evidence reviewed in the guidelines and many of the recommendations based on the evidence are clear and helpful. The clear organisation of evidence to support the limitation and/or reduction in use of opioids, spinal injections and spinal surgery for non-specific LBP is particularly welcome. However, as will be seen from some of the detailed comments on specific topics below, there are some recommendations	Thank you for your comment. The evidence review for exercise considered group and individual programmes separately, however, no difference between group and individual exercise in terms of benefit was observed. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				on which members of our organisation with expertise on the particular topic consider that the committee's conclusions are not clearly justified by the latest evidence. Two examples are the strong preference expressed for offering group-based exercise (which is not systematically superior in clinical effect or universally accepted by patients in comparison to individual exercise) and the advice against offering acupuncture (which a best-quality evidence synthesis individual-patient-data meta-analysis from a 2014 JAMA publication supported for chronic pain generally). These concerns from our group point to an apparent inconsistency in the criteria applied to the evidence base for different recommendations in the draft guidance. We would therefore welcome more explicit explanations of why similar levels of evidence for different interventions led to different recommendations. This is also the case for the selection of research recommendations where questions about invasive interventions and pharmaceutical interventions dominate, despite the guideline development group (GDG) highlighting relevant gaps in the research evidence about non-pharmacological interventions throughout the documentation. Reference: Vickers AJ, Linde K (2014) Acupuncture for chronic pain. JAMA. Mar 5;311(9):955-6. doi: 10.1001/jama.2013.285478.	Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the clinical and cost effectiveness evidence, the GDG concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. The GDG are aware that some people may not be able to fully engage with group exercise, and emphasise in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise. The GDG reconsidered the evidence for acupuncture following stakeholder feedback, and agreed that while acupuncture is low-risk, there was not consistent evidence of a treatment-specific effect for acupuncture. Further, they agreed that the high-cost does not justify the benefits seen in the short term only. Although the GDG agreed to ensure consistency across reviews by giving placebo/sham evidence priority across reviews, for some interventions sham/placebo comparisons were either not possible to conduct or not available This is reflected in the exercise review. Unlike acupuncture, where a sham intervention is possible (whether penetrating or non-penetrating), the GDG agreed it is much harder to achieve this for exercise. On revisiting the 'sham exercise' evidence that was included in the draft guidance, the GDG agreed that none of the included sham interventions could be considered as true forms of 'sham exercise' (one was a psychological therapy and the other was an alternate form of exercise), therefore these have now moved to another comparison or excluded as appropriate according to the review protocol. Therefore, the revised guideline will no longer have any evidence for exercise versus sham. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology). Whilst the GDG kept in mind the evidence for acupuncture versus usual care, they must give sham/placebo evidence priority where available. In the case of acupuncture, the evidence base was large, and did not consistently show a benefit in favour of acupuncture, as you highlight the differences that were deemed to be clinically important which were only observed in short term follow up and were not maintained in the long term. Therefore, the GDG did not agree that this inconsistent evidence of effect was great enough to recommend acupuncture. Research recommendations are made in areas where there is insufficient evidence or considerable uncertainty. In the case of acupuncture, and some other interventions, there was a considerable evidence base, and the GDG agreed that further research would not reduce the uncertainty. Other considerations are also taken into account when writing and prioritising research recommendations, such as feasibility, which have led to some other areas not being prioritised for future research.
Arthritis Research UK	Full	General	General	We were very pleased to read that the STarT Back risk stratification tool which was developed, tested and evaluated in practice by our research team is highlighted by the committee as an example of a risk stratification tool that clinicians should consider using as part of their routine consultations with LBP patients.	Thank you for your comment.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Arthritis Research UK	Full	General	General	We understand and recognise the problems that are faced in any systematic attempt to allocate large quantities of literature to a simple quality-of-evidence scale, and we are impressed with the magnitude and care of what the GDG has taken on and delivered. It needs to be clear however to commissioners and providers of clinical services, that even though evidence may be rated by the GDG as being of low-to-moderate quality, it should still be implemented, as much of the evidence that commissioning/service provision is based upon is not of high quality. Having discussed this with commissioning colleagues, our group is concerned that wording such as 'low quality' or 'moderate quality' will result in recommendations not being implementation even when something has been shown to have a positive impact on clinical outcomes, health care and societal costs (e.g. STaRTBack- Hill et al, 2011).To this end, we feel that it would also be useful if the GDG could provide context for the quality ratings e.g. commenting on specific points that have contributed to quality scores, for example, more explicitly acknowledging that it is not always possible to blind clinicians delivering interventions or patients receiving interventions, or that replication studies of large pragmatic RCTs takes time.	Thank you for your comment. NICE guidelines are developed according to processes detailed in 'Developing NICE guidelines, the manual (November 2012)' and processes set out in the methods chapter of the guideline. These processes state that evidence is assessed for quality according to GRADE methods which rate quality (sometimes thought of as 'confidence' in the evidence) per outcome. This is a measure of risk of bias, imprecision, indirectness and inconsistency. The full GRADE profiles are provided in appendix J and further details of risk of bias ratings for individual studies which result in the pooled assessment of quality are provided in the evidence tables in appendix H. It is acknowledged that in some cases it is not possible to blind clinicians or patients to certain interventions, however this does still represent a risk of bias in determining the true effect of a treatment.
Arthritis Research UK	Full	General	General	Overall, as stated above, we like and support much of this guidance and the work that has gone into it, including the caution about use of strong drugs (opioids in particular) and invasive treatments. However, some members of our organisation had the overall sense that judgements regarding risk and benefits made by the GDG are less favourable for non-invasive treatments generally than is the case for other international back pain guidelines. In particular evidence from implementation research stresses that there must be resources to ensure that recommendations for non-invasive treatments can be properly implemented (e.g. behavioural therapies) (reference to Chenot et al 2008; Bishop et al 2015). References: Chenot JF, Scherer M, Becker A, Donner-Banzhoff N, Baum E, Leonhardt C, Keller S, Pfingsten M, Hildebrandt J, Basler HD and Kochen MM (2008) Acceptance and perceived barriers of implementing a guideline for managing low back in general practice Implementation Science 3:7: DOI: 10.1186/1748-5908-3-7. Bishop FL, Dima AL, Ngui J, Little P, Moss-Morris R, Foster NE, Lewith GT (2015) "Lovely Pie in the Sky Plans": A Qualitative Study of Clinicians' Perspectives on Guidelines for Managing Low Back Pain in Primary Care in England. Spine (Phila Pa 1976). 2015 Dec;40(23):1842-50. doi: 10.1097/BRS.0000000000001215. PubMed PMID: 26571064. In the context of our many positive thoughts about the guidelines, we offer the following suggestions and queries for amendments or more explicit explanations on specific topics.	Thank you for your comment. NICE guidelines apply to settings in which NHS care is provided and therefore need to take into account the context in which they apply. International guidelines apply to a range of healthcare systems with different financial, resourcing and implementation considerations. This may lead to different, yet more relevant, recommendations being made for those settings.
Arthritis Research UK	Full	17	general	Medication: (see also short). The guideline does not give clinicians much to offer patients in terms of medications. There is great inter-individual variability in response to analgesic medications, and mean pain reduction from RCTs conducted on highly selected but at the same time heterogeneous patients with LBP do not predict response in an individual patient. There is little or no good evidence to guide analgesic choices in patients with acute / chronic LBP and consequently we should expect failure of trial medications with this in mind (See Moore A et al BMJ 2013:346;f2690). We therefore feel it would be more useful to point out the lack of good evidence to guide choices and give guidance about trialling analgesics in individual patients (including how / when to stop them in the absence of effectiveness) who are struggling to engage in self-management / rehabilitation without them - or at least suggest that specialist assessment is required prior to offering antidepressants / anticonvulsants / muscle relaxants / opioids in chronic LBP. Reference: Moore A, Derry S, Eccleston C, Kalso E. Expect analgesic failure; pursue analgesic success. BMJ 2013; 346; f2690. Are the GDG recommending NSAIDS in chronic pain?	Thank you for your comment. The recommendations are based on the evidence reviewed and the GDG agreed that it was appropriate to recommend against treatments where there was no evidence of benefit and therefore do not agree that other pharmacological treatments should be recommended. Where the chronicity of the LBP has not been specified in the recommendation, the recommendation applies to both acute and chronic LBP. All recommendations for pharmacological interventions can be found in chapter 16, section 16.6. NSAIDs are recommended for people with either acute or chronic low back pain. The pharmacological interventions review only covers low back pain, and not sciatica, as stated in table 302 in section 16.2. Pharmacological management of sciatica is covered within the NICE neuropathic pain guideline.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				What medications are the GDG recommending for chronic LBP with or without sciatica?	
Arthritis Research UK	Full	17	27	Return to work: (see also Short, 6, 5) Promote and facilitate return to work: this is rather vague and would be strengthened by incorporating evidence for return to work outcomes in back pain, drawing the attention of the reader to the nature of effective interventions that result in better work outcomes.	Thank you for your comment. Programmes with a specific focus on return to work have been evaluated in the review leading to this recommendation. The GDG agreed that although the evidence reviewed was not strong, that it was important to highlight the importance of return to work and therefore the recommendation from CG88 was maintained. We are unable to make this recommendation more specific as there was no evidence for which interventions would produce the best outcomes.
Arthritis Research UK	Full	604	general	A frequent criticism of cognitive behavioural or psychological studies is that the intervention was not actually delivered, either because it wasn't defined, wasn't actually what it claimed to be (e.g. cognitive behavioural therapy), wasn't delivered by clinicians with appropriate or sufficient training, was delivered by clinicians with insufficient expertise and/or the treatment dose was suboptimal (see van der Windt D, Hay E, Jellema P, Main C. 2008. Psychosocial interventions for low back pain in primary care: lessons learned from recent trials. *Spine (Phila Pa 1976)*, vol. 33(1), 81-89 for an example of this). Whilst the GDG indicate that in some of the included studies, the interventions were not provided by a qualified clinical psychologist and varied greatly (one study assessed cognitive behavioural approaches delivered by video which the patient followed themselves), we feel that the guidelines would benefit from greater distinction between treatment provided by accredited cognitive and/or Behavioural Psychotherapists (usually CBT therapists or psychologists), and cognitive behavioural approaches, behavioural approaches and cognitive approaches, delivered by clinicians who are not accredited cognitive and/or Behavioural Psychotherapists (usually physiotherapists). Cognitive and/or Behavioural Psychotherapists are health professionals who have received additional cognitive and/or behavioural therapy training and supervision (Grazebrook & Garland, 2005). Reference: Grazebrook K & and Garland A 2005 What is CBT? BABCP June http://www.babcp.com/files/Public/what-is-cbt-web.pdf	Thank you for your comment. Behavioural therapies, cognitive therapies, cognitive behavioural approaches, mindfulness and acceptance and commitment therapy (ACT) were separately reviewed in the Psychological therapies chapter. Details regarding interventions featured in the included studies can be found in the Summary of evidence tables (Table 285, section 15.3) and Appendix H, section H.4. The GDG agreed there was no evidence to recommend who should deliver the intervention, but agreed it should be an appropriately trained healthcare professional.
Arthritis Research UK	Full	606	general	Psychological: (see also table B of the algorithm on page 15) 'Consider psychological therapies for managing non-specific low back pain with or without sciatica but only as part of multi-modal treatment packages'. This recommendation is in the short document (5, 20). However, it is missing from the recommendations in the full invasive and non-invasive guidelines.	Thank you for raising this. This was a typo and has now been added to the full list of recommendations section in all guideline documents.
Arthritis Research UK	Full	809	general	The GDG define behavioural therapy as a treatment to help change potentially self-destructing behaviours in people with chronic low back pain. However, the definition of cognitive-behavioural approaches is not chronic pain specific. Can the GDG explain this difference? Can the GDG confirm whether all the behavioural studies considered were conducted with chronic low back pain participants and whether the GDG behavioural recommendations (based on these studies) pertain to just chronic low back pain?	Thank you for your comment. All the studies included featured a population with back pain and not more generalised or widespread pain. The guideline pertains to the population detailed in section 4.3.1.1.2 of the Methods chapter. The population considered for each review is detailed in the PICO table at the beginning of each chapter; for the psychological review, this can be found in table 284, section 15.2.
Arthritis Research UK	Full 1	16	2	(see also short, 3, 5 Stratified care) Currently, there is no research evidence about superior outcomes using a risk stratification approach specifically for patients with spinal radiculopathy and so the recommendation for stratification would be more closely matched to best evidence if it were to be recommended for patients with NSLBP. We assume this is what the GDG is intending, i.e. that stratification (for example with the STarT Back tool) be considered in patients with 'non-specific LBP with or without sciatica' in the context of the clinician applying clinical judgement and that radiculopathy may require other specific interventions. We would like to draw attention to the GDG that a current randomised trial is ongoing that is testing a stratified care intervention specifically for patients with sciatica (NIHR HTA funded SCOPiC trial, Chief Investigator Prof Nadine Foster at Keele University; 2014-2018).	Thank you for your comments and information about the ongoing trial. The GDD acknowledged that all of the tools reviewed are validated in either solely low back pain populations or mixed populations of people with low back pain and/or sciatica, rather than for sciatica specifically. This is reflected in the 'Other considerations' box, section 6.6 on page 114. As there was evidence for the use of stratification tools in populations with low back pain and sciatica, the GDG agreed it was appropriate to state 'low back pain with or without sciatica' in the recommendation.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Arthritis Research UK	Full 1	16	7	(see also Short 15, 13) The GDG recommend providing self-management for all yet 'consider' offering exercise, despite the evidence on exercise showing clearly that exercise is superior to self-management. See previous point on this.	Thank you for your comment. The GDG have clarified that the recommendation for self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practise rather than a separate intervention that is offered. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified. This is further supported by evidence from the review of multidisciplinary programmes where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this.
Arthritis Research UK	Full 1	16	15	Self-management: (see also short 4 5) Self-management and exercise: We noted that self-management is recommended yet supervised exercise is only to be 'considered'. This does not match the evidence for these interventions quoted by the GDG, since the effect size from self-management is negligible / much smaller than the effect size for exercise (see next points below). It would be helpful to relook at these recommendations, to therefore consider recommending exercise, and having an explicit statement about how the evidence is being used and interpreted in relation to these recommendations Full, non- invasive Page 196-200 concludes there is inconsistent evidence for self-management and no benefit of it over sham. Full 16, 15 (see also Short, 4, 5) Studies involving unsupervised exercise were considered by the GDG under self-management, yet these studies were heterogeneous and some included patient-clinician contact, which is not 'unsupervised exercise'. Full non-invasive Page 197-198. There is no benefit of unsupervised exercise yet it is recommended for all patients with LBP in the draft guidance (and is in the top box of Figure 1 algorithm, page 15 along with some pharmacological interventions). This does not appear to be in line with the evidence underpinning self-management or exercise, presented in the guideline	Thank you for your comment. The GDG have clarified that the recommendation for self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practise. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified This is further supported by evidence from the review of multidisciplinary programmes where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this. To reinforce this concept, the wording of the self-management recommendation was edited as follows: All healthcare professionals should provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, at all steps of the treatment pathway. This should include: information on the nature of non-specific low back pain and sciatica; encouragement to continue with normal activities as far as possible. The GDG agreed that the evidence for supervised exercise, reviewed in the exercise chapter, supported a 'consider' recommendation, and believed this was consistent with the approach to the self-management recommendation. Unsupervised exercise has been categorised within self-management for the purpose of this review as stated in the protocol, and it included interventions such as exercise prescription and advice to exercise at home (Appendix C.4). The GDG acknowledged that for some of these there would be some clinician contact, but the distinguishing factor for determining where the intervention should be considered was the exercise component being carried out without supervision.
Arthritis Research UK	Full 1	16	20	Exercise: (see also Short, 4, 13) Our main concern is that the evidence from usual care comparisons and placebo controlled comparisons for exercise (i.e. that usual care comparisons are allowed to predominate in the GDG's decision-making) has been treated differently to the way in which, for example interventions such as manual therapy or acupuncture have been handled (i.e. placebo comparisons must predominate). Once again it would be helpful to reconsider this such that these therapist-led interventions are treated similarly by the GDG or to include explicit statements about why the criteria should be different for these different interventions.	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore the revised guideline no longer has any evidence for exercise versus sham. Given the absence of placebo/sham evidence, the recommendation for exercise is now predominantly based on usual care evidence and comparisons with other interventions, as it is not possible to be based on sham comparisons as in other reviews.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Linked to the above point, Appendix K p60 Fig 219 There appears to be no evidence that exercise is superior to sham, albeit there are only a small number of sham controlled exercise trials (Appendix K p60 Fig 219 data from Albert 2012 seems different from the data extracted from the paper and included in appendix H pg 146? – the paper by Albert concludes no difference between exercise and sham in the primary outcomes; another trial also concluded no significant benefit of exercise over sham Appendix K, pg 70), but a positive recommendation is made.	
Arthritis Research UK	Full 1	16	20	(see also page 232, 244, 245 full guidance) It is unclear why a definite priority has been given to group-based exercise interventions, in the absence of evidence that they are systematically superior in clinical effect to individual interventions. We understand there may be economic advantages to group delivery of exercise, however the GDG do not provide economic evidence on the comparison between group and individual exercise or an economic model on this. Furthermore some individuals prefer group-based treatments, but it also evident that others do not like group treatments and do not engage with them, there is variable take-up of group sessions and often limited availability. Given the above, we therefore suggest that supervised exercise be recommended for all patients with LBP and that this can be either delivered in groups or individual treatment sessions. There is evidence in favour of individualisation of exercise – the guideline recommends 'tailoring' (see pg 307). This suggests the recommendation should be for 'supervised exercise that incorporates individualisation and progression of exercises'. Is the UK BEAM trial missing from the evidence for exercise (it is in the cost effectiveness analyses)?	Thank you for your comment. The GDG found no difference between group and individual exercise in terms of clinical evidence. There was no economic analysis of group exercise directly compared with individual exercise, as there was no evidence for this comparison, however each type of exercise intervention was analysed where cost effectiveness data was available. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care. Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the cost effectiveness evidence, the GDG concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. The GDG are aware that some patients may not fully engage with group exercise, however do state in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise, in order to promote engagement. We apologise that the UK BEAM trial was not previously fully extracted, and is now included in chapters 9 and 12.
Arthritis Research UK	Full 1	16	33	Manual therapy: (see also short 5, 1) The GDG acknowledge the complexity of different treatments and comment that it is easier to have sham/placebo for some treatments than others. However the GDG appear to have used different criteria for their decision-making about manual therapy than for other interventions such as self-management of exercise (i.e. they appear to have set the bar higher for manual therapy), and the evidence for it is regarded as weak. Despite this, they have recommended manual therapy as part of a multi-model package (i.e. only to be used alongside exercise). This is an example of the inconsistency of use of the evidence for recommendations about different interventions.	Thank you for your comment. The GDG agreed that the evidence for manual therapy was not strong enough to recommend as a single intervention alone, however based on evidence of studies using treatment packages of 2 or 3 elements including manual therapy, they concluded that the evidence did support a recommendation for manual therapy only when part of a treatment package. This is consistent with criteria applied to all recommendations within the guideline.
Arthritis Research UK	Full 1	16	36	Acupuncture: (see also short 5, 6) The language used when talking about acupuncture (pg 493 of full guidance) is an example of the different approach to evidence that has been taken for this intervention compared to others, such as exercise, CBT (pg 581) etc. The higher bar used by the GDG was that acupuncture needed to show superiority over sham controlled trials. Pgs 492 and 494 show that acupuncture had clinically meaningful benefits in pain and function over usual care (the same type of evidence that provided the basis for exercise being recommended). However, Vickers and Linde in a 2014 JAMA publication based on IPD meta-analysis found that a best-quality method of evidence synthesis supported acupuncture for chronic pain on the basis of significant differences against both sham intervention and usual care. It is unclear why the previous NICE guidance in favour of acupuncture should now be overturned in the light of this new evidence. Reference: Vickers AJ, Linde K Acupuncture for chronic pain. JAMA. 2014 Mar 5;311(9):955-6. doi: 10.1001/jama.2013.285478.	Thank you for your comment. The GDG were careful to ensure consistency in their decision making across the evidence reviews. They noted that the evidence from the review was weak, however it was also acknowledged that this review for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to demonstrate a treatment effect separate from the non-specific treatment effects (as mentioned in the methods chapter). The Vickers IPD meta-analysis was not included in the original review due to it pooling populations with low back pain with/without sciatica and low back pain only, as well as pooling across time points. However, we agree that the data for the relevant studies could have been extracted and used in the meta-analysis. We have subsequently undertaken a sensitivity analysis to

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Appendix K pg 153 Check for data entry errors within the analysis (appendix K pg 153, Brinkhaus 2006 data and Leibing data (change value inputted rather than absolute value of pain?)) that may have resulted in a reduction in the total effect size and higher heterogeneity. Despite this, the point estimate and lower 95%CI were still clear of the zero effect line, and thus acupuncture was superior to sham for pain at up to 4 months (7 RCTs and 1359 patients), acupuncture was also superior to sham in the longer-term with no heterogeneity (4 RCTs, 1159 patients). The GDG state the benefits for pain were not sustained beyond 4 months (pg 494) but the forest plot for acupuncture compared with usual care clearly shows superiority (appendix K, pg 159). In addition, the health economic data show a more favourable cost per QALY for acupuncture compared with the cost of either exercise or manual therapy (Appendix I, pgs 18, 27, 29). This appears to underline inconsistency of decision-making specifically about acupuncture as an intervention, in comparison to other non-pharmacological interventions.	demonstrate the difference in the review had the data from the IPD meta-analysis been used. This is presented alongside the forest plots in sections K.9.1 and K.9.2, demonstrating no difference to the conclusions made. Of the errors highlighted, data from Brinkhaus 2006 has been amended as suggested. The data from Leibing 2002 however has been checked, and the change scores, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, have been accurately meta-analysed, therefore no changes were made for this study. The updated forest plots do not show any clinical benefit for acupuncture, with the heterogeneity still present within the meta-analysis. For the evidence comparing acupuncture to usual care, clinical benefits for pain severity was only seen at equal to or less than 4 months in both low back pain without sciatica and low back pain with/without sciatica populations, but maintained at greater than 4 months. With regards to the economic evidence, as we have reported in the linking evidence to recommendation section, overall the GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not considered relevant.
Association of Chartered Physiotherapists in Reflex Therapy	Full	298	21	Spelling mistake: 'thouse' - should be 'those'	Thank you for highlighting this, it has now been amended.
Association of Chartered Physiotherapists in Reflex Therapy	Full	301	36	Not a clear statement – sentence does not make clear distinction of comparison, of which combination.	Thank you for your comment. The sentence has been amended to add more detail about the comparison that is referring to.
Association of Chartered Physiotherapists in Reflex Therapy	Full	302	16	Economic – wrong name of title. Must define a economic of 'what' – or be plural.	Thank you for your comment. The subsection title refers to the main section which is Evidence statements.
Association of Traditional Chinese Medicine and Acupuncture	Full 1	493-494	general	1. For mixed populations, in the report, acupuncture treatment is not reported as better than sham placebo. The implication of this statement is incorrect since no studies making this comparison are presented. In addition, this statement does not tack into account studies showing evidence that acupuncture treatment is significantly better than usual care in pain relief (VAS 0-10 for acupuncture over usual care: -1.28 [-2.09, -0.47]). In addition, evidence shows that acupuncture treatment of lower back pain is similar to that of NSAIDs in pain relief (VAS 0-10 for acupuncture over oral NSAIDs: -0.37 [-1.21, 0.47]).	Thank you for your comment. The evidence for acupuncture versus sham in a mixed population (low back pain with or without sciatica) has been checked again to ensure the validity of this statement. There were 3 studies included for this population, with no outcomes showing clinical benefit of acupuncture over sham. Although there were similar effect levels observed for acupuncture and NSIADs, the GDG noted that these were only from 2 small studies of low and very low quality. Given the more positive results seen in the pharmacological review for NSAIDs compared to placebo, the GDG agreed that the limited evidence for acupuncture versus NSAIDs was insufficient to consider equivalence between them.
British Acupuncture Council	Appendix B	17	1	*Conflicts of Interest for the GDG Chair*: see comment 6	Thank you for your comment. Because GDG members were recruited in 2013, the DOI policy that was followed for the purposes of this guideline was the 2007 policy (updated October 2008). This was stated in appendix B and has now also been added to section 3.4 of the full guideline for clarity. The Chair and all GDG members were recruited in accordance with this policy. All GDG members' private practice was discussed and declared in appendix B and it was agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					members who had not withdrawn from the discussions were involved in all recommendation making and it was agreed that no member unduly influenced the decision of the committee.
British Acupuncture Council	Appendix B	26	1	*Conflicts of Interest for another GDG member*: see comment 6	Thanks you for your comment. All GDG members' private practice was discussed and declared in appendix B and it was agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and it was agreed that no member unduly influenced the decision of the committee.
British Acupuncture Council	Appendix K	60	198	Fig 219. Albert data incorrect – see comment 8	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore the revised guideline no longer has any evidence for exercise versus sham, and the Albert study has been excluded due to the intervention previously labelled as the sham arm comprising of another form of exercise.
British Acupuncture Council	Appendix K	153	719	Fig 667. Brinkhaus and Leibing data incorrect in this forest plot: see comment 8 above	Thank you for your comment. The data in figure 667 has been checked and data from Brinkhaus 2006 has been amended. However, no amendments were necessary for data from Leibing 2002 as the change scores reported, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, which were correctly included in the meta-analysis.
British Acupuncture Council	Appendix K	153	720	Fig 668. Leibing data incorrect here: see comment 8	Thank you for your comment. The data in figure 668 has been checked. Leibing 2002 has reported change scores which have been correctly meta-analysed in this forest plot.
British Acupuncture Council	Appendix K	155	729	Fig 678. Haake data incorrect: see comment 8	Thank you for your comment. This figure and corresponding GRADE tables have been amended.
British Acupuncture Council	Appendix K	156	737	Brinkhaus (2006) data for healthcare utilisation is missing (hence there is no utilisation data in this stratum). Pain medication use was less than half in the verum group	Thank you for your comment. This figure and corresponding GRADE tables have been amended.
British Acupuncture Council	Appendix K	156	737	Also missing entirely is any responder criteria data for the without sciatica population, compared to sham. Molsberger (2002) reported this using the criterion that pain VAS should be at least 50% better. For Haake (2007) the criterion was ≥33%. These appear to comply with your specifications so we are not sure why they were excluded	Thank you for your comment. Responder for Molsberger 2002 has now been added to the acupuncture review. The responder criteria data for Haake 2007 has been reported as pain, as the description best fits this outcome.
British Acupuncture Council	Appendix K	158	742	Fig 691. Why is Witt (2006) not included in this forest plot? Their SF36 data don't seem to feature at all.	Thank you for your comment. Data from Witt 2006 has now been fully extracted and added to the review.
British Acupuncture Council	Full	General	General	The GDG here has followed the same approach as for the 2014 osteoarthritis guideline, where acupuncture was referred to as a 'device'. Acupuncture is only partially a device; it is also the person using the device - what they say and how they act. These are seen as an integral part of the therapy by most acupuncturists, not as context. Some elements are theory-driven and specific to acupuncture, not simply generic good practice for attentive and supportive healthcare practitioners of any discipline. In this respect acupuncture is more akin to psychological than physical therapies and the argument is exactly the same as that about the use of attention controls, which may be contra-indicated because attention is an intrinsic part of the intervention (Freedland et al 2011). Sham controls of the type allowed in this guideline only answer research questions about needle insertion (penetration /depth/manipulation/location), not the whole intervention. Thus sham controls would not inform you about the 'specific treatment efficacy element that relates to acupuncture as opposed to contextual response' (2014 Osteoarthritis (OA) guideline: response to comments)	Thank you for your comment. The GDG acknowledge that the practitioner-effect is important and well known in the literature, which impacts all therapist-delivered interventions (including psychotherapy). However the delivery of interventions is not an area reviewed in this guideline. The GDG recognise that acupuncture is a therapist-delivered complex intervention with multiple components, and needling somatic tissues is one of the components. However, since both penetrating and non-penetrating shams were included within this guideline, the GDG were confident they could use the evidence to assess whether the effects seen with acupuncture were above and beyond contextual or placebo effects.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Reference Freedland KE, Mohr DC, Davidson KW, Schwartz JE. Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. Psychosom Med. 2011 May;73(4):323-35	
British Acupuncture Council	Full	General	General	Even were acupuncture to be defined solely as the needling there is still a considerable problem. There is no acupuncture sham that controls successfully for placebo and non-specific effects but not for specific effects; they exhibit physiological effects due to the mechanical stimulation: they are not biologically inert. There is a considerable literature supporting this. Mechanistic studies show that acupuncture and sham share some physiological responses but that the verum has more of them (e.g. Harris et al, 2009). This would fit the clinical evidence picture and also accords with the practice viewpoint that needling less deeply (or not at all, just pressing), less strongly or further from the designated points equates to a gentler form of the therapy but is still most definitely acupuncture. The Japanese Toyohari style, for example, tends to use minimal or even non-insertional needling. In a wider context acupuncture and sham could be described as stronger and weaker doses of the intervention, and the trials as dosing trials. Reference Harris, R. E., Zubieta, J.-K., Scott, D. J., Napadow, V., Gracely, R. H., & Clauw, D. J. (2009). Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on μ-opioid receptors (MORs). NeuroImage, 47(3), 1077–1085	Thank you for your comment. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
British Acupuncture Council	Full	General	General	Not surprisingly, non-penetrating shams provide less stimulation than penetrating and hence do a better job as placebos, but there is no differentiation between them in the guideline. In an individual patient meta-analysis (IPMA) on acupuncture for chronic pain the non-penetrating sham trials produced an effect size of 0.76 SD, vs 0.17 for penetrating (MacPherson et al, 2014). A sub-group analysis on this basis may have given you quite different answers for the different sham types. Understandably you excluded relaxation as an attention control for exercise if it involved tensing and relaxing muscles, as this could be seen as providing some portion of the specific treatment in the sham. Why then did you not exclude penetrating shams (even better, all shams), as they do likewise? Reference MacPherson H, Vertosick E, Lewith G, Linde K, Sherman KJ, Witt CM, Vickers AJ; Acupuncture Trialists' Collaboration. Influence of control group on effect size in trials of acupuncture for chronic pain: a secondary analysis of an individual patient data meta-analysis. PLoS One. 2014 Apr 4;9(4):e93739	Thank you for your comment. Unfortunately we could not include MacPherson 2014 into the review as it was a prospective survey and therefore did not meet the inclusion criteria. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
British Acupuncture Council	Full	General	General	The review question for acupuncture (and equivalent for other interventions) is 'what is the clinical and cost-effectiveness of acupuncture…....?' Effectiveness is defined in NICE's own glossary as 'How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care'. Hence clinical effectiveness evidence should come from trials with waiting list, usual care or other therapy comparators; sham comparison doesn't enter into it. No clinician would look to the difference between a strong and weak dose of a treatment for information about the overall benefit of providing that treatment for patients. Likewise they wouldn't look to the difference between CBT and pretend CBT to tell them the value of a CBT service. Use of the sham comparison moves you away from patient, clinician and commissioner interest altogether; it is for researchers not real world decision making.	Thank you for your comment. In the acupuncture review, we searched for and included studies which compared against sham, usual care, waiting list, no treatment and other interventions. Evidence against all of these comparators is considered by the GDG when developing recommendations where available. However, any evidence for comparisons against placebo/sham has been given priority in order to determine the treatment effect is over and above any contextual or placebo effects. This was determined a-priori before the evidence was reviewed, and is stated in the methods of the guideline. Effectiveness is used here as a broad term to include efficacy and this has now been clarified in the glossary. All of the reviews do look to determine both

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The bottom line in this argument appears to be that it would be unethical to recommend a treatment that was thought to be largely placebo (2014 OA guideline, response to comments).. Questions of ethics are tricky, and may require skills not available in this guideline development group (GDG). There are stronger ethical counter-arguments: is it ethical to deprive many people of the opportunity to receive cost-effective treatments that may benefit them. Maximising the benefit to harm ratio is surely the ethical priority and the GDG has shied away from it. If all interventions were to be vetted in the manner used in the guideline for acupuncture then there would be nothing left for the GDG to recommend. Surely statistical superiority over sham should be sufficient to guard against accusations that you are offering just a placebo, and hence satisfy ethics and professional integrity. Cherkin's (2016) very recent contribution is worth looking at: he suggests there is too much focus on specific effects and too little on context. Acupuncture is a great vehicle for delivering good context, and its context is also its specifics. Reference https://www.grouphealthresearch.org/news-and-events/blog/2016/03/call-more-patient-centered-approach-treating-back-pain/?utm_source=newsletter&utm_medium=email&utm_content=call-more-patient-centered-approach-treating-back-pain&utm_campaign=GHRN%20-%20April%202016%20-%20External	(using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. Please be reassured that we have not considered weak doses of any treatment as a sham/placebo for any interventions within this guideline. The GDG felt the sham comparisons included in this guideline were credible since both penetrating and non-penetrating shams showed no strong benefits for acupuncture.
British Acupuncture Council	Full	General	General	Just because there are many sham acupuncture trials does not make it right for you to use them for clinical effectiveness evaluation: they are, as discussed above, designed for efficacy research questions. Few of the other interventions considered in the guideline have a significant body of sham or placebo evidence, which has allowed their shortcomings to be glossed over in this respect, and the usual care data to come to the fore. By contrast, acupuncture has been evaluated solely on its sham data. Even though you acknowledge it to be both clinically and cost-effective this evidence is ruled inadmissible because stronger dose acupuncture is not clinically superior to weak dose (even though statistically superior). The approach elsewhere appears to be that if there are sham trials then use them, and if not, then simply assume that there is a specific effect and move onto the non-sham data. An extra clause has been inserted into the acupuncture procedure, specifying that clinical superiority over sham will be required as a starting point. This requirement (in any explicit form) is absent for the other interventions – just as well, because they would not satisfy it, leaving very little to recommend. Exercise has no evidence of superiority over sham (despite the errors that persuaded the GDG to say otherwise: see below for details). Manipulation barely reaches statistical significance, certainly not clinical, and massage is not much better. Psychological therapies aren't even effective, let alone efficacious, and the case for recommending them is particularly baffling. Thus CBT failed to reach clinical significance for any of the pre-defined critical outcomes: it didn't even manage to out-perform a waiting list for psychological distress! The GDG appear to have moved the goal posts to accommodate this: a) re-specifying the outcome to 'reducing the fear of pain', b) recommending packages of care even where the individual interventions are ineffective. Even in combination the evidence is not encouraging: a two-element MBR programme (physical and psychological) did not differ from waiting list for pain or psychological distress. There's a similar story with paracetamol and opioids: neither is better than sham and even combined they aren't very convincing. The likelihood that any of these are operating through specific effects rather than placebo seems pretty low. There is a striking inconsistency, a lack of equity, in the way these different interventions are treated: acupuncture has to jump through hoops that don't exist elsewhere. Even worse, the hoops appear to have been erected by the GDG during the process, rather than specified up front, and there is no explanation of how or why they came to be there (and not elsewhere)	Thank you for your comment. Effectiveness is used here as a broad term to include efficacy and this has now been clarified in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight on the basis that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. Giving priority to evidence for comparisons against placebo/sham was determined a-priori before the evidence was reviewed. This has been done consistently across all reviews when developing recommendations. On re-visiting the evidence for exercise versus sham, the GDG agreed that the sham exercise controls included were either other interventions or other forms of exercise and have therefore been removed from the exercise review for this comparison. Furthermore, the GDG acknowledge the difficulty in achieving a plausible sham for exercise. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology). Regarding psychological therapies, the GDG acknowledged that the evidence from single intervention CBT trials was not convincing and therefore were unable to recommend its use in isolation. The GDG considered however, that psychological therapies would often be offered in combination with other interventions in clinical practice, and that the improvement of pain and function is not the primary aim of this type of intervention, possibly explaining the lack of meaningful effects observed in these outcomes. Evidence from the combination and the MBR supported the recommendation of psychological therapies to be offered as part of a treatment package including exercise, with

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					or without manual therapy. This is detailed in section 15.7 (Recommendations and link to evidence). Regarding MBR, CPP programmes showed some benefit over usual care/waiting list comparator. Although there was no clinical difference between groups for pain and psychological distress outcomes, there was evidence of benefit of a 2-element MBR programme for the function and return to work outcomes compared to usual care/waiting list in people with or without sciatica. There was also clinical benefit there of a 2-element MBR for pain and function in people with low back pain without sciatica. The GDG acknowledged that the evidence for 3-element MBR versus usual care/waiting list was mixed. Overall the GDG felt that CPP should nonetheless be recommended on the basis of the evidence showing benefit over waiting list, single and combined interventions, alongside evidence from single intervention chapters. This is detailed in section 17.6 (Recommendations and link to evidence).
British Acupuncture Council	Full	General	General	NICE's conflicts of interest (CoI) policy (version 2.5) states that Chairs of advisory committees should not have any specific interests but the GDG Chair has a personal pecuniary interest as director of a pain management service. It's hard not to see this as a specific interest, which should have barred him from this appointment. He's also been a board or council member of organisations that publicly criticised the inclusion of acupuncture in CG88, certainly a specific interest even if >12 months ago. Another member declared an ongoing anti-acupuncture stance and may have published on this in the last 12 months. The decision to let him participate, given a specific, personal, non-financial CoI would have been at the discretion of the Chair, who is himself somewhat compromised. We understand that it may be difficult to recruit members to NICE GDGs but the danger in using people with vested interests and entrenched views is clear. This has certainly been an issue in the past with respect to attitudes to Chinese medicine.	Thank you for your comment. The COI policy that was followed for the purposes of this guideline was the 2007 policy (updated October 2008). This was stated in appendix B and has now also been added to section 3.4 of the full guideline for clarity. The Chair, and all GDG members were recruited in accordance with this policy. The Chair's declarations of interest, including his director position at Back@Work were explored at interview and it was confirmed that this was a primary care interface service funded by the NHS offering a range of NHS treatments. Subsequently it was agreed that this was not a conflict to Chairing the guideline on that basis. The GDG member who declared having previously expressed views on acupuncture confirmed all decisions made in the guideline would be based on the evidence that was presented as a result of the reviews undertaken, and would support any recommendation made, in accordance with NICE's code of conduct for committee members. Throughout development of the guideline, all GDG members who were not conflicted were actively involved in discussing the evidence and making all recommendations. No single individual influenced recommendations that were made.
British Acupuncture Council	Full	General	General	There was no acupuncture representative on the GDG. We recommended that there should be during the scoping workshop and subsequent written comments. This idea was supported by the members of our workshop discussion group but not by the GDG Chair. Having a research acupuncturist on the committee, rather than just an acupuncture practitioner as an external expert, would have provided a fairer context for the guideline. It is noteworthy that exercise (via physiotherapy), manual and psychological therapies all had representation on the committee and all were recommended, despite their poorer evidence base. The decision on representation was in all likelihood hugely significant for acupuncture. A research savvy acupuncturist is also likely to have spotted some of the data errors in the draft. Aside from the patient representatives, the GDG is heavily populated by consultants. This was precisely the concern in our scoping workshop discussion group, even by the	Thank you for your comment. After careful consideration, it was decided that, as with other single review question topics (return to work, risk stratification and imaging), a co-opted expert would attend a GDG meeting to aid the GDG in understanding the evidence for acupuncture. Recruiting a full member GDG member with expertise in only one of the 24 guideline chapters was agreed as not appropriate for the committee. This was discussed at the stakeholder workshop during scoping for the guideline and following stakeholder consultation of the scope and proposed GDG membership.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				consultants themselves. It moves the guideline further away from frontline clinicians and patients and tends to make it more of an academic exercise.	All decisions on recommendations were based on the evidence presented in the guideline and not on the representation of the GDG. The GDG was openly recruited and had representation from both frontline clinicians and consultants agreed during scoping as being the appropriate mix of expertise.
British Acupuncture Council	Full	General	General	There are some major data errors, particularly in the extraction of outcome group means. In some cases the sign is wrong, so that results favouring acupuncture are presented as the reverse. These have arisen through confusing the mean change from baseline with the absolute mean at an outcome time point. As well as possible sign errors this also results in inaccurate values, depending on the size of the baseline differences between the groups. The most significant we've seen in the acupuncture data relates to the analysis for VAS pain at ≤4 months, vs sham, without sciatica. Brinkhaus 2006 mean difference should be -0.85, not +0.51; Leibing should be -1.1 rather than -0.6. Correcting these would deliver an overall effect of -1.03 (Cummings, 2016) rather than -0.80, hence clinical significance for the best piece of evidence in the sham comparisons (it has the largest number of studies and participants). For the corresponding longer term analysis Leibing's values are again wrong, both in sign and size, though this does not alter the overall effect significance. There is also a sign reversal error for the sham FFbHR function at >4 months (Haake 2007), which now leads to a statistically significant effect. There also appears to be missing sham comparison data: Brinkhaus 2006 for healthcare utility; Molsberger 2002 and Haake 2007 for responder criteria. Both of the latter appear to satisfy the guideline criteria. Errors are not confined to acupuncture. Another major one appears for the only two sham exercise trials included. Albert 2012 is reported as showing clinical benefit for exercise (for pain ≤4 months) but the original paper found no differences in primary outcomes (including pain). The sham was superior in Smith 2001, as reported in the Evidence Statements, but the opposite conclusion appears in the Recommendations. There are also instances of the same sort of errors in the means as described above for acupuncture. We looked for errors only in a few particular places, so the presumption must be that there are plenty more to be found in the whole guideline. This is not surprising given the massive size of it but it is disturbing to find that major conclusions may be incorrect and the recommendations rest on shaky foundations. <u>Reference</u> Cummings M. Musings on heterogeneity in quantitative outcomes of acupuncture trials in LBP. Acupuncture in Medicine blogs. 4 April 2016. <u>http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/</u>	Thank you for your comment. All the mentioned errors have now been checked and amended for the exercise evidence review. The errors mentioned for the acupuncture review; regarding Brinkhaus 2006 and Leibing 2002, have also been checked. Data from Brinkhaus 2006 has been amended, however the revised mean difference for pain is -0.8 which does not reach the clinically important between group difference agreed by the GDG. No amendments were necessary for data from Leibing 2002 as the change scores reported, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, were correctly included in the meta-analysis. The error regarding the outcome FFbHR function outcome from Brinkhaus 2006 has now been amended, and the missing outcomes from both Haake 2007 and Molsberger 2002 have been extracted and added to the evidence review (please see chapter 13). On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise', and on reflection agreed a sham for exercise would be impossible to achieve. Therefore the revised guideline will no longer have any evidence for exercise versus sham including the Albert 2012 study which was subsequently excluded due to the sham arm comprising of another form of exercise, which does not meet the protocol. The Smith 2001 study has also been excluded due to the sham arm comprising of a relaxation audio tape, and therefore not fitting in with any of the interventions being addressed in the review.
British Acupuncture Council	Full	General	General	Looking at the evidence in the light of the above errors we see quite a different picture to that painted by the GDG. It would no longer be correct to say that there were 'no clinical benefits for pain or function' in the sham comparisons. Even using NICE's inappropriate definition of clinical benefit we can say that acupuncture is superior to sham for SF36 physical composite (2 large trials), for most SF36 individual domains (1 moderate), pain (7 studies), psychological distress (1 moderate) and probably healthcare utilisation (1 large) and at least one of the responder criteria trials. Function is statistically significant for one measure (largest study). Adverse events are no more frequent for acupuncture than for sham. What other interventions come anywhere near this level of benefits (vs harms)? Certainly not exercise, which can now be seen to have no supporting evidence at all re sham. Compared with usual care acupuncture delivers clinical superiority for quality of life, pain and most measures of function (and the others are very close to it). Acupuncture is also comfortably cost-effective. Again the evidence stands up favourably against any other treatment.	Thank you for your comment. Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. However the GDG observed that the evidence was still conflicting for acupuncture versus sham, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up. Although the GDG has considered and appreciate the evidence against usual care, the GDG agreed that the body of evidence available for the sham comparison should be given priority when developing the recommendation and do not agree that consistent benefit is observed.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It is hard to see how this level of consistent benefit, with evidence that is superior to that of other treatments, including those due to be recommended, would not merit your endorsement.	
British Acupuncture Council	Full	General	General	An interesting subsidiary issue is that of whether clinical effects are maintained in longer-term follow-up. The GDG generally found little evidence of this, though perhaps the analytical methods used were not the most appropriate for this purpose. The trials with longer-term data were mostly a sub-set of the short-term group, so the longer-term results are heavily dependent on which of the originals are still represented. In the acupuncture usual care comparison data for pain, the three out of seven studies with both long and short-term data maintained nearly 90% of their earlier response at the later follow-up. Nevertheless, taken on the >4 month data alone they were (just) short of clinical significance, leading the GDG to its rather misleading negative conclusion. We believe that an appropriate analysis across outcome time points would demonstrate sufficient retention of effect to satisfy the GDG, certainly for the usual care data.	Thank you for your comment. To ensure consistency the GDG apply the same minimum important difference (MID) thresholds on outcomes across all reviews when determining clinical significance (see chapter 4 for MID details). The analysis methods take into account the number of people included, the drop-out rate and the mean difference between groups, therefore we do not agree that the analysis method disadvantage the long term follow-up. Furthermore, the GDG agreed that evidence compared to placebo or sham would be given priority to comparisons against usual care when developing recommendations. This is to ensure that the intervention effects are over and beyond any contextual and placebo effects.
British Acupuncture Council	Full	General	General	The GDG considered that inadequate blinding in some sham studies may have inflated effect sizes. There is no evidence that this has happened here: please refer to Vickers et al's (2013) response to this argument re their IPMA paper. Reference Vickers AJ, Maschino AC, Lewith G, MacPherson H, Sherman KJ, Witt CM; Acupuncture Trialists' Collaboration. Responses to the Acupuncture Trialists' Collaboration individual patient data meta-analysis. Acupunct Med. 2013 Mar;31(1):98-100.	Thank you for your comment. As mentioned in Vickers 2013, "in most studies comparing acupuncture and sham acupuncture, providers obviously were aware of the treatment provided and, as such, a certain degree of bias of our effect estimate for specific effects cannot be entirely ruled out". Although Vickers 2013 goes on to suggest that acupuncture would impose a lower risk of bias for unbinding than other non-drug interventions, it is not possible to measure this. Therefore, this risk of bias has been considered consistently for all studies included in this guideline where the providers or outcome assessors were not blinded to the treatment allocation.
British Acupuncture Council	Full	General	General	The GDG also discussed the idea of passive acupuncture promoting dependence. On the contrary, there is evidence that it excels in promoting self-confidence, resilience, self-reliance, self-efficacy (eg.MacPherson, 2015). As delivered by professional acupuncturists, including those with NHS contracts, it includes lifestyle advice as standard. Reference MacPherson, H., Tilbrook, H., Richmond, S., Woodman, J., Ballard, K., Atkin, K., et al. (2015). Alexander Technique Lessons or Acupuncture Sessions for Persons With Chronic Neck Pain. Annals of Internal Medicine, 163(9), 653	Thank you for your comment. This statement has now been removed from the guideline.
British Acupuncture Council	Full	General	General	It is explicit that a strong driver for dropping acupuncture is the cost saving for the NHS in not having to pay for it, but, as with other influences discussed already, this was not a part of the pre-specified protocol. As it stands, the guideline will restrict patient and practitioner options in primary care to a very small offering. Rather than opening new avenues for them to explore you will be closing them down. Acupuncture may provide a strong solution for particular patient groups, it may be a valuable optional addition for packages of care, or it may usefully substitute for an existing orthodox treatment. Currently we don't have the data to address any of these possibilities. Rather than casting it out and saying that further research won't change the situation NICE could be looking at recommending research on how best to incorporate an intervention that is at least as good as anything else on offer. And if cost-saving rather than cost-effectiveness is the critical consideration then consider group acupuncture as an option (e.g. White et al, 2013). Reference White A, Richardson M, Richmond P, Freedman J, Bevis M. Group acupuncture for knee pain: evaluation of a cost-saving initiative in the health service. Acupunct Med. 2012 Sep;30(3):170-5	Thank you for your comment. Our methods for reviewing and forming recommendations are explained in Chapter 4. Here we explain that when forming a recommendation the GDG consider both the clinical and cost-effectiveness evidence. This is not part of the review protocols but an underpinning principle in NICE guidance. For this review, the health economic review protocol (Appendix D) was followed and one economic evaluation was identified that was based on a large RCT included in the clinical review, which found that acupuncture was cost-effective compared to usual care. However, overall when considering all of the clinical evidence the GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not relevant. This is explained more fully in the 'Trade-off between net clinical effects and costs' section of the recommendation and link to evidence table for this chapter. The decision against having a research recommendation for acupuncture comes from the large body of evidence included in the acupuncture review. The GDG have prioritised research recommendations for areas where the GDG felt they could determine the clinical effectiveness of an intervention due to the lack of or limited evidence available.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Acupuncture Council	Full	General	General	Alternative approaches to interpreting sham trial data (as outlined above) have polarised opinion, with debates appearing frequently in the scientific literature, the media and previous NICE guideline comments pages. The alternative view (to yours) is scientifically based and has considerable academic support; it is not confined to acupuncturists, though it benefits from their input. It would be good to see NICE paying heed to both lines of argument and taking a balanced, pragmatic position, as it did for CG88. It appears now to be moving in a direction determined more by ideology than science.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
British Acupuncture Council	Full	11	1	*GDG members*: see comment 7	Thank you for your comment. Please see our response to this comment
British Acupuncture Council	Full	40	22	Mock TENS is excluded as a sham on these grounds but perhaps should have been included as an attention control	Thank you for your comment. The GDG agreed that sham comparisons will only be included if they are a sham form of the intervention of interest, e.g. acupuncture versus sham acupuncture. Therefore acupuncture versus sham TENS would have been excluded as an incorrect comparator. Please see chapter 4 for more details.
British Acupuncture Council	Full	41	17	See comment 3 above. The issue is why relaxation controls are excluded for exercise but sham needling is allowed for acupuncture, given that both contain elements of the specific intervention	Thank you for your comment. The GDG considered that given the differences between exercise and relaxation, relaxation could not be considered a sham control for exercise as it would be clear to the participants that they were not receiving any form of exercise. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
British Acupuncture Council	Full	297	27	Incorrect: this study did not demonstrate a *benefit for exercise over placebo*: see comment 8	Thank you for your comment. This has been corrected.
British Acupuncture Council	Full	303	7	Trade-off, 1st paragraph: incorrect to say that there is any *evidence of benefit for exercise compared to sham*	Thank you for your comment. This has been amended to reflect that there was no evidence of a benefit of exercise compared to sham.
British Acupuncture Council	Full	303	7	Trade-off, 2nd paragraph: incorrect to say that either Albert 2012 or Smith 2001 reported *benefits in favour of exercise over sham:* see comment 8	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore the revised guideline will no longer haves any evidence for exercise versus sham including the Albert 2012 study which was subsequently excluded due to the sham arm comprising of another form of exercise. The Smith 2001 study has also been excluded due to the sham arm comprising of a relaxation audio tape, and therefore not fitting in to any of the interventions being addressed in the review. Therefore this paragraph has been reworded to reflect that no evidence was found reporting a benefit of exercise over sham.
British Acupuncture Council	Full	493	7	Trade-off between clinical benefits and harms: introductory paragraph. *Acupuncture must demonstrate specific effects over context/placebo*. This paragraph/requirement is unique to acupuncture in the guideline. See comment 5 above.	Thank you for your comment. As stated in methods chapter 4, where possible priority has been given to evidence for comparisons against placebo/sham. This has been done consistently across all reviews when developing recommendations.
British Acupuncture Council	Full	493	7	In the same paragraph, the second sentence talks about *sham acupuncture providing placebo controlled evidence*. See comment 2 above	Thank you for your comment. . The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
British Acupuncture Council	Full	493	7	In the same paragraph. *The approach used here follows the precedent set in the OA guideline*. Yes, but both of these are at odds with the approach used in CG88, and no explanation is given for this U-turn. Also at odds with the review question and with the approach used for the other interventions	Thank you for your comment. The methodology for best practice when conducting systematic reviews has developed since CG88, highlighting the need for an intervention to show treatment effects separate to non-specific effects before considering pragmatic trials. The importance of which has been recognised by the GDG. This was the same approach taken by CG150 when considering acupuncture for headaches as well as the OA guideline GC177. All of the reviews do look to determine both effectiveness and efficacy of treatments using 'effectiveness as a broad term to cover both). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components.
British Acupuncture Council	Full	493	7	In the same paragraph: *using sham comparisons for clinical decision making*. See comment 4 above	Thank you for your comment. As stated in methods chapter 4, where possible priority has been given to evidence for comparisons against placebo/sham. This has been done consistently across all reviews when developing recommendations.
British Acupuncture Council	Full	493	7	Acupuncture versus placebo/sham in low back pain without sciatica. *No clinical benefit for pain or function*. This needs to be reconsidered given the major data errors referred to above. See comment 9	Thank you for your comment. Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. However the GDG observed that the evidence was still conflicting for acupuncture versus sham. The GDG have therefore agreed that the updated evidence will not impact the recommendation.
British Acupuncture Council	Full	493	7	Same paragraph: *the heterogeneity seen in the short-term pain meta-analysis*. Even with the corrected data there is still substantial heterogeneity but this all results from one trial, Haake (2007). There are good reasons why this might be so and Cummings (2016) discusses the issues. What you do about it, and whether it should be a marked down as a negative characteristic of these data is another matter. Perhaps it could have been explored further (Gagnier et al, 2016). References Cummings M. Musings on heterogeneity in quantitative outcomes of acupuncture trials in LBP. Acupuncture in Medicine blogs. 4 April 2016. http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/ Gagnier JJ, Morgenstern H, Altman DG, Berlin J, Chang S, McCulloch P, Sun X, Moher D; Ann Arbor Clinical Heterogeneity Consensus Group Consensus-based recommendations for investigating clinical heterogeneity in systematic reviews. BMC Med Res Methodol. 2013 Aug 30;13:106.	Thank you for your comment. Subgroup analysis based on pre-specified criteria as agreed by the GDG during protocol setting i.e. chronicity of pain (acute or chronic) and individual therapies within a class of therapies (e.g. type of acupuncture) , was carried out to explore the heterogeneity, but did not explain this. Where heterogeneity remains unexplained, the evidence for that outcome is downgraded for inconsistency and a random effects meta-analysis is used as a more conservative estimate of the effect.
British Acupuncture Council	Full	494	1	Acupuncture vs usual care It is incorrect to say that one *study's quality of life data were only represented by the bodily pain domain*. This was so with the individual domains but there were also SF36 composite scores	Thank you for your comment. This is in reference to the study Thomas 2006 which only reported bodily pain at greater than 4 months' time-point.
British Acupuncture Council	Full	494	1	Same section as 32. *Whether or not there are sustained benefits in the longer term*: see comment 10 for a full discussion of this	Thank you for your comment. Please see our response to comment number 473.
British Acupuncture Council	Full	495	1	Summary *It's stated that there is no compelling evidence of a treatment-specific effect.*	Thank you for your comment, The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In fact there is excellent evidence that acupuncture is statistically superior to sham (Vickers et al 2012), which would indicate a treatment-specific effect There is quite good evidence that it is clinically superior using the guideline definition: see comment 9 Acupuncture has more compelling evidence in this respect than most other interventions and certainly better than the recommended exercise, manual and psychological therapies: see comment 5 Reference Vickers AJ, Cronin AM, Maschino AC, Lewith G, MacPherson H, Foster NE, Sherman KJ, Witt CM, Linde K; Acupuncture Trialists' Collaboration. Acupuncture for chronic pain: individual patient data meta-analysis. Arch Intern Med. 2012 Oct 22;172(19):1444-53	different. Where placebo or sham comparison evidence is available, this has been given priority in the review process to demonstrate a treatment effect separate from the non-specific treatment effects. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. Based on the sham evidence available for acupuncture, the GDG agreed that the evidence was conflicting, with limited short-term benefits seen for acupuncture.
British Acupuncture Council	Full	495	1	In the same paragraph as comment 33: *the concern that there was insufficient reporting of adverse events*. There is a wealth of evidence of acupuncture's safety from very large prospective surveys (e.g. MacPherson et al 2001), in which low back pain was the most frequent presenting complaint. There was no difference in adverse effects between acupuncture and sham or usual care in this guideline's analyses. Reference MacPherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34 000 treatments by traditional acupuncturists. BMJ. 2001 Sep 1;323(7311):486-7	Thank you for your comments. Prospective surveys were not included in this evidence review however in the linking evidence to recommendations section we do state that acupuncture was considered as a relatively safe procedure.
British Acupuncture Council	Full	495	1	Trade-off between net clinical effects and costs. *Acupuncture is cost-effective*: substantially more so than either exercise or manual therapies. *The evidence comes from only one RCT*: yes, but that's because you chose to exclude the high quality German economic evaluation in Witt (2006) that produced an estimate consistent with Thomas (2005). The trade-off is very much in favour of acupuncture: see comment 9	Thank you for your comment. Only included studies should be used to inform decision making and therefore an excluded study should not be used to reinforce the conclusions of an included study. The economic evaluation by Witt et al (2006) was excluded for the following reasons that are reported in Appendix M: total or incremental costs could not be extracted for an NHS perspective only and indirect costs are considered likely to account for a significant proportion of total costs. In addition, German resource use from 2001-2004 may not reflect current NHS context and the cost year was unclear. QALYs were estimated using a non-reference case measure (SF-6D).
British Acupuncture Council	Full	496	1	Quality of evidence *The issue of patient blinding and the effect estimate*: see comment 11	Thank you for your comment. As mentioned in Vickers 2013, "in most studies comparing acupuncture and sham acupuncture, providers obviously were aware of the treatment provided and, as such, a certain degree of bias of our effect estimate for specific effects cannot be entirely ruled out". Although Vickers 2013 go on to suggest that acupuncture would impose a lower risk of bias for unbinding than other non-drug interventions, it is not possible to measure this. Therefore, this risk of bias has been considered consistently for all studies included in this guideline where the providers or outcome assessors were not blinded to the treatment allocation.
British Acupuncture Council	Full	496	1	Other considerations *'The GDG considered that other treatments reviewed in the guideline had specific and clinically important treatment effects, beyond contextual effects'*. Please tell us which these are, as they evidence does not appear to support this.	Thank you for your comment. When reviewing the evidence, the GDG felt that evidence for other treatments which showed clinical benefit against a placebo/sham comparison, such as epidurals for the subgroup of people with acute sciatica, NSAIDs for people with low back pain with or without sciatica and combined psychological and physical packages for people with low back pain or sciatica, should be recommended in a NHS setting.
British Acupuncture Council	Full	496	1	Same section, second paragraph. *The GDG 'noted the lack of effect of acupuncture on pain outcomes in the sham-controlled trials'*. This no longer appears to be true (comment 8), so it's perfectly reasonable for specific pain effects to be driving the quality of life benefit	Thank you for your comments. Having reviewed the amendments to the evidence, the GDG agree that this statement is still valid.

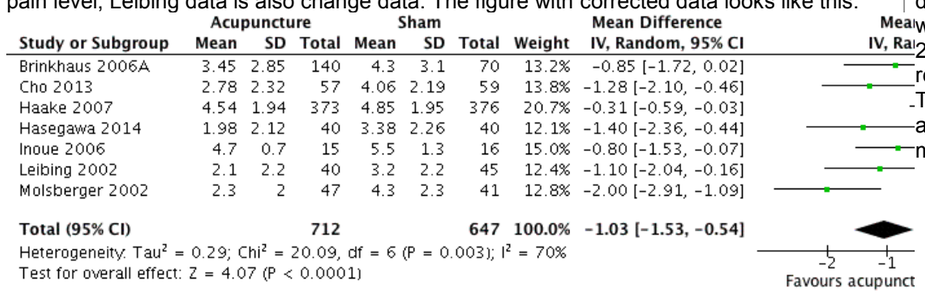
Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Acupuncture Council	Full	496	1	Same section, 4th paragraph. *NHS costs*: see comment 13	Our methods for reviewing and forming recommendations are explained in Chapter 4. Here we explain that when forming a recommendation the GDG consider both the clinical and cost-effectiveness evidence. This is not part of the review protocols but an underpinning principle in NICE guideline. For this review, the health economic review protocol (Appendix D) was followed and one economic evaluation was identified that was based on a large RCT included in the clinical review, which found that acupuncture was cost-effective compared to usual care. However, overall when considering all of the clinical evidence the GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not relevant. This is explained more fully in the 'Trade-off between net clinical effects and costs' section of the recommendation and link to evidence table for this chapter.
British Acupuncture Council	Full	496	1	Same section, 5th paragraph. *Passive treatment, dependence, self-management*: see comment 12	Thank you for your comment. The statement regarding dependency has now been removed from the LETR
British Acupuncture Council	Full	496	1	Same section, 6th paragraph. *Further research unlikely to alter conclusions*: see comment 13	Thank you for your comment. The GDG agreed that a research recommendation would not be necessary for acupuncture as there were a sufficient number of studies available and included within this review therefore, further research would be unlikely to provide more clarity on the effectiveness of acupuncture.
British Association of Prosthetists and Orthotists	Full	general	general	BAPO do not agree with recommendations 8, 9, and 10. These recommend against providing belts, corsets, insoles and rocker sole shoes. The draft guidance outlines the reasons that these statements were made. Essentially research surrounding the use of these orthoses is considered to be low strength and thus reliable conclusion cannot be made to support the use of these devices. BAPO would highlight that whilst evidence level is low, the majority of the studies considered did show positive outcomes using these devices. BAPO recognises that prescription of these items is currently a common modality with clinicians generally prescribing such items where professional expertise indicates that prescription may aid the patient to self manage the condition in acute stages principally to encourage participation in an active lifestyle and aid the return to work (particularly if manual/labour intensive). These goals are greatly supported by this draft guidance. To this end, BAPO would like to see the recommendations amended to the following: 'Do not routinely offer belts/corsets/insoles/rocker sole shoes without identifying that these devices may aid self-management return to work or maintenance of an active lifestyle. Clinicians should discourage long term reliance upon these devices." The amended statement highlights that these devices are not to be used for every patient but considered for on a case for case basis as a short term solution to symptoms. NICE do not suggest further research in the area. As evidence levels are low, BAPO would like to see recommendation for further research to support clinicians in identifying those who may best benefit from these orthoses.	Thank you for your response. As summarised on pages 344-346, the majority of evidence was not in favour for the use of orthotics and appliances. Of the 8 studies included for belts/corsets, short-term benefit was only seen in limited outcomes from 3 small studies; belts/corsets compared to massage, inextensible corsets compared to standard care (with serious imprecision), and corsets used in combination with manual therapy. Similarly, there was limited evidence in support of foot orthotics from the 4 studies included, with 2 small studies showing benefit of insoles in a total of 3 outcomes, and no benefit seen for rocker sole shoes. The GDG therefore felt confident in recommending against the use of orthotics and appliances for the management of low back pain with or without sciatica. The GDG also felt there was sufficient evidence included in this review; therefore a research recommendation was not required.
British Institute of Musculoskeletal Medicine	Full 1	General	General	The Council and members of the British Institute of Musculoskeletal Medicine are aware of the enormous difficulty of making guidelines for this area in which there are major scientific and conceptual variations between different groups leading to uncertainty in understanding, definition and terminology, of both conditions targeted and treatment given. Without robust entry criteria all studies are more vulnerable to Type II error. The paucity of reliable data could almost negate a process dedicated to evidence-based practice but the report has at least removed recommendations that have previously been made without support of robust data.	Thank you for your comments. The GDG considered research recommendations for all areas where there was a lack of evidence or an uncertain evidence base. As per the NICE manual for developing guidelines, 5 areas have been prioritised. The GDG recognised some promising results for the Alexander technique however results of a recent pilot study were not as positive and the GDG considered that as a pilot study for a larger research trial had recently been published, that other research areas were higher priority.

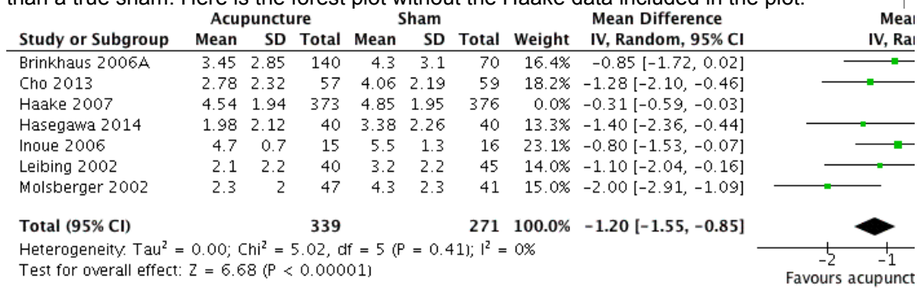
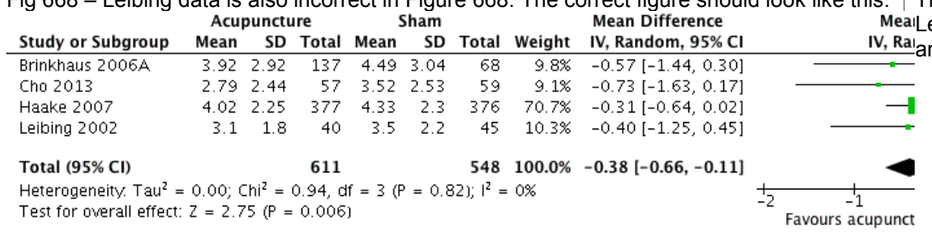
Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In this situation the recommendations for research could usefully highlight areas where uncertainty could be increasing burdens of cost and suffering. There are other national bodies charged with directing research policy but their targeted examination of the available data probably gives this GDG a unique opportunity to suggest priorities for a directive research policy as suggested by the Cochrane report of 1975. The latest trial evidence for manipulation and Alexander technique has not been generally appreciated but, in the case of the latter, dwarf the outcomes of any other published RCT, suggesting a potential for these two treatments to make enormous inroads into the burden of NSLBP both to sufferers and funders. This potential should lead to serious initiatives to confirm and if appropriate develop these methods. Any such promising trial results for a drug would lead to multi-million development programmes. The leisurely approach at present taken by the health service is not defensible. The implications for workforce training if these treatments are shown to be effective needs to lead to some contingency planning.	
British Medical Acupuncture Society	Appendix K	5-337	all	There appear to be numerous errors in the analysis of data in this draft guideline. Since recommendations are based on data, we can have little confidence in this guideline unless it is withdrawn and the data thoroughly checked and recommendations reconsidered.	Thank you for your comment. We apologise that there were some errors in the data analysis. All errors in the analysis of the data have now been corrected following stakeholder comments and changes have been re-presented to the GDG to consider the recommendations where necessary. Details of where amendments have been made are available in responses to the comments, however, please do note some of the suggested errors were misinterpretations of the data analysis; in these cases explanations have been provided.
British Medical Acupuncture Society	Appendix K	60	198	Fig 219 – the data in this figure is incorrect – there was no significant difference between groups in Albert 2012. This figure gives the impression of short-term efficacy of exercise over sham, yet the paper on which this is based demonstrates no such efficacy. The Guideline Development Group has recommended exercise in the absence of evidence of efficacy – this must be reconsidered, and the superior efficacy data on acupuncture must be reconsidered.	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore, the revised guideline will no longer have any evidence for exercise versus sham, including the Albert 2012 study which was subsequently excluded due to the intervention previously labelled as the sham arm comprising of another form of exercise.
British Medical Acupuncture Society	Appendix K	151	713	Fig 661 - the weighting in this forst plot appears to be incorrect. Haake has 742 participants and Brinkhaus has 210, yet the weighting is 58% vs 42%. The weighting in Fig 662 seems more likely to be correct.	Thank you for your comment. The values in figure 661 have been double checked and they have been accurately reported. The differences in weighting of the studies between the two forest plots is a result of the random effects analysis used in figure 661 due to the unresolved heterogeneity.
British Medical Acupuncture Society	Appendix K	151	713	Fig 661 - heterogeneity is high in Fig 661 and zero in Fig 662 with data from the same trials at different time points. This can be explained by the application of sham techniques in Haake as explained in point 2 above.	Thank you for your comment. The GDG agreed that heterogeneity would be assessed based on subgroup analysis for chronicity of pain or the type of acupuncture administered where applicable. However, this was not possible for these studies.
British Medical Acupuncture Society	Appendix K	153	719	Fig 667 – some of the data in this figure is incorrect – Brinkhaus is change data not absolute pain level; Leibing data is also change data. The figure with corrected data looks like this:  There is a mean difference of -1.03 ie over the minimum important difference. The lower confidence interval for the mean difference is -0.53, making this a very highly statistically significant result.	Thank you for your comment. The data in figure 667 has been checked and data from Brinkhaus 2006 has been amended. However, no amendments were necessary for data from Leibing 2002 as the change scores reported, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, which were correctly included in the meta-analysis. The GDG discussed the Haake data but agreed that this was considered an appropriate sham, and therefore the data should not be eliminated from the meta-analysis.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The heterogeneity here is explained by Haake – a multicentre trial with 300 participating centres, which resulted in the sham group receiving treatment closer to real acupuncture than a true sham. Here is the forest plot without the Haake data included in the plot:  The I² figure is now 0%. The mean difference is -1.20, and the lower confidence interval of the mean is -0.85. Heterogeneity is entirely explained by the outlying trial. The result is a significant and clinically meaningful effect above sham. Acupuncture should be recommended in the management of low back pain.	
British Medical Acupuncture Society	Appendix K	153	720	Fig 668 – Leibing data is also incorrect in Figure 668. The correct figure should look like this:  This demonstrates longterm efficacy of acupuncture over sham in low back pain. There is no such data for exercise or manual therapies. Acupuncture should be recommended in the management of low back pain.	Thank you for your comment. The data in figure 668 has been checked. Leibing 2002 has reported change scores which have been correctly meta-analysed in this forest plot.
British Medical Acupuncture Society	Appendix K	158	745	Fig 694 – the weighting in this forst plot appears to be incorrect. Haake has 734 participants and Yun has 123, yet the weighting is 17.9% vs 16.3%.	Thank you for your comment. The data for these studies have been checked and no change to the figure is needed as they have been accurately reported
British Medical Acupuncture Society	Appendix K	160	752	Fig 700 – the weighting in this forest plot is clearly erroneous. You have a study with 2841 participants given the same weighting as one with 40.	Thank you for your comment. Since Zaringhalam 2010 reports function on a RMDQ scale, this study has now been removed from figure 700 and pooled in the meta-analysis for RMDQ. Witt 2006 has a study population of low back pain with or without sciatica and has therefore been removed from this figure as well, and added to the evidence for the appropriate population. Haake 2007 is now the only study in figure 700.
British Pain Society	Full	General	General	<u>Comments on NICE draft guideline – Low Back Pain and sciatica: management of low back pain and sciatica. February 2016</u> Elected council members of the British Pain Society have reviewed the document on behalf of the BPS and comment as follows: The scope of the guideline and inclusion/exclusion criteria need to be clarified Section 4.3.1.1.1 states that the guideline includes the management of degenerative disc disease, spinal stenosis and pain secondary to lumbar degenerative disease. It also states	Thank you for your comments. The scope of the guideline was agreed following a stakeholder workshop and public consultation. The final version was published in January 2014 and amendments cannot be made at this stage. We have added detail in the introduction to clarify some of the exclusions that were agreed. The introduction has been clarified regarding the included and excluded causes of low back pain. Section 4.3.1.1.1. has also been updated, specifically to remove spondylosis from this list which was included with the

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				that the GDG agreed that spondylosis and osteoarthritis were excluded from the scope of the guideline. This is inconsistent because degenerative disc disease, spinal stenosis and lumbar degenerative disease generally are all manifestations of spondylosis and one of the most frequent consequences of lumbar spondylosis is painful facet osteoarthropathy. The guideline must be more specifically addressed: if it is intended to target the huge problem of low back pain in the young and middle aged population without substantial degenerative change, then the older population of patients with predominantly degenerative pathologies should be specifically excluded. Failure to do this will result in valuable treatments such as facet joint steroid injections being decommissioned because it is not understood that the elderly population generally do not have non-specific low back pain. Age has not been considered properly in the equality impact assessment If, in the alternative, it is intended that the management of elderly patients with low back pain due to degenerative pathologies is included in this guidance then the evidence considered by the GDG in coming to their conclusions is insufficient to support their recommendations. For example the two main studies used in the assessment of the efficacy of image guided lumbar facet joint steroid injections for low back pain include patients with different disease conditions from those encountered in elderly patients. The average age of patients in Carette (1991) was 42 years, and the patients in Mayor (2004) were suffering from chronic disabling work-related lumbar spinal disorders. These are entirely different study populations to elderly patients with back pain, who are likely to have advanced degrees of lumbar spondylosis including degenerative facet joint arthropathy that can reasonably be expected to respond better to locally injected steroid. This is particularly relevant because the treatments for non-specific low back pain that are suggested in the guideline are generally unsuitable for elderly patients (compared to non-elderly patients). These include exercise whether or not combined with psychological therapies, NSAIDs and radiofrequency denervation of the facet joints, which is more technically difficult and often impossible to perform in the presence of the advanced degenerative changes that are part of the ageing process. Furthermore the operative procedure to denervate the lumbar facet joints is often intolerable to elderly patients with back pain because of discomfort during a prolonged procedure. The Equality Act 2010 requires that *"the potential impact of a decision on people with different protected characteristics (in this case age) is always taken into account by a body subject to the duty as a mandatory relevant consideration"*. Furthermore, *"Where large numbers of vulnerable people – very many of whom share a relevant protected characteristic – are affected, consideration of the matters set out in the duty must be very high"*. The GDG have noted that *"image guided facet joint injections of steroid are widely used"* (22.6) and this is predominantly in the elderly population. The scoping equality impact assessment did highlight *"that advancing age may increase the likelihood of low back pain (associated with degenerative changes) or the complexity of the pharmacological management of pain because of an increased likelihood of co-morbidities with advancing age which may affect prescribing decisions"*, but the final equality impact assessment omits any reference to the potential for the guidance to have an untoward and disproportionate effect on elderly patients with painful degenerative lumbar conditions. In summary, facet joint injections amongst other procedures are widely used predominantly in elderly patients with lumbar spondylosis and repeated use is a strong indicator of clinical utility. This benefit of this has not been challenged in the draft guideline by any relevant scientific evidence and there are no reasonable alternative treatments for many elderly patients. NICE has a statutory duty to take this into account in providing the guidance.	guideline. Osteoarthritis were excluded if that was an inclusion criteria or primary focus of the trial as NICE guidance on the treatment of osteoarthritis already exists: CG177. The GDG considered throughout the reviews whether there were any groups that would be disadvantaged by the recommendations, and did not think that anyone was disadvantaged due to their age, as all recommendations should apply to adults of all ages. Older people are often not included in clinical trials, however the GDG did not believe there was any reason that the recommendations should not apply to people of all ages. Where studies of specific populations were included, this was detailed and discussed with the GDG. The trials reviewed for radiofrequency denervation did not suggest that increasing age was associated with a poorer response to radiofrequency denervation. The meta analysed trials varied in terms of inclusion criteria (22-55 yrs, 18-65 yrs, 36-79 yrs, 20-60 yrs , >17 yrs) and as such, no assumption can be made regards the contribution of age to treatment success or failure. Therefore we have not considered this as part of the equalities assessment form. It is expected that decision on appropriateness of the procedure would be based on shared decision making between the patient and the healthcare professional, in alignment with the NICE guideline on Patient Experience (CG138). Where there might be physical reasons that require interventions to be tailored, we have stated so in the recommendations (for example the recommendation for exercise). The recommendations made have been based on the evidence that was reviewed. It was agreed that there was no evidence of benefit of tricyclic antidepressants for low back pain, and therefore they should not be recommended. Unfortunately we were unable to cover sciatica within this review as this is already covered by the neuropathic pain guideline as you highlight. We acknowledge the concerns you raise regarding the gap that may occur for people with sciatica without well-defined neuropathic pain symptoms and have highlighted this to NICE. The evidence reviewed for pain management programmes was not restricted to populations who had already tried other interventions, therefore the GDG agreed that for certain subsets of people with low back pain or sciatica who were identified as high risk by stratification tools for example, or had significant psychosocial obstacles to recovery, these should be an option early in the pathway. The recommendation for self-management has been reworded to clarify that this should be a principle that applies across the treatment pathway. Regarding your comment about subgroups of responders. We recognise that there are areas where there may be subgroups of people who respond to treatment. Where there was evidence to define differential effectiveness in these subgroups, we have done so. We have also recommended that stratification should be considered to help identify groups and inform management.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Members' comments on clinical management: The proposal to actively recommend against any attempts with adjuvant analgesics (tricyclics and antidepressants) to alleviate chronic non-specific background pain seems to ignore clinical reality and research findings of central sensitisation in most patients with long-term pain. The review of pharmacological therapies restricts itself to only examining non-specific low back pain (i.e. excluding sciatica) whereas the remainder of the guidance considers low back pain with or without sciatica. I believe that this will be confusing to non-specialist readers. Neuropathic pain is covered in other NICE guidance, but patients with sciatica rarely present as people with just a well-defined neuropathic leg pain and most will present with accompanying back pain. In these instances the non-specialist may just recall the headlines of the NICE low back pain guidance and conclude that there are hardly any therapies that are worth trialling and patients won't be given medication that could well help (such as Amitriptyline, Duloxetine, Gabapentin and Pregabalin which NICE Guideline CG173 suggests may help). Other comments noted concern about: Recommending a pain management programme before interventions are performed, which may discourage commitment to self-management during the programme and, therefore, jeopardise the outcome of the programme. The current underprovision of pain management services, which must be addressed before recommendations for discouraging alternative management strategies are enacted. Members' comments on scientific method Since Andrew Moore's publications: (BMJ 2013;346:f2690 doi: 10.1136/bmj.f2690, Anaesthesia 2013, 68, 400–412) it should have been clear to the GDG that the majority of research studies, seemingly failing to show significant statistical effects on an entire study population, actually fail to report significant effect on subgroups of patients. Sadly, this means that potential treatment responders are taken hostage by the larger group of non-responders, hiding a significant subgroup effect. It would be scientifically more accurate to explicitly state that insufficient evidence of useful effect does not mean proof of lack of effect. A useful effect may still well be present but could not be proven beyond error of 5%, and only for the overall population of patients studied. The document is almost impossible to read, partly because of its length and partly because there are so many questions and then those questions are divided again and again. This makes it extremely difficult to understand. It also means that the authors have made many decisions about what studies should be grouped together and which should be considered separately. Furthermore, the reasoning behind those decisions is often unclear (and often lost in other parts of the overwhelmingly huge document). Unfortunately, these multiple divisions frequently leave the authors drawing conclusions on the basis of one study, with a relatively small number of participants and of low quality (see specific points below for examples). It may be that many busy pain clinicians will simply be baffled by the document and defer to the authors' expertise; meaning that they rely solely on the report's recommendations, without fully understanding how those conclusions were drawn.	We note that the document is large due to the breadth of the scope and the evidence reviewed. When setting protocols the GDG discussed and agreed the most appropriate pooling or splitting of the evidence to inform decision making. This included agreeing what outcomes would be considered and which were appropriate to pool and what treatments should be grouped. These are detailed in the protocols in Appendix C. Where outcomes could be pooled, they were, but for methodological reasons (explained in the methods chapter of the guideline) for example if change score and final values were reported from pain measures on different scales, results could not be pooled. The rationale for all recommendations has been detailed in the 'recommendation and link to evidence' tables at the end of each chapter. A shorter version of the guideline is also produced by NICE where a list of all the recommendations and priority research recommendations is available. Thank you for highlighting the American guidance which we were aware of. The evidence reviewed did not support the use of spinal injections for low back pain, although we have recommended that epidurals should be considered for people with acute severe sciatica.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Specific points: *Dividing effects according to arbitrary judgement about the specific measures used being different from one another* The divisions referred to above are at least questionable and, more broadly, are not clearly justified. For example, results relating to function and pain outcomes are frequently considered separately dependent on the specific measure that was used. Table 291 on Page 584 reports outcomes from two different pain intensity measures at less than or equal to 4 months follow-up (McGill and back pain log, specifically). Why are these considered separately? It seems that an *a priori* judgement has been made that these two measures are not measuring the same thing, which is an empirical question. This type of separation occurs repeatedly throughout the document. D*ividing effects according to arbitrary judgements about treatments being different from one another* There are many examples of this taking place throughout the document. For example in Section 15, Psychological Therapies, effects produced by cognitive therapy and those produced by cognitive behavioural therapy are analysed and presented separately. Are they really that distinct that they couldn't be considered together and then contrasted statistically to see if they really are different? This is one example, but there are many more throughout the guidance. D*ividing effects according to arbitrary judgements about controls being different from one another* This also happens frequently and doesn't seem to be particularly well justified. For example, Tables 195 and 196 on page 413 separate the effects produced by identical treatments – Manual therapy (manipulation) + exercise (biomechanical McKenzie) on the *a priori* basis that the control conditions, which are both forms of exercise (exercise – biomechanical – core stability vs exercise – biomechanical – stretching), are different and produce different effects. Again, an opportunity to compare these effects statistically has been missed because of assumptions that the authors make. After decades of research into treatments for low back pain one would have thought that there was by now enough research produced that would allow for an exploration of the various different factors, within and between treatments that are related to differences in the effects that are produced. This NICE guidance misses that opportunity by making, what seems like, arbitrary judgements about what those differences are. The result is a document that is so specific that the wood is lost for the trees and the evidence, unsurprisingly, when it is reduced to one study on n=47, is found to be lacking. Other considerations The BPS notes that The American Society of Anesthesiology has recently stated: "Maintaining access to spinal injection therapies can provide patients with the significant benefits of pain relief, improved function and quality of life, reducing their need for surgery or opioids, which is particularly important in light of the national opioid abuse epidemic." This opinion is supported by a wide number of organizations: American Academy of Pain Medicine, American Pain Society, American Society of Regional Anesthesia and Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, American Society of Spine Radiology, Congress of Neurological Surgeons, North American Neuromodulation Society, North American Spine Society, Society of	

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Interventional Radiology and Spine Intervention Society. Recommendations 1. The British Pain Society considers that the guideline is a helpful document in clarifying the evidence-based management of non-specific back pain and sciatica. 2. The scope of the guidance must be reconsidered and the management of mainly elderly patients with back pain due to specific degenerative conditions should be excluded from this guidance. 3. The guideline correctly highlights the lack of scientific evidence to support many elements of current clinical pain management but the use of the guideline to exclude these treatments in all patients would be unwarranted.	
British Society of neuroradiologists	FULL	115	general	Important to stress the importance of the so called ' red flag' signs and need for urgent imaging usually MRI. Again I refer the consultation to RCR iRefer Version 7.0.2 (Adult section/Musculoskeletal system)	Thank you for your comment. The importance of assessing an individual's signs and symptoms when considering the appropriate form of imaging has been highlighted in section 7.1, lines 24-26 on page 116 (Full guideline-Assessment and non-invasive). Furthermore, section 7.6, Other consideration' box states that 'the presence of symptoms or signs suggestive of possible serious underlying pathology (red flags), including a past history of cancer or trauma may warrant early imaging. We have included reference to common red flags in the introduction of the guideline and a list of these taken from NICE Referral Advice: A guide to appropriate referral from 563 general to specialist services in appendix P.
British Society of neuroradiologists	FULL	115	10-14	The BSNR would support this statement regarding the use of plain radiographs in lower back pain and would highlight the document iRefer Version 7.0.2 (available through the Royal College of Radiologists website). Unfortunately in practice many plain radiographs are performed which add nothing of value. The report goes back to the GP to consider MRI for those patients who have persistent severe symptoms and who may benefit from a surgical intervention. Those cases should have been referred for MRI initially.	Thank you for your comment and this information.
British Society of neuroradiologists	FULL	115	15-19	CT can be used when MRI contra-indicated and when further assessment of a spondylolisthesis (bony defect) is required	Thank you for your comment. Both imaging techniques were considered in the review. The use of CT scans is detailed in the introductory paragraph above that for MRI.
British Society of neuroradiologists	FULL	115	20-23	Agreed the preferred investigation for the diagnosis of most spinal disease and identifying those patients who may benefit from intervention (iRefer see above) Agree it is still a relatively expensive test but should be used as a first line investigation when symptoms are severe and interfering with life style. Avoid wasting resources on less 'sophisticated' investigations eg. plain radiographs and which add no diagnostic value.	Thank you for your comment. This introductory paragraph is intended to set the scene of current practice and the need for the review.
Central and North West London NHS Foundation Trust				You state that the report will also be useful for families and carers – but I cannot see anything in the report that would help me as a family member or carer of a person suffering from back pain and sciatica.	Thank you for your comment. NICE produces a range of materials to accompany the publication of this guideline. The Information for the public document will provide the key information in a more digestible format.
Central and North West London NHS Foundation Trust	Full 1			You discuss people with lower socioeconomic back pain being more susceptible to low back pain. I cannot see cultural factors and their effects on back pain being discussed in the report	Thank you for your comment. The GDG did not believe that any recommend would disadvantage this group. Where specific needs should be taken into account, this has been stated in the recommendation (for example the recommendation for exercise).
Central and North West London NHS Foundation Trust	Full 1	19	25-30	I would like to express my agreement for the statement beginning 'whilst the term 'non specific back pain' may be helpful to clinicians….'	Thank you for your comment. The introduction has been amended to clarify the different terms that may be used, and for uniformity, the term 'low back pain' is used throughout.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				I agree with your explanation of what non-specific back pain is and realize that there are many people with this condition but I also agree that the term is risky in terms of professionals and laymen interpreting it in the wrong way and merely seeing it as a psychological problem which would be devastating for the person suffering with it. Wouldn't the term 'un –diagnosed' back pain be less open to interpretation?	
Centre for Rehabilitation Research, University of Oxford	Full 1	570 - 606	general	Section: Psychological interventions As authors of the Back Skills Intervention and Trial, currently included in the section on Psychological Interventions, we disagree with the way that the intervention has been classified. The study should be re-classifed as MDR. The Back Skills Intervention uses cognitive behavioural approaches to target physical activity and exercise as the key behaviours. The intervention included assessment and prescription of exercise tailored to each individual, and identification of a physical activity goal which also formed an important part of the intervention. The importance of exercise was reinforced during the sessions, and in each one and a half hour session, dedicated time was given to performing and reviewing exercises. This is much more similar to the "exercise and cognitive intervention" described by Smeets and included in the Multi-disicplinary Biopsychosocial Rehabilitation (MBR) section (p673). The Back Skills Training intervention fulfils the criteria stated on p 674 Table 348 as "*A uni-disciplinary programmes including combined concepts: where it is one profession (usually Physio) who may be using cognitive - behavioural principles or a cognitive - behavioural approach, alongside exercise / education"* The description of the intervention is brief in the Lancet paper (Lamb et al Lancet. 2010; 375(9718):916-923), but expanded in Hansen, Z., Daykin, A. and Lamb, S., A cognitive-behavioural programme for the management of low back pain in primary care: a description and justification of the intervention used in the Back Skills Training Trial (BeST; ISRCTN 54717854), Physiotherapy, 2010, 96(2):87-94. See Table 1/Page 92. *And also in* Lamb, S. E., Lall, R., Hansen, Z., Castelnuovo, E., Withers, E. J., Nichols, V., Griffiths, F., et al., A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain. The Back Skills Training (BeST) trial, Health Technol Assess, 2010, 14(41):1-253, iii-iv. See page 7. We know that exercise component was implemented. In quality assurance checks, 97% of the groups observed (34/35) exercise was part of the session. The psychological elements which predominate were focused towards increasing physical activity, exercise and normal function despite pain.	Thank you for your comment. The intervention has been classified as a combination of psychological therapy (cognitive behavioural approach) and self-management (advice to stay active, the Back Book). This meets the criteria for inclusion in the Psychological therapies review and has therefore not been re-classified.
Centre for Rehabilitation Research, University of Oxford	Full 1	15	Figure 1	In Figure 1 it is stated *If there is an inadequate response to B then consider….* What is considered an inadequate response?	Thank you for your comment. The GDG has used this to mean when previous treatments failed to improve pain sufficiently, or have not helped enough to enable people to return to normal activity of daily life, including work
Chartered Society of Physiotherapy	Full 1	General	General	The Chartered Society of Physiotherapy (CSP) welcome the opportunity to comment on this guideline. We recognise the enormous amount of work that has gone into preparing this document and the potential for improving the quality of life for people with non-specific low back pain (NSLBP) and sciatica if this guideline is implemented. Whilst we welcome the guideline, aspects of it have highlighted tensions within the profession. Some recommendations are welcomed, but other recommendations are seen as very restrictive, with concerns about	Thank you for your comment. Please see our responses to each of your specific comments.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				how the recommendations were reached. This may act as a barrier to implementation and we would urge NICE to consider this when developing an appropriate approach to implementation. Whilst we agree with the general movement towards a biopsychosocial approach (rather than biomedical) with inclusion of exercise and self-management, we do have some concerns about specific aspects of the guideline, and the consistency of the guideline development group (GDG) approach to the evidence presented. These specific concerns are addressed in more detail below.	
Chartered Society of Physiotherapy	Full 1	15	Box A	As discussed above, our interpretation of the evidence is that this recommendation should be offered to all, and therefore should appear in Box A of the algorithm.	Thank you for your comment. We are unsure which recommendation you refer to specifically, however the algorithm has now been redrafted following stakeholder comments and we hope this addresses your query.
Chartered Society of Physiotherapy	Full 1	17	general	Psychological interventions Recommendation 18 is missing from the list on page 17 – please add the recommendation here.	Thank you for your comment. This omission has been fixed.
Extended Scope Practitioners Professional Network	Full 2	120	24	When recommending epidurals for acute sciatica, please clarify your definition of acute. If less than 6 weeks this would not be possible, or appropriate. If the patient has needed to have failed medication, physiotherapy and have had a MRI this would probably be nearer 3-5 months. These recommendations should improve access to epidurals in primary care, and reduce secondary care referrals and interventions	Thank you for your comment. 'Acute' was defined in the recommendations and link to evidence section of this review (28.6) as less than 3 months. This has now been added to the glossary of the guideline.
Extended Scope Practitioners Professional Network	Full 1	16	general	At times some of the recommendations appear contradictory. This is because they relate to different conditions such as NSLBP or acute sciatica or chronic LBP etc. Could these be better grouped together	Thank you for your comment. The recommendations in this guideline are first ordered by the nature of the intervention and secondly by whether it is for low back pain or sciatica. We feel that this is the most logical way of presenting the recommendations, and is in accordance with how the evidence reviews were conducted and presented. The algorithm has been remodelled for clarity and we hope this representation is clearer.
Extended Scope Practitioners Professional Network	Full 1	16	2	The STartBack Tool has been available for GPs for a number of years but is frequently omitted. Could this tool be put onto systmone for ease of use? Could a national back pain website be created incorporating the STartBack tool and subsequent self-management advice for patients and self-referral forms for patients dependant on their scoring? Our understanding is this tool was designed for back pain alone and not sciatica. Due to the high levels of distress experienced by patients with acute sciatica this could mean patients are stratified incorrectly into the high risk group and subsequently miss out on more active and hands on treatment.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. Regarding stratification of people with sciatica, the GDD acknowledged that all of the tools reviewed are validated in either solely low back pain populations or mixed populations of people with low back pain and/or sciatica, but none are validated for sciatica specifically. This is reflected in the 'Other considerations' box, section 6.6 on page 114. STartBack is provided as an example of a stratification tool that may be used, but other risk stratification tools could be considered. As there was evidence for the use of stratification tools in populations with low back pain and sciatica, the GDG agreed it was appropriate to state 'low back pain with or without sciatica' in the recommendation.
Faculty of Pain Medicine	FULL	General	general	Question 1: Diagnostics: Diverting the investigation Low Back Pain and Sciatica with MRI scanning totally away from primary care will have significant cost implications for the parts of the health service responsible for this part of the pathway. There needs to be an awareness of this with a change accounted for in contracting. There appears to have been considerable creep in the term to include diagnostic entities which were previously excluded.	Thank you for your comment. The guideline recommends referral for an opinion. There is no evidence that performing scans in primary care reduces subsequent referrals. The GDG were aware of the poor sensitivity and specificity of MRI scanning for undiagnosed low back pain and felt that this was not a helpful investigation unless it would change management. Advice from commissioners is that the cost of scanning is broadly the same in any setting of care. Local commissioners can decide how to commission a specialist opinion. In some localities, this is available in Musculoskeletal (MSK) Interface Clinics in hospital and community settings.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Faculty of Pain Medicine	FULL	general	general	Question 1 continued: The Faculty of Pain Medicine (FPM) consider that there is potential for substantial increase in costs for some CCG's that have put resources into acupuncture or spinal manipulation on the basis of the last NICE guidance. Facet joint injections are widely performed by various specialists (e.g. Orthopaedic Surgeons, Pain Medicine Specialist, Radiologists) If this procedure is reduced or stopped altogether, there will be some cost savings which can be directed towards MBB and Facet Radiofrequency, (RF) which has a stronger evidence base. However, the FPM has concerns regarding the Medial Branch Blocks (MBB)/Facet joint denervation financial model used in the new guidance is. It appears to be based on a single test MBB followed by denervation lasting 28 months. There is great variability in how long a denervation lasts, and many patients will gain substantial relief for periods considerably less than the over two years benefit suggested. It is possible that the number of repeat denervation procedures will be considerably higher than modelled, and as this will increase the costs. Criteria for what is a "positive response" or a "prolonged response" need to be clearly defined. It would be helpful if the guidance specified the degree of pain relief that should be achieved following MBB before proceeding to RF. Clarification is essential regarding what is meant regarding timing and repeats for epidurals. What constitutes a new episode? How will repeat epidurals be commissioned? The implementation of non x-ray guided caudal epidurals (without imaging) for management of sciatica prior to referral to secondary care throws up a number of concerns: Access of the epidural space via the sacro-coccygeal membrane is unpredictable when using the landmark technique in adults. This is supported through studies by Barham and Hilton (Barham G, Hilton A, (2010) Caudal epidurals; the accuracy of blind needle placement and the value of a confirmatory epidurogram. Eur Spine J (2010) 19: 1479-1483) and further by Price (2000) (CM Price, PD Rogers, NK Arden (2000) Extended Report : Comparison of the caudal and lumbar approaches to the epidural space. Ann Rheum Dis 2000;59: 879-882). The FPM strongly takes the view that landmark techniques into the epidural region for longterm pain problems where a procedure has failed due to (unrecognised) incorrect positioning (with or without increased pain) is an unacceptable clinical position Ref:Price CM, Rogers PD, Prosser AS, Arden NK Comparison of the caudal and lumbar approaches to the epidural space. Ann Rheum Dis. 2000 Nov;59(11):879-82. There is little in the proposed guidance that would refer to the cost of treatment failures - which may occur with this technique. The variation in response to analgesia and pain relief, has not been considered (Moore BMJ 2013). Whilst research seems to have a jumped a significant way in this to achieve more personalised medicine for pain in general, including low back pain, the GDG do not appear to have not taken this into account. The FPM would advocate that the guidance is more measured and only makes "Do Not" statements where the PICO's have taken both level of psychosocial distress and individual variation into account.	Thank you for your comment. Resources may be released by decommissioning interventions no longer recommended. If there are resource implications from implementing these guidelines, the GDG were reassured that the interventions were likely to be cost effective at a willingness to pay the threshold of £20,000 per QALY. The time period of 28 months was horizon for the economic model, and is not the recommended interval for repeat procedures. Whilst the economic review showed that procedures lasting 15 months were likely to be cost effective, the GDG urged caution when considering repeat radiofrequency denervation given the lack of long term outcome data. A prolonged response would be a period of pain relief significantly beyond the expected duration of local anaesthesia and one that would preclude the need for further treatment. In terms of a positive response, the majority of the trials in the review of radiofrequency denervation (Van Kleef, Van Wijck, Tekin) required 50% pain relief or greater from medial branch blocks. The topic experts suggested that >50% relief was the accepted practice in the UK currently. Timing for repeat epidurals was beyond the scope of epidurals in the review. Regarding imaging guided epidurals, the GDG were aware of existing special interest group guidance in the UK suggesting epidurals should be given under image-guidance based on safety grounds. However, there was limited evidence for a difference in effectiveness of image guided compared to non-image guided epidural injections from the evidence reviewed in the Epidurals chapter. The GDG decided to formulate a research recommendation to evaluate the clinical and cost effectiveness of image guided compared to non-image guided epidural injections in people with acute sciatica. A distribution around the duration of denervation effectiveness was used in the model to account for variability and uncertainty in the mean estimate. Therefore the base case results already capture this variability. The sensitivity analysis whereby the intervention was repeated, showed that this was cost effective; cost increases together with the overall QALYs; if the procedure is able to obtain a similar level and duration of pain relief, repeating the intervention is always cost effective. Regarding pain relief, the recommendation has been drafted on the evidence reviewed. Besides self-management, other recommendations apply to primary care. GPs and physiotherapists would be expected to assess and support people with low back pain, provide management and treatments listed in the recommendation, and monitor results. Regarding risk stratification, the GDG recommended STarTBack tool as an example of a stratification tool that may be used to inform stratified management. The GDG felt there was not enough evidence to recommend specific sets of interventions for stratified management. However, the recommendation has now been edited for clarity and the following has been

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It would appear that the GP and the Physiotherapist have little to do other than support the patient through adapting and problem solving. This risks a massive disengagement of what is a very large population from primary care management. The net result will be a massive shifting of costs to secondary care. The justification for this in the guideline is based upon the multiple systematic reviews carried out by the group. This assumes that once the very limited steps indicated in the algorithm are completed, those patients with poor outcomes will not continue to take up considerable primary and secondary care resources on a postcode lottery of other options. The "Startback tool" demonstrates that psychosocial factors are very important for some but not all patients in the outcome of treatment for back pain. This, and similar questionnaire systems (e.g DRAM) are useful tools to help guide early therapeutic interventions, but are simple statistical models. Large numbers of patients will not be reliably treated using these direction indicators alone. Oxford's large suite of pain rehabilitation programmes are now split by level of psychosocial distress and psychological interventions matched. Whilst the GDG recommends its use, the resultant PICO's are not adjusted to take splitting of the population into account and thus the reasoning is fundamentally flawed.	added: Based on risk stratification, consider simpler and less intensive support for those likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach).
Faculty of Pain Medicine	Full	General	General	Question 2: This guidance may increase demand for injection treatments in secondary care. Some acute trusts or community based pain teams may need assistance in providing this. There are significant limitations placed on pharmacology or therapies with low risk that might normally be considered when all else fails and undoubtedly help some people. The suggestion that analgesic and co-analgesic medication have no part in the management of long-term pain (of whatever site) has questionable clinical utility, and by limiting its remit to nonspecific low back pain and not more general analgesic models has limited the applicability of its guidance in this area. It is unlikely that either in primary or secondary care such a draconian policy would be implementable. TENS and acupuncture will likely fall into this category. The place of Pain management services providing care beyond the limits of the guidance may increase referrals from those that fail the pathway or are repeatedly referred into it and this will lead to the need for an increase in specialist in Pain Medicine, equipment and facilities. This may be a challenge for some commissioners and providers. Significant challenges will be implementing a). widely available delivery of psychologically based rehabilitation for low back pain b). delivery of programmes that return people to work and c)supporting GP's to explain to patients why MRI scans are not usually the answer and the limitations of analgesia, apart from NSAIDS. The pool of psychologists and physiotherapists with the required training to deliver the proposed scale of programmes envisaged by the draft document does not, we believe, currently exist and substantial posts and training opportunities will need to be created to support the increased workload To return people to work requires trained negotiators in vocational rehabilitation working in collaboration with NHS practitioners. Currently such services do not exist or only in small	Thank you for your comment. The recommendations developed in this guideline are in accordance with the evidence included in the evidence reviews. Where reviews have shown benefits demonstrated in the short-term which are not maintained in longer term follow-up, the GDG must take this into account during their decision-making process. Furthermore, where interventions have not proven superior in terms of clinical benefit over placebo/sham, where such comparisons are possible, the GDG are unable to recommend such an intervention in a NHS setting. Your comments will be considered by NICE where relevant support activity is being planned.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				pockets. The workforce outside general practitioners needs to understand what it takes to achieve this as it is often work conditions that prevent return to work rather than the individual per se and stigmatisation of the person with back pain often occurs. The new Fit4work service whilst admirable in its intentions does not achieve this as there is insufficient on the ground collaboration between NHS clinicians dealing with back pain and such agencies. Advising against TENS and acupuncture narrows down the management options and may paradoxically for some patients affirm the "medical model" of care delivery - and its failures ("No further treatment is likely to help"). This may in particular apply to the elderly, frail and those with central spinal stenosis (for whom the guidance offers very few options).	
Faculty of Pain Medicine	Full	General	General	Question 3: Improved patient and GP awareness/education of new guidelines would help implementation and align expectations. Improved working between primary and secondary care. Clarity as to the population this is aimed at and who it is not aimed at. Improved working between hospital specialties medical and non-medical. Oxfords Optimise suite of back pain rehabilitation programmes are a model of good practice. THE CQUIN for spinal networks needs to be extended to ensure that providers of conservative therapies have the opportunity to participate on an equal footing. Setting up fast track services for acute radicular pain (sciatic pain) so that they can be seen by a specialist, MRI organised and treatment planned- as in the PathFinder Project. The challenges outlined will have to be addressed through improved education and training; consideration of models already tested (Map Of Medicine spinal pathways, interface services) to assure timely assessment and diagnostics (including MRI if appropriate screening & triage procedures are implemented) and initial investment ('pump priming') for services at any level where mandatory elements of a coherent pathway are missing. Local priorities will vary, depending on the composition of already existing services. Local services will need to work together to provide a continuous and reliable care pathway.	Thank you for your comment, your comments will be considered by NICE where relevant support activity is being planned. Please submit your highlighted examples of good practice to the NICE website at the following link: https://www.nice.org.uk/about/what-we-do/into-practice/local-practice-case-studies/submit-a-case-study-example.
Faculty of Pain Medicine	Full	general	general	General comments: There is little strategic view of how to manage chronic pain and the use of Pain Management Programmes. There is a risk that Commissioners will remain confused. It is difficult to perceive any alternative treatments for patients unable to tolerate NSAIDS, opioids, neuropathics and who are not fit for surgery. It would appear that there is a common approach for all patients with low back pain with or without sciatica. There are many patients who present with a single episode or intermittent recurrence with essentially pain free periods in between. There is also a population (seen in primary and secondary care) who have continued significant pain and disability with fluctuations in severity. Do all these, especially the last group fit into these guidelines? Some clarification would help. It is this last group who utilise significant amounts of the clinical activity, revolve around multiple specialties (in and outside of secondary care), have a very poor quality of life and also impact on the broader national budget (out of work, carers, social support, not paying	Thank you for your comment. This guideline covers patients with non-specific low back pain with or without sciatica. All of the groups specified in your response are included within this. All review questions covered both acute and chronic pain, and were only separated when heterogeneity was observed, or where all evidence was for one of these specifically. Otherwise the GDG agreed that recommendations should apply to both acute and chronic pain. Where recommendations apply to very specific subsections of the population, this is specified in the recommendation to clarify,for example the recommendation for radiofrequency denervation specifies that such intervention should only be considered for people with chronic non-specific low back pain when non-surgical treatment has not worked for them, and the predominant source of pain is believed to originate from structures supplied by the medial branch nerve, and they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) when referred. Otherwise people with continued pain and disability are covered by all recommendations within the guideline.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				tax etc). The Pathfinder project is unlikely to address this as it will send this group of patients to specialist (secondary care) but the interventions and management strategies likely to be commissioned will come from this document. A concern is that with this guidance, these patients will be either be excluded from potential options in difficult scenarios, continue to attend primary care whose guidance is highly circumscribed or be seen in specialised units whose remit must be beyond the remit of this document as those options will have been tried and failed while continuing to have a very poor quality of life and high health care utilisation. Accepting not all can be improved is quite different from excluding all other options.	
Faculty of Pain Medicine	Full	general	general	General Comments: There is a broad assumption that the vast majority of patients will have their problems solved by the expanded use of pain management programmes. The research on this, which like most other situations, does not show 'success', but good results against usual care/placebo, there are still a large number of people who find the outcome inadequate for long-term (self) management. There is confusion over a general theme to avoid imaging, and a clear need to establish a diagnosis (and obtain any diagnosis or perform any intervention safely) The algorithm gives very few agreed options concluding with the bold statement: 'Additional treatment unlikely to be of benefit'. The remit of providing some symptomatic relief will largely be overridden by a very limited therapeutic repertoire. There is little or no acknowledgement of the good prognosis of back pain in the algorithm eg approximately 70-90% get better in first year. There is little consideration of the risk and costs of overtreatment (eg CPP) or of invasive treatment (eg RF) applied to those who will get better anyway. The timing of treatments and stratification to risk is crucial yet relatively underemphasised which threatens best patient care for chronic back pain. Though the pathway shows meticulous detail to evidence base of individual treatments, elements of the order of the pathway are not evidence based (e.g. radiofrequency lesioning occurring after combined psychology and physiotherapy (CPP)). This order may be irrational especially. PMPs for most refractory patients is not mentioned possibly because the evidence is not specific to back pain yet most attendants have these problems. The BPS PMP guidelines offer a clear consensus view and way forward to address the weaknesses fit for clinical use. Most experts would lean differently towards RF in different age groups given the limited duration of long-term benefit. The pathway would put overemphasis on RF in young patients. Acute and chronic are not defined in relation to time nor are there clear timelines for treatment.	Thank you for your comment. Regarding pain management programmes, when setting the protocols the GDG considered that such programmes would be considered under the broader heading of Multidisciplinary Biopsychosocial Rehabilitation programmes. Pain management programmes were considered within this definition. Please refer to chapter 17 for more details. The recommendation on imaging states that imaging should not be routinely offered in a non-specialist setting for low back pain with or without sciatica, but should be considered in a specialist setting of care if the result is likely to change management. Please see section 7.6 (Recommendations and link to evidence) for more details. The algorithm has now been updated. The statement regarding additional treatment unlikely to be of benefit has now been edited. Please see section 1.1. Regarding the order of the intervention in the pathway, the GDG based their decisions on the evidence by referring to the trials included in the reviews. For example, all trials of surgical interventions included people who had had previous treatments. Regarding people at low risk of poor outcome, the GDG recommended that risk stratification at first point of contact with a healthcare professional for each new episode of non-specific low back pain with or without sciatica be considered to inform shared decision-making about stratified management. This recommendation has now been edited to add the following sentence: Based on risk stratification, consider simpler and less intensive support for those likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach). The trials reviewed did not suggest that increasing age was associated with a poorer response to radiofrequency denervation. The meta analysed trials varied in terms of inclusion criteria (22-55 years, 18-65 years, 36-79 years, 20-60 years , >17 years) and as such, no assumption can be made regards the contribution of age to treatment success or failure.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				There is lack of distinction between evidence for early functional restorative type interventions (on a mixed risk group) and last-line PMPs to enable coping-for-life. The programmes are different, the patients are at different stages of their journey, the purpose is different and the outcome evidence must be interpreted differently. "No further treatment is likely to help" is a dangerous line. It is irrational as it ignores the evidence for expert pain management. We have concern that the algorithm for medicines in chronic pain is likely deeply flawed as it relies on poor trials indicating "lack of evidence for back pain" while ignoring what is known about the efficacy of painkillers in general. Low back pain and sciatica: management of non-specific low back pain and sciatica algorithm and 'full list of recommendations' suggests the definitive guide to managing this condition. Effectively this guidance is for facetogenic, discogenic, sacroiliac joint-related lower back pain with or without radicular pain, and the algorithm and 'full list of recommendations' will in all probability be considered the template and limits for future management and commissioning. However the content has a number of omissions and is considerably inconsistent with current practice and so could have significant and potentially negative impact. Omission or presentation of evidence as low quality or inadequate will be judged as direction not to commission High demand and demand versus capacity issues with impact on RTT and non-applicable waiting list delivery mean trusts may also be willing to jettison patients from their waiting list if endorsed to do so by commissioners and NICE. There is no money to expand contracting to meet current demand.	Acute and chronic pain are defined according to the pre-specified cut-off of 3 months. This cut-off has now been added to the Glossary, and has been reported for all studies in Appendix H. Where recommendations apply to a specific population, this has been made clear in the wording. The pharmacological treatment review was restricted to people with non-specific low back pain and sciatica. Reviewing the use of painkillers in other conditions was beyond the scope of this guideline. What this guideline covers and what this guideline does not cover is stated in section 2 (introduction) and further detailed in section 3.4.1 and section 3.4.2, respectively. The quality of evidence has been appraised following consistent methods and using consistent terminology throughout the guideline. These are outlined in section 4.3.4 (Appraising the quality of evidence by outcomes). Your comments will be considered by NICE where relevant support activity is being planned.
Faculty of Pain Medicine	Full	general	general	Psychology in the form of education around the concept of chronic pain and importance of self-management should be integral to pathway. Such a pain management programme should not be considered only at the end of the line or in the presence of significant psychological obstacles. Failure to understand and engage with fundamental chronic pain concepts is a barrier to progress in the majority of patients and fosters a persistent acute pain model and dependency on escalating and long-term medication as well as on intervention. Would a recommendation be to consider a significant public health campaign vis a vis the Buchbinder trial? This used social marketing techniques and TV adverts as opposed to Health backs Scotland which used only radio so probably missed many people with sedentary behaviours. The place of the combined psychology/physiotherapy programme seems about right as Psychological techniques are about getting people to make changes when they are finding it difficult to do so. Education = advice on self-management which people need to know and some may find it easy to adapt and make changes and agree very much needs to be provided very early –as education is a very weak way to change behaviour Price C1, Williams AC, Main CJ. Rehabilitation for chronic low back pain. Review was of little help in selecting treatment.BMJ. 2001 Nov 24;323(7323):1251-2.	Thank you for your comment. The GDG felt that every healthcare professional is expected to provide advice and education to their patients and that every programme should contain some elements of self-management. The wording of the recommendation has been updated to clarify this. Furthermore, psychological therapies are considered if provided as a package of treatment including exercise with or without manual therapies. This has been recommended as a treatment early in the pathway. Please note that it is outside the remit of this guideline to consider public health campaigns.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Faculty of Pain Medicine	Full	general	general	• *'Consider epidural injections of local anaesthetic and steroid in people with acute sciatica.'* Define acute, first episode and/ or acute exacerbation? Guidance appears to be referring to pain for less than 3 months. However evidence is drawn from heterogeneous group of acute and chronic radicular pains. Repeat epidurals for chronic radicular pain is a significant part of clinical practice. Is this to end? What are the alternatives? SCS for radicular pain as an alternative to surgery? There is also no mention of nucleoplasty or pulsed radiofrequency. .	Thank you for your comment. Acute has been defined within the guideline as less than 3 months duration. This has been added to the glossary for clarity. Although the evidence reviewed was for mixed populations of acute and chronic pain, and in some cases this was not clear, most of the RCT evidence in the review came from people with acute and moderately severe sciatica, and the GDG considered that this would be the population most likely to benefit from epidural injections. This is stated in the 'recommendation and link to evidence' section of this chapter. The recommendation is not specific to the first episode of pain however as this is recommended for people who have had pain for < 3 months, the GDG considered it unlikely that repeat injections for the same episode would be offered within this timeframe. The trials reviewed did not suggest that increasing age was associated with a poorer response to radiofrequency denervation. The meta analysed trials varied in terms of inclusion criteria (22-55 yeas, 18-65 years, 36-79 years, 20-60 years , >17 years) and as such, no assumption can be made regards the contribution of age to treatment success or failure.
Faculty of Pain Medicine	full	general	General	• *'Do not allow a person's BMI, smoking status or psychological distress to influence the decision to refer them for a surgical opinion for sciatica.'* Does this influence decision to operate? Smoking and obesity are common criteria for rejection.	Thank you for your comment. The objective of this review was to determine the optimal clinically and cost effective criteria for referral for surgical opinion of people with sciatica (see protocol in table 20, Appendix C, section C.18) and looked at the response to surgery as an outcome. The review is therefore not specific to the decision to operate, but it is acknowledged in the evidence and link to recommendations that the decision to operate should be a process of shared decision making of the benefits and risks, and that BMI, smoking or psychological distress should not be used to deny people surgery for low back pain or sciatica.
Faculty of Pain Medicine	full	general	general	Is it practical to deliver diagnostic block, assess outcome and then perform RF for all facetogenic back pain? Facetogenic back pain may make up 1/3 of patients. There is not theatre time available to do this in a timely fashion and it takes at least 3 times as long to perform RF than standard medial branch blocks presenting significant capacity issues. There was acceptance that some patients had repeat procedures but the evidence for this was not reviewed and the practice was discouraged 'Clinicians should be cautious about offering repeat procedures until long term effectiveness data becomes available. If repeat procedures are to be offered we need to be certain of effectiveness and cost effectiveness.' No mention of sacroiliac joint related back pain. No guidance on when sacroiliac joint injections or sacroiliac joint radiofrequency denervation are indicated. If people have predominantly neuropathic pain then it makes sense to treat this. Why were screening tools such as Pain Detect not recommended? Low back pain and sciatica are a highly heterogenous group covering a huge proportion of the population. It is unclear whether any form of assessment of the diagnostic criteria of the various papers included, or excluded, where consistent or robust enough out with their stated aims of	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. However we have limited the population within the recommendation to only those with chronic low back pain who have received an inadequate response to non-surgical treatment and a pain score of 5 or more on a visual analogue scale. Therefore we believe this will only be a subset of those with facetogenic back pain. Sacroiliac joint pain has not been included within the guideline due to being pelvic ring pain. Screening tools were not prioritised as an area to cover within the guideline during the scoping phase, therefore we cannot comment on tools such as Pain Detect. The specific questions you suggest regarding effectiveness of biopsychosocial assessment in determining the right treatment pathway and stepped care approach to management were also not prioritised as reviews within the guideline. However, the reviews on risk tools and stratification were included to determine if subgroups of people could be identified to target treatment. Unfortunately the evidence review did not enable specific recommendations for stepped care to be made.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'assessing an intervention in low back pain' rather than just confine the review to risk stratification tools and Eg to ask the questions ○ What is the evidence for the clinical and cost effectiveness of a biopsychosocial assessment in determining the right treatment pathway? ○ What is the evidence for the clinical and cost effectiveness of a stepped care approach to the management of low back pain and sciatica? (Von Korff) Sciatica is a term used very loosely. It is seems confused and mixed with referred pain from the back for the purposes of this guideline. Whilst this distinction is not made in primary care, it can be understood why the GDG took the decision to do this this then impacts on the rest of the epidemiology, potentially any cost benefits calculations and the type of treatment given. It is a unclear that the GDG did not classify it into neuropathic pain which is its natural diagnostic home. One study suggested 55% still had symptoms of sciatica 2 years later, and 53% after 4 years. Another suggested 30% of patients experiencing persistent troublesome symptoms at 1 year, 20% out of work and 5–15% requiring surgery (Weber H, Holme I, Amlie E. The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam. Spine 1993;18:1433–8., Bush K, Cowan N, Katz DE, Gishen P. The natural history of sciatica associated with disc pathology. A prospective study with clinical and independent radiologic follow-up. Spine 1992;17:1205–12. Tubach F, Beaute J, Leclerc A. Natural history and prognostic indicators of sciatica. J Clin Epidemiol 2004;57:174–9. Beyond 12 weeks the outcomes are very poor indeed. There has been very little research into prognostic factors in this group however high psychosocial risk seems to predict response to surgery (Boogaard S, Heymans MW, de Vet HC, Peters ML, Loer SA, Zuurmond WW, Perez RS.Pain Physician. Predictors of Persistent Neuropathic Pain--A Systematic Review. 2015 Sep-Oct;18(5):433-57. The GDG potentially have underestimated the impact of lack of timely care for this much smaller group. The same could be said of those with spinal stenosis and true radicular pain whose outcome is even worse. Surely with this level of prognosis even a small improvement is significant? The outcome measures described and assessed for clinical significance only apply to low back pain and not neuropathic pain secondary to nerve root compression. This appears to fail to recognise nerve root compression symptoms as neuropathic symptoms Does a firm radiological diagnosis then take the management outside these guidelines? E.g Sacroiliac joint, kyphoscoliosis etc The document states: *This guideline does not cover the evaluation or care of people with sciatica with progressive neurological deficit or cauda equina syndrome.* Many patients show some neurological deficit +/- progressive which are not neurological emergencies. Thus is this document suggesting that it covers only radicular pain not radiculopathies? Some clarification of the issue of repeat procedures would be welcomed. (Ref: Novak S, Nemeth The basis for recommending repeating epidural steroid injections for radicular low back pain: a literature review. Arch Phys Med Rehabil. 2008 Mar;89(3):543-52. Pain Physician. 2016 Feb;19(2):E283-90. Can Repeat Injection Provide Clinical Benefit in Patients with Lumbosacral Diseases When First Epidural Injection Results Only in Partial Response?	The introduction has been reworded to clarify the use of the term sciatica within the guideline. The GDG agreed the outcomes for each review question when setting the questions and believed they were the most appropriate outcomes relevant for both low back pain and sciatica. The population covered by this guidance excludes those patients with progressive neurological sensory or motor deficit. Whilst not all patients with progressive neurological deficit require emergency referral, they do require a course of management outside the scope and remit of this guideline. The GDG wished to highlight the lack of evidence identified for benzodiazepines, and hence drafted a high priority research recommendation. There was no available evidence to inform a treatment recommendation. The review of multidisciplinary biopsychosocial rehabilitation programmes informed the recommendation for combined physical and psychological programmes. The evidence suggested that the key components of such a programme were physical and psychological interventions, however the treatments used in the trials were tailored to the individuals and varied in the trials, therefore the GDG agreed that the recommendation should not be more prescriptive. Diagnostic blocks for suspected facet joint/posterior element pain are included in the recommendation for radiofrequency denervation. Suspected sacroiliac joint pain was considered during the scoping review to represent a pelvic pain problem and was excluded from the guideline. Trigger point injections were reviewed in the spinal injections review. The recommendation for risk stratification has been reworded to suggest that low intensity treatments should be considered for those at low risk, and higher intensity for those identified as being at high risk.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Murthy NS1, Geske JR, Shelerud RA, Wald JT, Diehn FE, Thielen KR, Kaufmann TJ, Morris JM, Lehman VT, Amrami KK, Carter RE, Maus TP. The effectiveness of repeat lumbar transforaminal epidural steroid injections. Pain Med. 2014 Oct;15(10):1686-94. The document mentions benzodiazepines in the research section but appears to avoid it in the guidance section. This should be mentioned in the latter if only to state that evidence is equivocal. It should at least highlight that any treatment should be limited on a temporal basis to a few days with acute problems. No discussion of the use of specific diagnostic/therapeutic blocks e.g. SIJ which was specifically omitted. No discussion regarding trigger point therapy. There should be more comprehensive guidance on: *Combined physical and psychological programmes.* No mention of stratified care other than startback, length of input, which care staff most appropriate.	
Faculty of Pain Medicine	FULL	19 39	general	Question 1 continued: CG888 p4 "Non-specific low back pain is tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain. Several structures in the back, including the joints, discs and connective tissues, may contribute to symptoms". Current Draft: " (p19)A diagnosis of non-specific low back pain simply means that the back pain is very unlikely to be caused by serious pathology.....(p39) Non-specific low back pain : Discogenic pain, Degenerative disc disease, Spinal stenosis, Lumbar disc herniation, Secondary to lumbar degenerative disease. There is no clear indication when "Non-specific" becomes "Specific".	Thank you for your comment. The introduction has now been reworded to clarify the definition of non-specific low back pain used in this guideline and the term low back pain is now used throughout (with the exception of the review questions) for clarity.
Faculty of Sport and Exercise Medicine	Full 1	General	General	This is an excellent and highly topically review. The combining of the scopes of the previous guidelines is very useful. As a first timer involved in this consultation exercise it has been an enlightening experience into the effort that goes into producing these guidelines.	Thank you for your comment.
Faculty of Sport and Exercise Medicine	Full 1	General	General	In general, outside of classification at the start of an episode for prognostic factors, there is no further discussion of the role of further sub classifying patients with non specific low back pain with or without sciatica. As stated in the introduction non specific low back pain is a common and heterogeneous condition where it can be difficult to pin point the pain origin. We feel that this contributes to the mixed evidence presented for most interventions. We feel that this excellent review of the current evidence base presents an ideal opportunity for a call to research the effectiveness of interventions after further sub classification and, indeed, into the methods of sub classification themselves.	Thank you for your comment. We agree that sub-classifying of people with low back pain and sciatica could help identify groups who may benefit from specific interventions. Where evidence reviews enabled subgroups to be defined (e.g. radiofrequency denervation, or epidurals for acute severe sciatica) we have indicated specific groups in the recommendation. However, beyond the stratification review, sub-classification for intervention response was not reviewed specifically, therefore we are unable to prioritise a research recommendation in this area.
Faculty of Sport and Exercise Medicine	Full 1	15	1	Box B: the 'OR' could be considered confusing as it only appears between two statements whereas in fact there are four options for approaches to be considered in this box which are not mutually exclusive	Thank you for your comment. The algorithm has been extensively remodelled for clarity.
Faculty of Sport and Exercise Medicine	Full 1	15	1	Box for 'sciatica predominant treatment': what are the definitions of 'acute' & 'non specific low back pain' and 'sciatica'? Non specific low back pain and sciatica are defined in the introduction but not 'acute'. Although there is some reference to this being less than 3 months in relation to epidural injections (Invasive guidance, page 122 in 'Trade off between bet clinical effects and costs' section). Would it be useful to consider including these definitions within the algorithm?	Thank you for your comment. Footnotes have been added to the algorithm to define acute sciatica (symptoms present for less than 3 months).

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Federation of Holistic Therapists	Appendices K-Q	153	719	Figure 667 shows a forest plot for pain severity (VAS 0–10) ≤4 months for the studies included in the review that compared acupuncture to sham acupuncture. The FHT would like to highlight that data errors were made in Figure 667, which shows a forest plot for pain severity (VAS 0–10) ≤ 4 months in the studies included in the review that compared acupuncture to sham acupuncture. In a recent BMJ blog post, Dr Mike Cummings[1] highlighted there were data errors in Figure 667, which impacted clinical significance. When Cummings dropped the pain VAS outcome figures from the trials of acupuncture versus sham into RevMan 5, the total mean difference in pain reached clinical significance. The FHT is concerned that errors have been made when analysing data as this can potentially impact GDG/NICE recommendations. 1. http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/	Thank you for your comment. Of the 2 errors highlighted, data from Brinkhaus 2006 has been amended as suggested. The data from Leibing 2002 however has been checked, and the change scores, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, have been accurately meta-analysed, therefore no changes were made for this study. We apologise for any inaccuracies.
Federation of Holistic Therapists	Appendices K-Q	153	720	Figure 668 shows a forest plot for pain severity (VAS 0–10) > 4 months in the studies included in the review that compared acupuncture to sham acupuncture. The FHT would like to highlight that data errors were made in Figure 668, which shows a forest plot for pain severity (VAS 0–10) > 4 months in the studies included in the review that compared acupuncture to sham acupuncture. In a recent BMJ blog post, Dr Mike Cummings[1] highlighted there were data errors in Figure 668, which impacted clinical significance. The pain VAS outcome for Leibing was published as a negative value. Cummings highlights that: 'the negative figure is clearly a change value, not an absolute value of pain at the relevant time point (this is the same data entry error made for the Brinkhaus data)'. The FHT is concerned that errors have been made when analysing data as this can potentially impact GDG/NICE recommendations. 1. http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/	Thank you for your comment. The data in figure 668 has been checked and no amendments were necessary as Leibing 2002 reports change scores which have been correctly included in the meta-analysis.
Grunenthal	Full	15	1	Existing guidance promotes the availability of a range of pharmacological and non-pharmacological treatment options in order to maximise the potential for a positive response given that only a minority of people with chronic low back pain respond to any given intervention. The efficient use of NHS resources is best managed by the prompt discontinuation of ineffective therapies, rather than denying their use from the outset. We are concerned that the reduction in the number of treatment options recommended in this draft guideline will lead to a reduction in the number of patients achieving significant relief from chronic low back pain and a resultant increase in the referral of patients to secondary care due to an inadequate response to treatment.	Thank you for your comment. Since the aim of this guideline is to offer the most clinical and cost effective treatments, the GDG have drafted recommendations for areas they feel will be of most benefit to people with low back pain and sciatica and therefore to make best use of NHS resources.
Grunenthal	Full	32	Table 1 Chapter 16	The review questions cite healthcare utilisation (prescribing, investigations, hospitalisation or health professional visit) as important outcomes to evaluate when considering the use of an intervention. However healthcare utilisation cannot be collected in RCTs as the structure imposed to ensure high interval validity of such trials interferes with the naturalistic use of resources observed in routine clinical practice. Healthcare utilisation can best be measured using observational study methodology. If the GDG define healthcare utilisation as an important outcome, the study type filter in the systematic evidence searches should be amended to include observational studies.	Thank you for your comment. This was agreed as an important outcome when setting the protocols with the GDG. We have identified data which report this as an outcome, including from RCTs. We can further confirm that where evidence was lacking or limited, searches were extended to observational studies, as detailed in the protocols.
Grunenthal	Full	607	6-9	By excluding the pharmacological management of low back pain with sciatica and referring to the clinical guideline on neuropathic pain (CG 173) this review inadvertently excludes pertinent evidence on the use of tapentadol prolonged release (PR); the most recently introduced strong centrally acting analgesic.	Thank you for your comment. Since CG173 was published in 2013 and updated in December 2014, and included sciatica within the conditions covered, it was agreed that pharmacological management of sciatica did not need to be included within the scope of this update.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Tapentadol is a centrally-acting analgesic that combines two mechanisms of action in a single molecule. Tapentadol acts as a μ-opioid receptor (MOR) agonist and noradrenaline reuptake inhibitor (NRI) throughout the whole duration of action of the drug, which may explain its synergistic effect on pain relief[1]. Despite an 18-fold lower affinity for human μ receptors than morphine[1,2], tapentadol's NRI mechanism of action has an opioid-sparing effect resulting in strong analgesia, comparable to that of classical strong opioids, but with a reduced opioid load. This results in reduced opioid-typical side effects such as nausea and vomiting, constipation, and the potential for abuse[1]. The following RCTs on the use of tapentadol PR in the management of severe chronic low back pain with a neuropathic component were published after CG 173:- A study by Baron et al[3] demonstrated that the effectiveness of tapentadol PR was clinically and statistically comparable to tapentadol PR / pregabalin combination therapy with improved CNS tolerability, suggesting that tapentadol PR monotherapy may offer a favourable treatment option. Tapentadol PR treatment resulted in a clinically significant drop in pain severity (NRS -1.6) and clinically significant improvements in SF-12 physical functioning, role-physical, bodily pain, general health, vitality and social functioning subscale scores and the physical health composite score from randomisation to final evaluation. In a second study by the same author[4] tapentadol PR demonstrated a statistically superior reduction in pain severity (NRS -0.9) vs oxycodone/naloxone PR. In addition significantly greater improvements from baseline to final evaluation were observed in the tapentadol PR group compared with the oxycodone/naloxone PR group for the mean physical component summary score and six of the SF-12 domain scores (all P ≤ 0.017 for superiority, tapentadol PR vs. oxycodone/naloxone PR)[5]. The above-mentioned evidence suggests that tapentadol PR exhibits an improved risk vs benefit profile and therefore provides a suitable alternative to conventional strong opioids as part of the holistic management of severe chronic low back pain, particularly in patients where a neuropathic component to their pain cannot be excluded. Given the extended remit of the revised guideline to include sciatica, consideration should be given to including evidence on the pharmacological management of low back pain with sciatica published since the neuropathic pain guideline (CG 173) in November 2013. [1] Tzschentke T.M. et al. (2014). The mu-opioid receptor agonist/noradrenaline reuptake inhibition (MOR-NRI) concept in analgesia: the case of tapentadol. CNS Drugs 28(4): 319-329. [2] Tzschentke T.M. et al. (2009). Tapentadol hydrochloride: a next-generation, centrally acting analgesic with two mechanisms of action in a single molecule. Drugs Today (Barc) 45(7): 483-496. [3] Baron R. et al. (2015) Effectiveness and Safety of Tapentadol Prolonged Release (PR) Versus a Combination of Tapentadol PR and Pregabalin for the Management of Severe, Chronic Low Back Pain With a Neuropathic Component: A Randomized, Double-blind, Phase 3b Study. Pain Pract. 15(5): 455 – 470. [4] Baron R et al. (2015) Effectiveness of Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR for the Management of Severe Chronic Low Back Pain with a	

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Neuropathic Component: A Randomized, Controlled, Open-Label, Phase 3b/4 Study. Pain Pract. (DOI: 10.1111/papr.12308) [5] Baron R et al. (2015) Tolerability, Safety, and Quality of Life with Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR in Patients with Severe Chronic Low Back Pain with a Neuropathic Component: A Randomized, Controlled, Open-label, Phase 3b/4 Trial. Pain Pract. (DOI: 10.1111/papr.12361)	
Grunenthal	Full	607	24 - 26	Most pharmacological therapies have dose dependent limitations to treatment therefore it is inequitable to only highlight the limitations to opioids in this section. Furthermore there is no acknowledgement of the fact that drugs acting on μ opioid receptors have different side effect profiles. The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System demonstrated that abuse of tapentadol immediate release tablets in the US was lower than either oxycodone or hydrocodone during its first 24 months on the market[1]. Thus tapentadol is creating less public health burden (e.g. arrests, admissions to public detoxification programmes, calls to poison centres etc.) than oxycodone. In addition tapentadol tablet diversion remained lower than either oxycodone or hydrocodone and was comparable to tramadol[1]. A second database study confirmed that abuse of either tapentadol prolonged release or tapentadol immediate release preparations was reported significantly less often than a number of other strong opioids including morphine and oxycodone (P< 0.001)[2]. This finding remained when the results were adjusted for variations in prescription volume (calculated as risk of abuse for every 10,000 prescriptions dispensed)[2]. [1] Dart R. et al. (2012). Assessment of the abuse of tapentadol immediate release: the first 24 months. J Opioid Management 8: doi:10.5055/jom.2012.0139 [2] Butler S et al. (2015). Tapentadol Abuse Potential: A Postmarketing Evaluation Using a Sample of Individuals Evaluated for Substance Abuse Treatment. Pain Med 16(1): 119-130.	Thank you for your comment. Evidence for tapentadol was included in this guideline as a form of opioid, however the GDG did not look at within-class comparisons. Therefore tapentadol was not be directly compared to other opioids. Evidence for adverse events was sought for all pharmacological groups included in the review and highlighted where available.
Grunenthal	Full	662	Table 347	Failing to ensure that equianalgesic doses are included in the table of the costs of analgesics results in a distorted view of the comparative annual costs of opioid therapy. The equianalgesic dose ratio of tapentadol to oxycodone is 5:1. Therefore the equianalgesic dose of 30mg oxycodone is 150mg of tapentadol per day at an annual cost of £487.08, similar to the cost of oxycodone.	Thank you for your comment. We have explained in footnote b in the table that the cost per day is calculated based on the maximum recommended dosage as described in the BNF. The costs presented in the table are only indicative as we are aware that dosages would vary for each individual patient.
Grunenthal	Full	664	35 – 40	This evidence statement fails to capture the favourable clinical benefit of tapentadol over placebo in terms of physical quality of life (least squares mean difference in; physical component summary (2.3), physical functioning (4.1), role physical (9.9) body pain (5.5) and vitality (3.2); and the 30% and 50% responder criteria for improvement in pain severity observed in the study by Buynak et al. (46% and 43% increase in the proportion of patients experiencing a ≥ 30% and ≥ 50% improvement s respectively).	Thank you for your comment. The benefits of tapentadol have been captured within the evidence statements. However, since the GDG consider evidence for opioids as a whole rather than for each type of drug included in this category, the evidence statements will not specify which opioid is being referred to for the outcomes mentioned.
Grunenthal	Full	671	Other considerations	The GDG noted that no studies reported outcomes beyond 4 months. However In November 2015 Buynak and colleagues reported that pain relief, improvements in quality of life and the safety and tolerability profile achieved during preceding studies were maintained on tapentadol prolonged release in an open-label extension study of 1,154 chronic pain patients for up to 2 years of treatment[1]. Whilst this study also involved patients with osteoarthritis as well as patients with chronic low back pain, the result has greater validity than referring to the guideline on neuropathic pain for the management of sciatica, in which the evidence in the neuropathic pain was derived	Thank you for your comment. Unfortunately we are unable to include this study due to the population including patients with osteoarthritis, which is beyond the scope of the guideline and it was agreed when setting protocols that only direct populations would be included.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				principally from studies in post herpetic neuralgia (PHN) and Diabetic Peripheral Neuropathy (DPN). [1] Buynak R et al. Long-Term Safety and Efficacy of Tapentadol Extended Release Following up to 2 Years of Treatment in Patients With Moderate to Severe, Chronic Pain: Results of an Open-Label Extension Trial.	
GSK	Full	17 666	3 34	The guidelines recommend offering oral NSAIDs for managing non-specific low back pain. GSK is concerned that the proposed guidelines make no reference to the potential role of topical NSAIDs in the management of this. Most cases of non-specific low back pain do not result from serious pathology, but are frequently due to minor sprains, strains or injuries of low back muscles and may be triggered by posture (sitting or standing), awkward movement, lifting incorrectly or overuse of muscles; resulting in symptoms such as pain, soreness, stiffness and muscular tension. Many sufferers may choose to self medicate mild to moderate pain symptoms before presenting to their general practitioner or other healthcare access point; many experienced sufferers may choose to self-medicate their symptoms along with other management strategies. Non prescription products provide sufferers of low back pain useful self medication options. Topical NSAIDs are used for the treatment of local musculoskeletal conditions specifically for the local symptomatic relief of pain and discomfort in trauma of tendons, ligaments, muscles and joints due to sprains, strains or bruising. Topical NSAIDs may be a useful self medication treatment option for patients with acute low back pain where oral NSAIDs are either not chosen or may not be appropriate, for example due to well-documented gastrointestinal, liver and cardio-renal adverse events or in patients in whom use of oral NSAIDs is contraindicated such as gastrointestinal bleeding, renal impairment and cardiovascular disease. A number of studies have demonstrated the benefit of topical NSAIDs for the treatment of pain. 1. A recent Cochrane meta-analysis on topical NSAIDs in acute and chronic pain conditions concluded that topical NSAIDs provide good levels of pain relief in acute conditions such as sprains, strains and overuse injuries, probably similar to that provided by oral NSAIDs. Gel formulations of diclofenac, ibuprofen, and ketoprofen, and some diclofenac patches provided the best effects. Adverse events were usually minimal. (Derry et al. 2015). The meta-analysis included the following trials: i. A seven day randomised, double blind, parallel groups trial which compared felbinac foam with oral ibuprofen in 287 patients with acute lower back injury and moderate to severe pain on movement. Pain on movement was rated "none" or "mild" in 81 out of 127 subject in felbinac group and in 96 out of 133 in ibuprofen group. Spontaneous pain was rated "none" or "mild" in 99 out of 127 subjects in felbinac group vs. 108 out of 134 in ibuprofen group.(Hosie, 1993) ii. A randomised, double blind, placebo controlled, parallel group clinical trial compared piroxicam gel and indomethacin gel applied for up to 14 days in 271 patients affected by mild to moderate muscle pain or inflammation in the neck, shoulder, back, chest and upper and lower extremities, or a combination of these. Participant Global Evaluation (PGE) and physician rated improvement scores were positive for both of the treatment groups.(Fujimaki 1985)	Thank you for your comment. Topical NSAIDs were included within the protocol and search for the review, however no evidence was found and therefore no recommendation could be made specifically for topical NSAIDs. The Cochrane review mentioned in your comment was not considered in the review as it included studies with chronic musculoskeletal pain, and was not restricted to non-specific low back pain.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. An eight day randomised, placebo-controlled, parallel-group clinical trial comparing piroxicam patches, piroxicam cream and placebo patches in 180 patients with lumbar osteoarthritis demonstrated efficacy measures improved during the study in both active treatment groups. The results also showed a decrease in pain score during daily activities, recorded as 42.2%, 41.7% and 25.8% respectively for the groups at the end of the study. Safety was considered satisfactory in all groups. The differences between the pain scores of two active treatment arms vs. the placebo arm were statistically significant. (Allegrini 1999) Although it is not strictly classified as such, neck pain has anatomical, aetiological, pathogenic and symptom similarities to non-specific lower back pain. Neck pain is a common musculoskeletal disorder which will affect a significant proportion of the population at some point in their lifetime. 3. A five day randomised, double-blind, placebo-controlled study in 72 patients with acute neck pain compared diclofenac 1.16% gel with placebo. The primary outcome measure, pain on movement at 48 hours, was statistically significantly lower (improved) with diclofenac gel (19.5 mm on a 100 mm scale) vs. placebo (56.9 mm on a 100 mm scale) (P<0.01). Other pain on movement scores and outcome measures such as pain at rest and functional neck disability index were also significantly lower with diclofenac gel 1.16% gel vs. placebo (from first assessment (24 h) onwards; P<0.01). Response to treatment was significantly higher with diclofenac gel (94.4%) vs. placebo (8.3%) (P<0.01). (Predel 2013) In light of the evidence, GSK suggests that NICE consider acknowledging the role of topical NSAIDs for the management of non specific low back pain.	
GSK	Full	618	Table 307	The first study, Nadler 2002, is not a paracetamol vs. placebo controlled study. This study compared the efficacy of continuous low level heat wrap therapy (40°C, applied for 8 hours/day) with that of ibuprofen (1200 mg/day) and paracetamol (4000 mg) day in subjects with acute nonspecific low back pain.	Thank you for your comment. Nadler 2002 included 5 arms; heat wrap, paracetamol, ibuprofen, placebo and unheated wrap. As heat wrap and unheated wrap are not interventions in the protocol for this review, only the three relevant arms were extracted and presented in the guideline.
GSK	Full	667	22	The draft guideline currently recommends that paracetamol alone should not be offered for non-specific acute low back pain, due to lack of evidence This recommendation contradicts other treatment guidelines (Koes BW et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. Eur Spine J 2010; 19: 2075–94). Paracetamol is indicated and recommended for its analgesic effects in the treatment of mild to moderate pain in various pain types. Given the extensive experience and long history of use, the evidence base in this clinical setting has not changed over time (few RCTs or real world studies have been conducted). While acknowledging the limited high quality randomised control trial data, GSK recommends that, based on the long experience of use in addition to existing evidence, NICE acknowledge the contribution of paracetamol as a useful self medication treatment option for patients who choose to self medicate mild to moderate pain symptoms before presenting to their general practitioner or other healthcare access point. Experienced sufferers may choose to self-medicate their symptoms along with other management strategies. Non prescription products provide sufferers of low back pain useful self medication options.	Thank you for your comment. Although the GDG recognise the wide spread use of paracetamol, however the recommendations drafted must reflect the evidence available. As detailed in section 16.6 of the guideline, the GDG were unable to recommend paracetamol due to the very limited evidence available, 1 RCT, which showed no clinical benefit for paracetamol in any of the outcomes reported. We are unable to comment on the over-the counter use of paracetamol as these guidelines apply to settings in which NHS care is delivered or provided only.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
GSK	Full	669	general	GSK acknowledges that limited data is available from high quality randomised clinical trials evaluating the use of paracetamol in non-specific acute back pain and note that the single large placebo-controlled study (Williams et al; Lancet 2014) reviewed in the GDG's dataset did not measure simple analgesia, ie pain relief shortly after taking paracetamol, but rather the ability of paracetamol to shorten episodes of back pain defined as ≥7 days with absent or near absent pain. Paracetamol is recommended as a first line pharmacological treatment for the management of acute low back pain in the majority of existing guidelines (Koes et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. Eur Spine J 2010; 19: 2075–94). GSK suggests that in developing these guidelines, NICE acknowledge the extensive experience and existing recommendations on the place of paracetamol in the management of lower back pain and does not conclude that a lack of recent evidence from RCTs confirming a benefit means a lack of effect. Many sufferers may choose to self medicate mild to moderate pain symptoms before presenting to their general practitioner or other healthcare access point; many experienced sufferers may choose to self-medicate their symptoms along with other management strategies. Non prescription products provide sufferers of low back pain useful self medication options. Paracetamol provides a useful treatment option, especially for patients who do not tolerate oral NSAIDs or for whom NSAID use in either contra-indicated or not appropriate	Thank you for your comment. Although the GDG recognise the wide spread use of paracetamol, however the recommendations drafted must reflect the evidence available. As detailed in section 16.6 of the guideline, the GDG were unable to recommend paracetamol due to the very limited evidence available, 1 RCT, which showed no clinical benefit for paracetamol in any of the outcomes reported. The GDG recognised the need for a pharmacological treatment option for those in whom NSAIDs are contradicted and have therefore included a recommendation to consider weak opioids with or without paracetamol for that specific population.
Guy's and St. Thomas NHS Foundation Trust	Full	General	General	The broadened scope of the guidelines and the inclusion of sciatica is welcomed. We agree it does provide a more pragmatic framework that enables services to be tailored to local need. We agree that this broader approach is more likely to promote guideline uptake. However some of the recommended changes to practice in the guidelines may be challenging to implement.	Thank you for your comment.
Guy's and St. Thomas NHS Foundation Trust	Full	12	General	Lack of Physiotherapy representation on the panel is of concern. Note is taken of the co-opted member from Keele. Seeking a physiotherapy representative for any future guidance on musculoskeletal disease would add to its breath of view.	Thank you for your comment. GDG member Neil O'Connell was, until recently, a practicing a physiotherapist and is now a senior lecturer in physiotherapy.
Homerton University Hospital NHS Foundation Trust	Full 2	11-123	GENERAL	Part 2 Invasive treatments -Spinal Injection and Denervation – **There needs to be an auditable review of effectiveness of each invasive spinal procedure after administration** Good practice: At Homerton, all patients who receive spinal injections or denervation, are offered a post injection review with a senior physiotherapists working within Homerton's Locomotor pain team, within two weeks of the injection. This review assesses for effectiveness and response. Where the patient has benefited, rehabilitation, during the window of opportunity afforded by the injections analgesic effect is offered. Where no benefit occurs, other pain management options (such as pain management programs, functional exercise, pain Psychology, and a consultant review) are discussed and support arranged according to the biopsychosocial model with the interdisciplinary team. We believe this should be adopted as best practice nationally.	Thank you for your comment. The GDG agreed that the main area of uncertainty the spinal injection review would address was the effectiveness of various injectates, rather than the route or mode of administration. Furthermore, spinal injections have not been recommended by this guideline (see recommendation 30). The effectiveness of the spinal injections and denervation were assessed in the studies included for these evidence reviews, and the GDG considered this when formulating the respective recommendations. It would be a part of routine practise to assess responsiveness post-administration of any intervention.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Homerton University Hospital NHS Foundation Trust	full 1	40	4.3.1.1.2	**We disagree with the faith the guidelines have in sham acupuncture trials**. Sham trials vary in the nature of the sham used. Sham acupuncture needles can still provide a stimulus. The stimulus provided by some sham needles is comparable to the contact needling technique used by Japanese style acupuncture. Manual therapies, exercise and acupuncture share the same difficulty in administering a valid placebo. Acupuncture studies should be regarded as using an imperfect sham comparison treatment, although this will reduce the studies quality rating, it will provide a more realistic analysis of the potential contribution of acupuncture as a modality delivered within a multimodal package of care.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. The sham comparators included in all reviews were verified with the GDG for their appropriateness.
Homerton University Hospital NHS Foundation Trust	full 1	452	12.6.15	Specifically mentioning the word 'massage' within the headline recommendation is unhelpful and could give the impression that the evidence for massage is more robust than it actually is and undermine in the eyes of the public the greater value of self management approaches and active therapies such as exercise.	Thank you for your comment. The manual therapy recommendation has been reworded following stakeholder feedback. This now specifically refers to exercise rather than multi-modal therapy. This recommendation emphasises that any manual therapy should only be done as part of a package including exercise. Massage is only listed as an example of manual therapy. .
Homerton University Hospital NHS Foundation Trust	full 1	452	12.6.15	Manual therapy – general Physiotherapy informed by current best practice in chronic pain takes into account psychosocial factors before considering manual techniques. Overall these guidelines on manual techniques do not consider how Physiotherapy management of low back pain or sciatica might be informed by current knowledge in chronic pain.	Thank you for your comment. This guideline recommended packages of care that include spinal manipulation and psychological therapy where appropriate. The reviews consider a range of treatments that may be delivered by a physiotherapist, but look to determine the effectiveness of the specific intervention rather than focussing on the healthcare profession that may deliver it.
Homerton University Hospital NHS Foundation Trust	full 1	GENERAL	general	Occupational therapists provide valuable input into the management of chronic pain within specialist pain teams. **There is a lack of input from Occupational therapists into these guidelines**	Thank you for your comment. The proposed GDG composition was previously consulted on and agreed during the scoping phase of the guideline. A co-opted expert for the topic of return to work was recruited and attended a GDG meeting to help the group developing the protocol and understanding the evidence for this review.
Homerton University Hospital NHS Foundation Trust	full 1	560-561	GENERAL	The guidelines found no studies evaluating TENS for sciatica and only one for a mixed population, yet the guidelines make a recommendation to cover the use of TENS in populations where research does not exist. In clinical Physiotherapy practice TENS would never be used in isolation, but only as an adjunct to other therapies as part of a range of self management strategies explored with the patient. **TENS has an advantage over the passive modalities** (massage, corset, manual therapy used as comparators in the research cited) **as being delivered independently by the patient**, it is unfortunate that self-efficacy was not included as an outcome measure, which might demonstrate the advantage of TENS. TENS can be useful, provided it is issued on a 2 week trial basis. If patients find it helps their self management, then purchase may be considered.	Thank you for your comment. The recommendation is based on evidence from the 'without sciatica' and the 'with or without sciatica' populations. Although there was no evidence available for the 'with sciatica' population, the GDG were aware that 139 of the 236 people included in the 'with or without sciatica' population had sciatica. Therefore people with sciatica could not be excluded from the recommendation. The GDG considered evidence of TENS compared to sham TENS, usual care, and active comparisons. Although there were some clinically significant benefits for TENS, this was overall inconsistent and conflicting, therefore the GDG concluded that there was insufficient evidence of a clinical benefit to support a positive recommendation. Self-efficacy was not considered as a critical or important outcome in the scope or the protocols, and therefore was not reviewed. No evidence was found that considered TENS with self-management and therefore the GDG are unable to make any recommendations on this.
Homerton University Hospital NHS Foundation Trust	full 1	15	1.11 Algorithm	The algorithm gives the erroneous impression that psychosocial therapies could be an isolated entity from the patients MDT rehabilitation. There should be specific mention within this algorithm of referral to an integrated pain service (physiotherapy, prescribing clinicians, psychology, occupational therapy, pain consultant) as described by the British pain society guidelines.	Thank you for your comment. This guideline recommends treatments for management of non-specific low back pain and sciatica and not who should carry out these treatments.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Institute of Osteopathy	Full	general	general	Definition of self-management Self-management as defined in these recommendations is wide reaching. It includes self-management programmes such as education leaflets and advice with group psychological therapies. According to our researchers, this may have raised the effectiveness of 'self-management approaches' as part of the multi-modal package recommended. (See response from the National Osteopathic Research Council (NCOR)). While manual therapy clinicians routinely provide advice and self-management strategies (see comment 6 and 7 on definition and implementation of multi-modal therapy), the definition as used here may have raised its importance for inclusion, rather than as an adjunct to others such as manual therapy and exercise.	Thank you for your comment. The guideline reviewed self-management programmes (including patient education and reassurance for example, the Back Book), advice to stay active, advice to bed rest and unsupervised exercise (including exercise prescription, advice to exercise at home). Details of each intervention are given in the summary of included studies and in the evidence tables for the GDG to consider. The complexity of defining self-management is acknowledged and detailed in section 8.6 'Recommendations and link to evidence'. On reviewing this evidence the GDG agreed that the evidence was not strong, however that self-management should be a principle applied alongside all treatment options throughout the pathway. This has been clarified in the wording of the recommendation.
Institute of Osteopathy	Full	455-6	general	Evidence grading in pragmatic trials. The decision to down-grade evidence in the manual therapy analysis due to poor blinding (page 456) is of concern. It is unfeasible to double blind trials for non-invasive therapies, which is why pragmatic trial methodology is used, yet the pragmatic trial evidence is consistently down-graded because double and single blinding is not possible. There are methods, such as where allocation concealment at the analysis and data collection stage has been thorough, by which these studies could be graded accordingly.	Thank you for your comment. Quality assessment using GRADE criteria is undertaken by outcome, rather than per study, to reflect the quality of the body of evidence. A number of factors are considered in addition to blinding such as baseline comparability, dropout rates and outcome reporting, this is described in detail in the methods chapter. We also consider the likely impact of these factors before deciding whether to downgrade as per GRADE methodology. This is consistent across outcomes to reflect the overall confidence in the evidence and therefore even though blinding may not be possible in all scenarios, this is still considered a risk of bias if the outcome is subjective.
Institute of Osteopathy	Full	452-3	general	Inconsistent use of adverse event evidence We have concerns about the statement made in chapter 12 summary that states: *'Due to the possible risk of adverse events and conflicting nature of the evidence, the GDG agreed that this recommendation should be to consider manual therapy as part of multi-modal package of care, rather than offer manual therapy alone as a sole intervention to all people with low back pain with or without sciatica.' (Part 1 page 452).* Particularly as it does not reflect the statement made on page 453 where the GDG reports the following: *'Adverse events were common, MINOR and transient, consisting of mainly muscle soreness for a few days following treatment. No serious events attributable to manual therapy were reported by any of the studies reviewed.'* We would refer the authors to the NCOR response which provides more detailed information of the context of adverse events data which shows that the risk of major adverse events is extremely rare (0.007%) after manual therapy or 0.01% per manual therapy patient, (Carnes et al Adverse events in manual therapy: a systematic review. Manual therapy 2010; 15: 355-363). In short, this recommendation has been based on an extremely low risk of serious adverse events. This is in contrast to the rationale used to recommend invasive, surgical intervention such as discectomy, discussed in part 2 of the guidelines.	Thank you for your comment. The sentence in section 12.6 has been revised to clarify that the recommendation was not based on the risk of adverse events. Although the GDG were aware of the possibility of adverse events, we agree that they were minor and transient. The recommendation was based on the conflicting nature of the evidence. The GDG noted that there was mixed evidence for the effectiveness of manual therapy modalities and therefore they could not be recommended for low back pain or sciatica as independent interventions. However, evidence from their use in combination with other treatments, and as part of multidisciplinary biopsychosocial rehabilitation programmes provided more evidence of benefit. The GDG therefore agreed that the recommendation should be to consider manual therapy as part of treatment package.
James Cook University Hospital	Full	General	General	1. Conflict of Interest Previous NICE guidance for low back pain was followed by considerable controversy. Some criticisms were directed at the GDG and in particular at the balance of specialities represented.	Thank you for your comment. We were mindful of the comments that were received following consultation and publication of CG88. At the beginning of development discussions were held with the GDG regarding conflicts of interest and the appropriateness of declaring work in private practice. It was agreed, in accordance with the conflicts of interest policy relevant at the time of development, that this was not viewed as a conflict that would require members to withdraw from decision making. Members of committees are

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It would seem appropriate that the most stringent precautions should be taken to avoid any appearance of conflict of interest. In the operation of the previous GDG, members who were involved in providing a specific treatment left the room and took no part either in the discussion or in the decision relating to that treatment. With the exception of pharmacological treatments this does not appear the case with the current guideline development. This would be of particular relevance in the situations where the expert opinion of the GDG was used as a factor for decision making.	recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (please see appendix B).
James Cook University Hospital	Full	General	General	Consistency of Approach to Evidence Between the treatments considered there appear to be differences in the way the evidence is approached during the discussion and decision making process (see comments below)	Thank you for your comment. Please see our responses to the specific comments mentioned.
James Cook University Hospital	Full	General	General	Multimodal Therapy In a number of recommendations it is suggested that some treatments be offered only as part of a multimodal treatment package. The format or delivery of such a package is not defined within the guidance. It is not clear whether this is a package which might be delivered by a single individual, for example manipulative therapy delivered by a "psychologically informed therapist" with discussion and advice on other self-management techniques, or a package delivered by more than one person. Clearly the involvement of another practitioner would have significant effects on costs and cost effectiveness and might indeed alter the recommendation It is not clear why a treatment option should become more effective simply by including it with other options. BMR programmes are examined in their own right. It is suggested that the GDG may wish to consider avoiding the recommendation to consider only as part of a multimodal treatment package with reference to single treatment modalities, to maintain clarity of the document. If it is thought the recommendation should stand, it may be clearer if the same wording is used, i.e. multidisciplinary biopsychosocial rehabilitation (MBR) programmes.	Thank you for your comment. Manual therapies and psychological therapies have been recommended as part of a treatment package because there was insufficient evidence to recommend either as a standalone treatment. However there was evidence for each therapy in combination with other treatments (this evidence is in the individual reviews) as well as from the review of multidisciplinary biopsychosocial interventions (MBR). MBR programmes have also been reviewed separately as they are defined as interventions involving a physical component and at least one other element from a biopsychosocial approach, offered as an integrated programme. In this respect they are different from simple combinations of interventions. Where relevant, evidence on combinations of interventions has been collected and reported in a designated section of the chapter for each intervention. This evidence informed the recommendations on the effectiveness of interventions being offered in combination. Acknowledging the considerable variability of healthcare professionals who might deliver such combinations of interventions, and the variability in the evidence reviewed, it was not possible to make clear in the recommendation who or how many professionals should deliver such interventions.
Lumbacurve International	Full	204	general	We are awaiting publication of an independent clinical trials on our device Lumbacurve an abstract of which was presented to the Society for Back Pain Research and published in the Bone and Joint Journal "Determining the clinical effectiveness of the LumbaCurve™ in the management of simple mechanical low back pain" Jill Alexander, Ambreen Chohan, James Selfe, Karen May, Jim Richards http://www.bjjprocs.boneandjoint.org.uk/content/97-B/SUPP_2/9 As the results were very positive as a therapy for NSLBP, Would it be possible to include these findings in the studies if the full research paper can be published prior kto Serptember? Thank you David Pegg	Thank you for your comment and this information. However, we are not able to include any papers that are published after the final cut-off date for the searches.
Medtronic	Full	General	general	We ask you to consider that specific spinal pathologies should be excluded before a patient is given a diagnosis of non-specific low back pain	Thank you for your comment. Specific spinal pathologies are beyond the remit of this guidance. However, we have included detail to indicate certain conditions that are outside of the pathway in the Algorithms and have highlighted this in the introduction as well as including guidance on red flag symptoms in appendix P.
Medtronic	Full 1	147	23	*Recommendation 7.6 (4) "Consider imaging in a specialist care setting for people with low back pain with or without sciatica only if the result is likely to change management".*	Thank you for your comment. The objective of the review was to determine the clinical and cost effectiveness of imaging techniques in the management of non-specific low back pain and sciatica. Identifying criteria to

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We suggest that further criteria are needed to guide selection of people in whom the result of imaging is likely to change management.	guide selection of people in whom the result of imaging is likely to change management is beyond the scope of this review.
Medtronic	Full 2	58	7-12	*The GDG considered the various limitations of the model together with the main results and concluded that although radiofrequency denervation is a cost effective intervention in the base case analysis and in various sensitivity analyses, there is not enough confidence to make a firm recommendation for this intervention. In addition, as the low back pain population is wide, there are concerns on the potential cost impact of a firm recommendation if many people were eligible for the intervention.* We question whether the GDC concerns regarding the potential cost impact for this intervention may have affected their confidence in the cost effectiveness evidence and their decision not make a firm recommendation on this intervention. The GDC have concluded that radiofrequency denervation is a cost effective intervention in the base case analysis and in various sensitivity analyses. We respectfully request that you reconsider this recommendation in line with the "Developing NICE guidelines: the manual (2104) guidance. https://www.nice.org.uk/article/pmg20/chapter/7-Incorporating-economic-evaluation#the-role-of-economics-in-guideline-development *"It is particularly important for Committee members to understand that economic analysis is not only about estimating the resource consequences of a guideline recommendation, but is concerned with evaluating costs in relation to benefits (including benefits to quality of life) and harm of alternative courses of action".*	Thank you for your comment. The rationale for not making a strong recommendation is explained in the Recommendation and Link to evidence section which says: "The GDG considered the various limitations of the model together with the main results and concluded that although radiofrequency denervation is a cost effective intervention in the base case analysis and in various sensitivity analyses, there was not enough confidence to make a strong ('offer') recommendation for this intervention. In addition, as the low back pain population is potentially very large, the GDG expressed concern about the potential cost impact of a strong recommendation." Considerations about the cost impact had been made and this is reasonable within the NICE guideline process.
Medtronic	Full 1	15	1	Fig 1: First box at top of algorithm: *People with non-specific low back pain with or without sciatica. If No then patient moves out of pathway.* We ask you to consider that appropriate imaging is required to attribute a diagnosis of specific versus non-specific low back pain.	Thank you for your comment. The suspected underlying pathology that require further investigation and management have been added to the algorithm for clarity. The assessment and management of these is outside of the scope of this guideline.
Napp Pharmaceuticals	Full 1	17	General	Regarding pharmacological treatments for both acute and chronic low back pain, compared to Clinical Guideline 88 which this guideline will replace, the updated recommendations remove a large number of potential treatment options for patients. With the known difficulties in diagnosing and treating non-specific low back pain, the removal of clinical options for prescribers could limit their ability to individualise treatment for patients, and could render them unable to identify the best treatment option for a particular patient by trialling treatments.	Thank you for your comment. The aim of this guideline is offer the most clinical and cost effective treatments, therefore the GDG have drafted recommendations for areas they feel will be of most benefit to people with low back pain and sciatica and therefore to make best use of NHS resources.
National Council for Osteopathic Research	Full	general	general	Comment on inconsistent use of UK BEAM trial. There is inconsistent use of the UK BEAM trial data. UK BEAM trial had 4 arms: Best practice usual care (rebranded as self-management), exercise, manipulation package of care and manipulation package of care plus exercise. These data were extracted for mixed modality vs usual care but not extracted or included in the effectiveness analysis for exercise vs usual care. We would like more information and transparency about why studies were excluded (reasons not given for UK BEAM in Appendix L rejected studies).	Thank you for your comment. We note that the UK BEAM trial had the following four arms: 1) self-management; 2) self-management plus exercise; 3) self-management plus manual therapy; 4) self-management plus exercise plus manual therapy. On considering this alongside the protocols for the reviews in this guideline, comparisons of self-management plus manual therapy versus self-management (3 versus 1) and self-management plus exercise plus manual therapy versus self-management (4 vs1) had been included in the manual therapy chapter. Comparison of self-management plus manual therapy versus self-management plus exercise (3 versus 2) has now been added to the manual therapy review (chapter 12). Comparison of self-management plus exercise versus self-management (2 versus 1) has now been added to the exercise review (chapter 9). We apologise for any omissions in the consultation version of the guideline.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
National Council for Osteopathic Research	Full	general	general	Comment on definition of self-management. One would be hard pressed NOT to recommend self-management, but there is an issue with this chapter because the definition of self-management is too inclusive. The main evidence reviewed in this section centres on advice and guidance. Self-management interventions are more than just education leaflets and advice they usually involve some sort of active behaviour change component often using a cognitive behavioural approach (Self-management of long term conditions: PRISM NIHR HTA report 2014). Analysing the group self-management programmes with the group psychological therapies may have altered the effectiveness outcomes and raised the importance of these approaches as part of a multi-modal package of care, rather than as an adjunct to exercise. Suggestion: Review structured self-management programmes separately to and advice and guidance	Thank you for your comment. The GDG agreed to separately review self-management programmes (including patient education and reassurance for example, the Back Book), advice to stay active, advice to bed rest and unsupervised exercise (including exercise prescription, advice to exercise at home) from psychological therapies in alignment with the scope. Individual therapies within a 'class' of therapies (e.g. type of self-management programmes) were considered for subgroup analysis in case there was heterogeneity and were detailed in the summary of included studies and the evidence tables. The GDG acknowledged the complexity of defining self-management and this is detailed in section 8.6 'Recommendations and link to evidence'. This was taken into account when reviewing the evidence and as a contributing factor to the poor evidence for this intervention. However the GDG agreed that self-management should be a principle that is recommended across the treatment pathway for people with low back pain and sciatica. The wording of the recommendation has been amended to clarify this.
National Council for Osteopathic Research	Full	305	general	Exercise Implementation comment. The GDG recommend group exercise programmes. In reality clinicians individually prescribe bespoke exercise programmes, therefore the implications of implementing this recommendation is far reaching, especially if it is to be paid for and organised via the NHS and in an NHS setting. Little consideration has been given to patient choice in either group or individual exercise, even though studies have shown this is importance for compliance [Chown M, Whittamore L, Rush M, Allan S, Scott D, Archer M. A prospective study of patients with chronic back pain randomised to group exercise, physiotherapy or osteopathy. Physiother. 2008;94:21–28]. Exercise Evidence comment. The evidence does not support the recommendation for group exercise over individual exercise programmes. There are no real difference in effectiveness between individual or group. Should this be supervised exercise? The recommendation to have exercise as the mandatory component in the multi-modal delivery of non-invasive interventions does not seem to be fully considered due to the high drop-out rate consistently reported in the studies included. If the GDG make this recommendation in the hope of economies of scale (page 305 one line only yet this is a major recommendation) we suggest that some modelling is considered to assess the consequences of the costs of the high drop-out rate on the other components suggested in the multi-modal model recommended. This is not clear and we are unable to access the full economic analysis due to software issues. The short version says 'consider' a group exercise programme but recommend later as the key component of multi-modal package. Suggestion: Reconsider the strength of the recommendation for group exercise and consider supervised exercise instead for both individuals and groups.	Thank you for your comment. Whilst we recognise that there are some individuals who would prefer individual exercise, and that currently clinicians may prescribe individual exercise, we were unable to recommend it as an option based on the economic analysis. Whilst there was no difference between individual and group exercise in the clinical evidence, the GDG concluded that group exercise is likely to incur fewer costs compared to individual exercise, and therefore a recommendation was made for group exercise. The recommendation does however emphasise that people's specific needs, preferences and capabilities are to be taken into account when choosing the type of exercise. Furthermore, all patient treatment decisions would be discussed with the patient. Please see the introduction on page 4 of the short version about patient decisions, and the linked 'Your Care' web page. All exercise included in the exercise review is supervised exercise. Unsupervised exercise has been considered as self-management and can be found in the self-management review in Chapter 8. Exercise is included as the mandatory component in the multimodal treatment package as the evidence on which the recommendation is based all involved a treatment package where exercise was one of the components. The GDG reconsidered the strength of the recommendation for both group and individual exercise, and concluded that there is no evidence to show that exercise therapies delivered individually are cost effective, therefore decided that the recommendation should not change.
National Council for Osteopathic Research	Full	452-3	general	Comment on inconsistent use of adverse event information and evidence. The GDG state that the incidence of serious adverse events is very small for manual therapy (page 453) 'Adverse events were common, MINOR and transient, consisting of mainly muscle soreness for a few days following treatment. No serious events attributable to manual therapy were reported by any of the studies reviewed. The GDG were aware of case reports and	Thank you for your comment. We are aware that it is difficult to get an accurate estimate of adverse event occurrence from clinical trial data, however this applies to all of the interventions studied in the guideline, and where adverse event data was limited, GDG expert opinion and knowledge of adverse event occurrence in clinical practice has further informed the recommendations in this area. To clarify that the GDG used expert opinion

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				estimates of serious but very rare adverse events that may be related to spinal manipulation and took this into account when making a recommendation.' The evidence of case reports was not reviewed and should be dismissed, as other research has indicated over reporting of these extremely rare events by multiple practitioners and prospective cohort study meta-analyses have shown that the risk of major adverse events is extremely rare (0.007% after manual therapy or 0.01% per manual therapy patient) (Carnes et al Adverse events in manual therapy: a systematic review. Manual therapy 2010; 15: 355-363, CROAM study 2013. This is a prospective cohort study of adverse events in osteopathy http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/the-croam-study-february-2013/) In the summary of chapter 12, it is stated 'Due to the possible risk of adverse events and conflicting nature of the evidence, the GDG agreed that this recommendation should be to consider manual therapy as part of multi-modal package of care, rather than offer manual therapy alone as a sole intervention to all people with low back pain with or without sciatica.' (Part 1 page 452). This recommendation based on an extremely low risk of a serious adverse events and minor transient muscle soreness is in contrast to the rationale used to recommend discectomy in part 2 of the guideline. Invasive therapies part II page 219. Discectomy vs usual care: 'In terms of function, the randomised evidence showed no difference between treatments, although the non-randomised data suggested a clinically important difference favouring discectomy in both short and long term' and 'The GDG noted that re-operation may not be considered as adverse events following surgery, but may be a natural history of the condition since about 5% of patients will suffer from a recurrence of disc prolapse' (3rd paragraph page 219). On page 221 Quality of evidence it is stated: 'The evidence for all comparisons and all outcomes was rated as low or very low quality, mainly due to risk of bias (and some imprecision)……later page 222 'The group agreed that surgical intervention following a period of conservative management for around 6 weeks would be reasonable. However it was noted that there was little evidence to support this time point and that the conservative treatment interval was largely historical and consensus based'. This is in contrast to the decision rationale used for the recommendations for manual therapy and illustrates inconsistent interpretation of adverse events and evidence. We question the recommendation for the use of discectomy after 6 weeks based on the evidence presented in this chapter (Chapter 28 Spinal decompression for sciatica). Suggestion: Review adverse event evidence more consistently and transparently and include prospective cohort study evidence.	and knowledge on adverse events alongside the evidence included in the review, the sentence in Section 12.6 has now been edited to read as follows: 'The GDG were aware of possible serious but very rare adverse events that may be related to spinal manipulation and took this into account when making a recommendation'.
National Council for Osteopathic Research	Full	455	general	Comment on evidence grading in pragmatic trials. The non-invasive therapies are impossible to double blind in trials, which is why pragmatic trial methodology is used. The pragmatic trial evidence is consistently down-graded because double and single blinding is not possible. Where allocation concealment at the analysis and data collection stage has been thorough, these studies could be graded and reviewed accordingly.	Thank you for your comment. Quality assessment using GRADE criteria is undertaken by outcome, rather than per study, to reflect the quality of the body of evidence. A number of factors are considered in addition to blinding such as baseline comparability, dropout rates and outcome reporting, this is described in detail in the methods chapter. We also consider the likely impact of these factors before deciding whether to downgrade as per GRADE methodology. This is consistent across outcomes to reflect the overall confidence in the evidence and therefore even though blinding may not be possible in all scenarios, this is still considered a risk of bias if the outcome is subjective.
NHS North Derbyshire CCG	Full	666	Recommendation 22	Paracetamol has long been a first line analgesic for many different causes of pain and our feeling is that this should still be considered for patients who haven't already tried it. Although the evidence is less than convincing local feedback from GPs is that they have many patients who are successfully managed on paracetamol and this reduces the need to	Thank you for your comment. Although the GDG recognise these concerns, the recommendations drafted for this guideline are based on the evidence available. As detailed in section 16.6 of the guideline, the GDG were unable to recommend paracetamol due to the very limited evidence available; 1 RCT,

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prescribe NSAIDs. There is a large placebo effect for analgesia which may make it difficult to show a benefit in short-term RCTs but this does not mean that paracetamol is not working for individual patients. Paracetamol is cheap and relatively safe and, as low back pain is not a life threatening condition it would seem a reasonable management strategy to try paracetamol first and then progress to other drugs if the patient does not gain benefit. The alternative is that most patients will receive NSAIDs which are well known to be drugs associated with hospital admissions – heart failure, renal dysfunction, AKI and GI bleeds are all well-known issues. Many CCGs have been working hard to reduce the prescribing of NSAIDs and this would seem contrary to that aim. Also, the evidence base for NSAIDs doesn't seem to be that much better than the paracetamol evidence – the trials considered are all short-term (and so take little account of long-term side effects) and although the results are often statistically significant their clinical significance would appear to be questionable. Prescribing more NSAIDs would also lead to increased prescribing of PPIs, again increasing the patient's medication burden and the risk of side effects. The comment from our GPs is that they will ignore that bit of the guideline and continue to prescribe paracetamol, which begs the question what other bits of the guideline will they choose to ignore if their confidence in the advice has been reduced.	which showed no clinical benefit for paracetamol in any of the outcomes reported.
Pain Concern	Full	15	algorithm	As above pharmacological interventions for low back pain and sciatica should be grouped in context, including ref to NICE Guidance 173	Thank you for your comment. The reference to NICE guidance 173 is included within the algorithm, but only applies to sciatica within this guideline, so is grouped under 'Specific treatments for sciatica'
Pain Concern	Full	18	6-7	As above - pharmacological management of sciatica should be referenced in section covering pharmacological interventions	Thank you for your comment. We have now included a recommendation to cross refer to NICE CG173 for the pharmacological management of sciatica.
Primary Care Rheumatology Society	Full	General	General	The PCR Society (PCR)[1] welcomes the NICE draft guidelines on low back pain and sciatica.[2] The PCR agrees with the concerns about inappropriate prescribing and over medicalization of back pain. In particular we agree that Paracetamol and Opioids should not be first line medications. The PCR is concerned that Paracetamol is ineffective and has associated clinical risks making it effectively a clinically dangerous placebo for the majority of patients- see Appendix of OA NICE guidelines (2015).[3] The recent data from the National institute of Health (NIH) in America has highlighted that significant numbers of patients become addicted to opioids from prescription drugs and there is an associated rise in mortality from the inappropriate use of these drugs[4]. In the USA it has been estimated that 81.8% of unintentional deaths from all prescription drugs were due to opioids.[4] It is highly likely that these statistics are similar in the UK.	Thank you for your comment.
Primary Care Rheumatology Society	Full	General	General	The PCR is in agreement with the inappropriate use of medications such as Amitriptyline, Gabapentin and Pregabalin. The PCR Society is aware of recent advice to the UK Government by the Advisory Council for the Misuse of Drugs (ACMD) that an increasing, significant proportion of Gabapentin and Pregabalin prescriptions are inappropriately prescribed and there are increasing numbers of deaths.[5] The PCR believes a large proportion of these prescriptions are for low back pain issues. There is additional concern by the ACMD that many patients on opiates are also on Gabapentin or Pregabalin and this has been noted to reinforce the potential for drug abuse in patients.[5] The PCR feels that this is a particular problem in the treatment of low back pain with or without sciatica and risks the over-medicalisation of back-pain which it is important to avoid.	Thank you for your comment.
Primary Care Rheumatology Society	Full	General	General	The PCR Society requests that you consider topical NSAIDs as first line in those whom you have GI or cardiovascular concerns with and before the use of opioids. Whilst topical NSAIDs RCTs did not include low back pain specifically they are used commonly in General Practice for low back pain with or without sciatica. Oral opioids have also typically not been assessed *per se* for low back pain. Topical NSAIDs are typically safer and are not considered to be	Thank you for your comment. Topical NSAIDs were included in the search however, no evidence was found that met the review criteria; therefore no recommendations for topical NSAIDs could be made.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				placebos in comparison to many rubefacients. The use of placebo rubefacients should not be promoted but topical NSAIDs clinical usefulness should be acknowledged, especially in providing effective pain relief without the associated equivalent GI and CVS risk compared to oral NSAIDs. (It is noted that studies that have been done appear to indicate that opioids should not be used for low back pain). As such it appears to be an omission to not consider topical NSAIDs especially where oral NSAIDs are rejected. The omission of topical NSAIDs from the guidelines may put patients at inappropriate clinical risk from use of less safe or effective medications.	
Primary Care Rheumatology Society	Full	General	General	The choice of risk stratification tool (such as the Keele STarT Back) should be considered for its ease and speed of use in relevant, commonly used electronic patient record systems (such as SystmOne and EMIS) as well as the tool's validity. The PCR has been heavily involved in the development of the North of England low back pain guidelines and the current pilot study. [6] This pilot (ongoing) latest feedback data has found that the Keele STarT Back risk stratification tool on SystmOne is clunky and too slow. [7] Each question has up to a 2 second delay between answers before you can move onto the next question and the final summary gives only a risk stratification but no score which it has been found frustrates the practicing GP. As a result GPs have stopped complying with the risk stratification tool. Ensuring compliance with the proposed risk stratification tool is paramount. Both EMIS STarT Back Tool and Sheffield Back Pain tools appear to have got round these problems. [8] The Sheffield Back Pain Tool states that it takes 1 minute to complete; [10] 1 minute is manageable and favourable to GPs working in the constraints of 10 minute consultations. Health economic modeling should also be used to assess the likely impact of any changes on the cost-effectiveness and likely compliance of any proposed changes, especially risk stratification models.	Thank you for your comment. STarT Back is suggested in the recommendation as an example of risk assessment tool to inform shared decision-making about stratified management. Your comments will be considered by NICE where relevant support activity is being planned.
Primary Care Rheumatology Society	Full	General	General	The North of England low back pain guidelines note that the majority of patients with 'simple' low back pain with or without sciatica will recover spontaneously within 8 weeks. [6] There is no need for physiotherapy or other intervention in such patients. [6] GPs should be advised to reassure such 'low risk' patients, provide them with printed exercise sheets, NSAIDs and safety net these patients: - to return if red flags occur or if not better within 8 weeks. This is very different to what typically happens currently in primary care. It is suggested that this is important information which should be considered in the health economic model as it is likely to have significant impact on determining a cost-effective treatment model and hence the clinical guidelines. (Use of physiotherapy and other non-pharmacological treatment before 8 weeks is not cost-effective. Patients who do not need to be seen are clogging-up physiotherapy and low back pain treatment clinics wasting valuable, scarce resources and ultimately resulting in the inappropriate medicalization of low back pain).	Thank you for your comment. The risk assessment and stratification recommendation has now been updated and the following has been added: ''Based on risk stratification, consider simpler and less intensive support for those likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach)''. Also, the self-management recommendation has been updated to read as follows: "All healthcare professionals should provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, at all steps of the treatment pathway. This should include: information on the nature of non-specific low back pain and sciatica; encouragement to continue with normal activities." The pharmacological therapy recommendation addresses the use of NSAIDs and this applies to primary care. No health economic model was developed on low risk patients and economic considerations have been made for each recommendation.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Rheumatology Society	Full	General	General	Back pain is a common problem with many challenging, fixed perceptions as to its cause and effect. GPs have 10-minute consultations to deal with a given problem. It is suggested that the flow diagram consider splitting the problem into 2 types of patient: those with new presentations of acute low back pain, and those who have been treated for many years in a manner that is now considered 'inappropriate' according to the new guidelines. Incorporating this separation would aid GPs in dealing with low back pain, giving them confidence in dealing with challenging patients with fixed ideas, concerns and expectations and managing this within the 10 minutes available.	Thank you for your comment. The algorithm depicts the recommendations contained in the guideline in a graphical format. These populations are not split in the recommendations as the interventions used recommended are the same for both. The algorithm includes instruction to 'Consider whether every appropriate treatment above has been explored'.
Primary Care Rheumatology Society	Full	General	General	Consider how to treat those who appear to have been poorly treated for their back pain with therapies which are now, no longer recommended. In particular there are significant sub-populations of people with chronic low back pain with or without sciatica that are prescribed opiates, tricyclic antidepressants, anticonvulsants and/or benzodiazepines. These people are often clinically unfit with BMI issues. The guidelines should suggest GP practices and CCGs consider doing audits of patients who match these criteria and developing a systematic, targeted approach to addressing the clinical concerns of inappropriate prescribing and management. This is likely to require work in conjunction with the local chronic pain clinics (ensuring they abide by the new NICE guidelines), benchmarking and education of GP practices by their local CCGs and also referring where required to the local drug and alcohol addiction teams. It is suggested that health economic modeling should also be undertaken to take account of the costs of current prescribing and the resulting health costs (including to morbidity and morality e.g. from opiates) and the cost-effectiveness savings that are likely to result from changing to the proposed management of these chronic low back pain patients. The data should be easily available allowing a QALY cost-effectiveness calculation to be done. Doing this calculation would act as an incentive for CCGs and the NHS to ensuring that the proposed guidelines are adopted.	Thank you for your comment. This guideline provides recommendations for people with low back pain and sciatica irrespective of their previous treatment or duration of pain, therefore will cover people who are currently receiving treatment which may not effectively manage their symptoms. Your comments will be considered by NICE where relevant support activity is being planned.
Primary Care Rheumatology Society	Full	General	General	The recent data from the National institute of Health (NIH) in America has highlighted that significant numbers of patients become addicted to opioids from prescription drugs[4]-medication often prescribed initially with the best of intentions. It has been shown by the NIH that this has significant negative effects on patients' mortality and morbidity. [4] It is highly likely that the UK has a similar issue and PCR member's clinical experience is suggestive that this is a problem, especially in patients who are unemployed, from lower social classes or end-up in prisons. The North of England low back pain guidelines (on the Map of Medicine) working group have identified that opiate prescribing is a significant problem in the North of England. There appears to be poor understanding of this within the medical community given the level of opiate prescribing for low back pain. There is both a need to ensure that the new guidelines highlight more clearly the clinical risks and concerns of opiate prescribing. More importantly there is a need to consider these 'addicted' patient populations within the clinical guidelines and how best to manage them.	Thank you for your comment. The GDG recognise the risks associated with opioid use and factored in the potential harms of opioids when considering the evidence. Based on this, they agreed a recommendation that opioids should not be used in the management of chronic low back pain. 'Addicted' patient populations are beyond the scope of this guideline.
Primary Care Rheumatology Society	Full	General	General	Consider whether BMI is the route cause of mechanical low back pain with or without sciatica. If so consider offering weight reduction treatment in conjunction with physical and other therapies for their low back pain. This fits with public health concerns regarding the need to treat such patients more holistically including preventing DM-II and reducing risk of recurrence of low back pain.	Thank you for your comment. Causes of low back pain are beyond the scope of this guideline, which focuses on management of non-specific low back pain and sciatica. Weight loss was not prioritised as an intervention that should be covered within this scope of this guideline.
Primary Care Rheumatology Society	Full	General	General	It may be beneficial to advise GPs to consider suggesting referring chronic low back pain patients to see an occupational health therapist if no better within 6 months. This would reduce the risk of conflict between the GP and the patient whilst also acting as a break on longterm Fitnotes and an incentive to motivating the patient to return to work.	Thank you for your comment. NICE guidelines are evidence based, and therefore the GDG are unable to make recommendations where the evidence has not been reviewed.
Primary Care Rheumatology Society	Full	General	General	Consideration should be given to research to develop an approved NHS kite marked mobile app. This mobile app would be for patient self-management of triaged low risk back pain with or without sciatica. It is suggested that this would reduce the workload on GP practices and help de-medicalise low back pain in a timely and efficient manner.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Chiropractors	Appendix H	445	Protocol outcomes not reported section of table	It is incorrectly stated that Santilli 2006 did not report adverse events whereas the paper clearly states that there were no adverse events.	Thank you for your comment. Data from the Santilli study has now been added to the manual therapy review (chapter 12). Data on adverse events has been added to the 'Data unsuitable for meta-analysis' table in section 12.3.1.4.
Royal College of Chiropractors	Full 1	general	general	The care offered by chiropractors for the treatment of low back pain (as described in our quality standards for Chronic Low Back Pain and Acute Low Back Pain; http://www.evidence.nhs.uk/Search?ps=20&q=Chiropractic+quality) comprises manual therapy techniques often as part of a package of care which may include exercises, psychosocial intervention and other advice to support self-management. Thus, we are generally supportive of the recommendations regarding manual therapy.	Thank you for your comment.
Royal College of Chiropractors	Full 1	16	33	To ensure consistency and to avoid any confusion among health professionals and the public, where manipulation of the spine is discussed and recommended in the documentation, the specific term 'spinal manipulation' should be used rather than simply 'manipulation' (which is sometimes used in the context of soft tissue manipulation.)	Thank you for your comment. This change has been made throughout the guideline.
Society for Back Pain Research	Appendix B	General	General	The declarations of interest appear thorough and highlight relevant personal financial interest. We note however that few resulted in withdrawal from discussions or the development of recommendations. This raises concern related to; adherence to the NICE COI process, biasing interpretation and vested interest in recommended interventions.	Thank you for your comment. Because GDG members were recruited in 2013, the DOI policy that was followed for the purposes of this guideline was the 2007 policy (updated October 2008). This was stated in appendix B and has now also been added to section 3.4 of the full guideline for clarity. All actions determined as a result of conflicts declared were applied in accordance with this policy. Where a member held a conflict of interest that was deemed appropriate for them to withdraw from discussions, this was noted in appendix B and applied for the duration of the guideline.
Society for Back Pain Research	Full	General	General	We thank the GDG for producing such an extensive literature review with quality ratings/forest plots which will be of enormous value to clinicians and researchers in back pain. Although we welcome that the guidance covers the full spectrum of non-specific low back pain and sciatica, the number of key clinical questions and size of the document are major detractors for the user. As a result very few will read the full document in detail. It appears to have taken the GDG 2 years to cover the KCQ. It would be helpful to explain what measures were taken to ensure consistency of approach/standards throughout and how guideline fatigue was minimised.	Thank you for your comment. We agree it is a large topic area and covers a large number of review questions. To assist readers in this, NICE also produce a shorter version of the guideline which contains all of the recommendations as it is understood that not all will be able/want to read the full document in its entirety. The breadth to be covered within a guideline is agreed during the scoping phase where topic areas are prioritised. Time allocated to the development phase is judged accordingly to ensure adequate time and resource are available to produce a high quality document. Records of all decision making process are maintained throughout to ensure that the same approach is applied to all reviews, as detailed in the methods chapter of the guideline. A number of quality assurance processes are in place to ensure consistency of approach as detailed in the NICE guidelines manual. This includes quality assurance by the technical team throughout as well as additional quality assurance from the NICE technical team.
Society for Back Pain Research	Full	General	General	Throughout the document concerns have been raised about inconsistency in discussion/process leading to a recommendation. Examples will be raised section be section.	Thank you for your comment. Please see our responses to each individual comment.
Society for Back Pain Research	Full	11	General	Membership of the GDG. The majority of back pain and sciatica is managed by primary care clinicians. We note that the GDG is heavily biased to secondary care clinicians, and that there is over-representation from pain service clinicians. This is not reflective/representative of the spectrum of clinicians delivering services for back pain.	Thank you for your comment. The proposed GDG composition was previously consulted on and agreed as appropriate to cover the breadth of the guideline

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Concern about the resulting potential conflict of interest will be raised in the relevant sections which follow.	during the scoping phase of the guideline. All GDG members were recruited through an open advertisement, application and interview process. The GDG had representatives from a wide range of specialties as well as generalists. The inclusion of two general practitioners is a standard across most NICE guideline committees.
Society for Back Pain Research	Full 1	666-672	General	The guideline does not give clinicians much to offer patients in terms of medications We note the effect sizes (tiny) and evidence of adverse effects. Like other passive interventions, there is a risk of creating dependence, It is not clear why dependency is not discussed in this section as was the case in acupuncture. The pharmacological interventions (and acupuncture) will not have an effect beyond the period of use (+ a few hours). We note the guideline uses values closest to 4/12 cut off, but the effects would only be expected to be short term. Reference: Moore A, Derry S, Eccleston C, Kalso E. Expect analgesic failure; pursue analgesic success. BMJ 2013; 346; f2690. INCONSISTENCY of strength of recommendation: • The effect sizes of NSAID is tiny and much smaller than the effect size of acupuncture, yet the recommendation is to offer NSAID. • The evidence does not support the use of paracetamol. Perhaps it is better to be honest: Why are we using them We do not think pharmacology is helpful and results in unpleasant side effect and creates dependence. The risk is that with so many interventions out, the risk is that referrals to secondary care will increase. CONCERN • The GDG have acknowledged the harmful effects of Opioid. The risk of harm is also relevant for (even weak ones) for acute LBP. • We are concerned that many readers could overlook the rather weak caveats regarding opioids. SUGGESTED AMENDMENT TO THE RECOMMENDATION • put in a caution, like for NSAID • and if offered, use the lowest effective dose for the shortest possible period of time". SUGGESTED RESEARCH RECOMMENDATION: • What is the effectiveness and cost effectiveness of combinations of pain relief in people with acute, severe back pain, with or without sciatica which limits activity participation?	Thank you for your comment. The GDG felt that although there was evidence supporting the use of NSAIDs for low back pain, the evidence base did not warrant a strong recommendation such the one drafted, in light of this the GDG have changed the recommendation to 'consider' rather than 'offer'. The health issues associated with NSAIDs have been considered and highlighted within the recommendations formed around NSAIDs. The GDG felt the evidence for NSAIDs against placebo was stronger than that for acupuncture against sham, with the acupuncture versus sham evidence being conflicting over a large number of trials. The GDG recognised that there will be a number of people who won't be able to take NSAIDs, and therefore there needed to be a treatment option for them. As a result of which the GDG developed the recommendation for weak opioids for this subset of people with low back pain. The recommendation has been edited to further edited to clarify this; Where an NSAID is contraindicated, not tolerated or has been ineffective consider weak opioids (with or without paracetamol) for managing acute non-specific low back pain only. Research recommendations are developed based on priority areas which the GDG identify from the evidence available for each review question. Based on the evidence, the GDG have formulated a research recommendation looking into the effectiveness of codeine with or without paracetamol for low back pain with or without sciatica.
Society for Back Pain Research	Full 1	736-742	General	TERMINOLOGY: o CPPP	Thank you for your comment.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				○ GG88 and the national back pain pathway uses the term combined physical and psychological programme (CPPP). It is not clear why the GDG use the term MBR. This is confusing to the user. ○ We note that following the evidence review the GDG then adopt the term CPPP for the recommendation. ○ It would be helpful if CPPP were used throughout. ○ Multidisciplinary: ○ We have concern about the use of the term Multidisciplinary throughout the document, this is open to variability and interpretation. EVIDENCE: ○ There does not appear to be evidence to justify delivering exercise in groups only. ○ The intensity, content of the interventions are not clear. ○ We agree that evidence supports 2 elements CPPP is better than exercise. However it is important to emphasise that this is a different client group. DISCUSSION: ○ Downstream cost savings cannot be assumed. ○ There was no GDG discussion about how much is non-specific treatment effect. ○ It would be helpful if the GDG discussed whether the clinicians delivering these interventions have the training and competencies to do so. Previous papers have been criticised for this. ○ It is important for papers to demonstrate that the treatment delivered aligned with the research protocol. A range of professions can deliver physical and psychological programmes: ○ With appropriate training and measured competencies, a range of profession can deliver this intervention. ○ These are likely to be experienced clinicians of a band similar to a psychologist.	When setting the review protocols, the GDG agreed that the review question should be broader than CPPP. The definition of MBR was that it includes a physical component (such as specific exercise modalities, mobilisation, massage) and at least one other element from a biopsychosocial approach, that is psychological or social and occupational or educational. When the evidence review was carried out, the GDG agreed that the most evidence of benefit was for programmes with combined physical and psychological components and therefore this is the term CPP used in the recommendation. The definition of 'multidisciplinary' is reported in the protocol (section C.13) and in the PICO table (section 17.2, table 348). This term refers to multidisciplinary biopsychosocial programmes that target factors from the different domains (physical, psychological and social), irrespective of the number of people who deliver the programme. Such a programme must have a physical component plus at least 1 other core elements (psychological/educational): 3 core elements: Physical + psychological + educational; 2 core elements: Physical + psychological; 2 core elements: Physical + educational. Group exercise was recommended in the light of clinical evidence and cost-effectiveness analysis. No difference was observed between group and individually delivered programmes, however group exercise was demonstrated to be cost-effective. More details can be found in section 17.5 Recommendations and link to evidence, Trade-off between net clinical effects and costs. The components of the programme were analysed under three categories: physical (such as specific exercise modalities, mobilisation, massage), psychological, educational (defined educational intervention e.g. education on anatomy, psychology, imaging, coping, medication, family, work and social life). The majority of the evidence for the psychological element in the MBR review and in the combination section of the psychological therapies review was for a cognitive behavioural approach, so the GDG felt the psychological element of a combined programme should incorporate a cognitive behavioural approach. While the intensity of the components of the programme was not studied directly, the GDG noted that the intensity of the interventions where clinical benefits were seen varied. These considerations are reported in section 17.6 (Recommendations and link to evidence) Downstream cost savings are not explicitly assumed; however this possibility was one of the considerations taken into account by the GDG when discussing the recommendation. It was not possible to determine how much of the effect of the treatment was specific. Where possible, it was taken into account. This is consistent with the approach in all other intervention reviews in the guideline. The GDG agreed important to note that for all interventions the person delivering the therapy would have a large effect on the outcome of treatment and that it should be delivered by an appropriately trained individual. This is acknowledged in section 17.6 (Recommendations and link to evidence).
Society for Back Pain Research	Full 1	452-456	General	It would be helpful to have a definition of multi-modal care in the recommendation table. Multi-modal is not a term currently used. An alternative may be "package of care"	Thank you for your comment. Following stakeholder feedback, the recommendation has been reworded. It now reads; Consider manual therapy for managing non-specific low back pain with or without sciatica, but only as

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We note that trials of manual therapy show an effect on its own. Clearly manual therapy will be delivered individually, but if delivered as part of a multi-modal intervention with exercise, would the exercise still be in a group. If so, this would necessitate 2 appointments! There is an error in how the Hurley et al 2004 paper is described in the table, the study took place in the United Kingdom, Furthermore, the conclusions drawn concerning the effectiveness of interferential therapy are incorrect as it was found to be as effective as manual therapy when used alone or in combination. SUGGESTION: Manual therapy integrated (with) intervention that would include ********** There are no RCTs of multi modal treatment. Only RCT's of individual treatments INCONSISTENCY: the criteria for judging the effectiveness of manual therapy is set higher than for self-management and exercise. Despite the evidence being weak the GDG have recommended manual therapy as part of a multi-model package	part of a treatment package including exercise with or without psychological therapy. Although there were some trials demonstrating clinically important effects for manual therapy alone, overall the GDG agreed that the evidence was too inconsistent to make a recommendation for manual therapy as a sole treatment, whereas there was more supportive evidence of its use in combination with other treatments. It was therefore agreed that the recommendation should be to consider manual therapy as part of treatment package only. This recommendation was based on evidence from two studies that used a treatment package, which can be found in chapters 9, 12 and 17. The GDG are aware that packages of treatment may mean more than 1 appointment for patients but agreed this was where the evidence of treatment effect was. The error in table 242 has been corrected to reflect that the study took place in the UK. The Hurley 2004 paper had two comparisons that were included in the manual therapy review, and one in the electrotherapy review. The arms included in the manual therapy review were 1) manipulation/mobilisation versus inferential therapy, and 2) manipulation + inferential therapy versus inferential therapy. The results for comparison 1) showed that there was a clinically significant benefit for manipulation/mobilisation for two of the quality of life domains at both short and long term time points, and only for one domain for inferential therapy. The results for comparison 2) showed a clinically significant benefit for 3 quality of life domains in the short term and 8 in the long term all in favour of inferential therapy with manipulation. There was no significant benefit for inferential therapy alone. None of the comparisons showed a clinically important benefit for pain or function for either intervention. Therefore inferential therapy alone was not as effective as manual therapy or manual therapy with inferential therapy in terms of quality of life.
Society for Back Pain Research	Full 1	564-568	General	The Hurley et al 2004 paper is described in the tables in the Electrotherapy sections - the study took place in the United Kingdom, while it states the Republic of Ireland which is incorrect. Furthermore, the conclusions drawn concerning the effectiveness of interferential therapy are incorrect as it was found to be as effective as manual therapy when used alone or in combination.	Thank you for your comment. The error in table 242 has been corrected to reflect that the study took place in the UK. The Hurley 2004 paper had two comparisons that were included in the manual therapy review, and one in the electrotherapy review. The arms included in the manual therapy review were 1) manipulation/mobilisation versus inferential therapy, and 2) manipulation with inferential therapy versus inferential therapy. The results for comparison 1) showed that there was a clinically significant benefit for manipulation/mobilisation for 2 of the quality of life domains at both short and long term time points, and only for 1 domain for inferential therapy. The results for comparison 2) showed a clinically significant benefit for 3 quality of life domains in the short term and 8 in the long term all in favour of inferential therapy with manipulation. There was no significant benefit for inferential therapy alone. In the electrotherapy review, the comparison was inferential therapy with manual therapy versus manual therapy, and again clinical benefits were seen for quality of life domains, all favouring the combination arm rather than inferential therapy alone. None of the comparisons showed a clinically important benefit for pain or function for either intervention. Therefore inferential therapy alone was not as effective as manual therapy or manual therapy with inferential therapy in terms of quality of life.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society for Back Pain Research	Full 1	147-150	General	The setting in which imaging should be considered needs more clarity. In the UK diagnostics are often arranged/commissioned from primary care/interface musculoskeletal services. We are concerned about substantial cost implications if all diagnostics required secondary care referral as this would attract a tariff for a secondary care consultation and a tariff for the diagnostic. We appreciate that the evidence indicates that it is not cost effective for general clinicians to arrange diagnostics. However, it would be helpful if the GDG could offer a definition of a "specialist setting". We support that specialist clinicians may have less diagnostic uncertainty, but in the UK specialist clinicians increasing use diagnostics for defensive medicine (rising litigation). Hence you cannot assume that the use of diagnostics will be lower. It would be helpful if the focus of the recommendation was WHEN to do imaging. Suggested research recommendation: • Development of an imaging stratification tool for use in a specialist setting.	Thank you for your comment. This has been discussed further with the GDG and the imaging recommendation has been edited to read; for example, a musculoskeletal interface clinic or hospital to clarify the recommendation. The objective of the review was to determine the clinical and cost effectiveness of imaging techniques in the management of non-specific low back pain and sciatica. Analysing the timing of imaging was beyond the scope of the review. Research recommendations can only be drafted on areas where the evidence has been searched and it has been determined that there is a gap in the evidence base or uncertainty. Stratification for imaging was not prioritised as an area to cover within the scope of this guideline therefore we are unable to include the research recommendation as you suggest.
Society for Back Pain Research	Full 1	303-306	General	INCONSISTENCY: • Supervised exercise is to be" considered", but it has larger effect size than self-management which is to be "provided" • Based on the evidence exercise should be in Box 1. • It is not clear why this is the only recommendation that advises "NHS" • It is not clear why this is the only recommendation related to "specific episode" • It is not clear why this is the only recommendation related to " flare ups" No evidence of cost effectiveness for groups is provided. The GDG have not considered the following: • Many therapy services are small with no facility for groups • It is known that there is a high dropout rate from groups. It may be cheaper to deliver, but may reduce effectiveness and long term compliance • Group sessions can only delivered at certain times and finding a set time to suit individual patients is not possible. • Some patients do not/cannot engage in groups. Key papers which do not appear to have been included: • Hurley et al, 2015: walking versus group exercise and standard physiotherapy. This paper includes an economic analysis and shows that walking is a more cost effective option. • Other key walking paper that are missing are listed below (Eadie et a;, 2013; Krein et al, 2013) Hurley DA(1), Tully MA, Lonsdale C, Boreham CA, van Mechelen W, Daly L, Tynan A, McDonough SM. Supervised walking in comparison with fitness training for chronic back pain in physiotherapy: results of the SWIFT single-blinded randomized controlled trial (ISRCTN17592092). Pain. 2015 Jan;156(1):131-147. Eadie J, van de Water AT, Lonsdale C, Tully MA, van Mechelen W, Boreham CA, Daly L, McDonough SM, Hurley DA.Physiotherapy for sleep disturbance in people with chronic low	Thank you for your comment. The GDG acknowledged the complexity of defining self-management and this is detailed in section 8.6 'Recommendations and link to evidence'. This was taken into account when reviewing the evidence and as a contributing factor to the poor evidence for this intervention. However the GDG agreed that self-management should be a principle that is recommended across the treatment pathway for people with low back pain and sciatica. The wording of the recommendation has been amended to clarify this. Please note the algorithm has been revised. The wording of the recommendation refers to the provision of exercise programmes within the NHS. The recommendation of such programmes to be offered in the context of a specific episode or flare-up is based on a clinical and cost-effectiveness basis. These are detailed in section 9.6 (Recommendations and link to evidence). The importance of keeping active with normal activities outside specific episodes or flare-ups is addressed by the self-management recommendation, please see section 8.6 for details. Two economic evaluations of group exercise were included in the review: one comparing group-mind-body exercise to usual care, and one comparing group mixed modality exercise to cognitive behavioural approaches, and a 2 element MBR programme (combination of mixed modality exercise and cognitive behavioural approaches). Group mind body exercise was shown to be cost effective compared to usual care, and although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. This is explained in more detail in the 'Trade-off between net clinical effects and costs' section of the LETR alongside GDG considerations of the evidence. The GDG acknowledge that individually delivered exercise programmes may be preferable in some circumstances and that adherence is a key consideration for exercise programmes. However, the economic evidence suggested that group exercise could be cost effective for the NHS, whereas individual exercise therapy would be more costly. Furthermore, there was a lack of evidence from the review clearly demonstrating individually delivered

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				back pain: results of a feasibility randomized controlled trial. Arch Phys Med Rehabil. 2013 Nov;94(11):2083-92. doi: 10.1016/j.apmr.2013.04.017. Epub 2013 May 2. Krein SL(1), Kadri R, Hughes M, Kerr EA, Piette JD, Holleman R, Kim HM, Richardson CR. Pedometer-based internet-mediated intervention for adults with chronic low back pain: randomized controlled trial. J Med Internet Res. 2013 Aug 19;15(8):e181. doi: 10.2196/jmir.2605. It would be helpful to understand the GDG reasoning for not specifically recommending the alexander technique. There is 1 large trial showing evidence of effectiveness. Suggested research recommendations: : o One trial supports walking as a cost effective option, further studies in a UK setting should be considered to confirm this finding. o Offer supervised exercise for all patients with low back pain with or without sciatica. This can be either delivered in groups or individual treatment sessions.	exercise to be superior to group exercise. Therefore it was agreed that individual exercise could not be specifically recommended, but was emphasised in the recommendation that the specific needs, preferences and capabilities of the individual should be taken into account. The Hurley 2015 paper was considered, however excluded from the exercise review as it was considered a MBR intervention. However, it was also excluded from this review as the population included postpartum back pain, which is not covered by the scope. Krein 2013 was also excluded from the review as the comparator arm was considered inappropriate due to being an 'enhanced usual care' intervention where participants received a pedometer, as in the active group, but did not receive goals and reminders an in the active group. Therefore this did not fit into the protocol. Eadie 2013 has now been extracted and fully added to the evidence report. The results show some benefit for group exercise, which further supports the exercise recommendation made. The GDG considered a recommendation for the Alexander technique, and noted that the evidence was promising in terms of quality of life, however felt that as all evidence in favour of the technique came from a single study, they agreed that this was not enough for a recommendation. Furthermore, although the overall number of participants in the trial was large, the number of participants per intervention arm was quite small.
Society for Back Pain Research	Full 1	493-496	General	INCONSISTENCY: GDG reasoning is very explicit in this section compared to other treatments. • There are many passive treatments (e.g. injection) discussed/reviewed by the GDG, all of which may "promotes dependence, discourages self-management or participation in activity/exercise". Why is acupuncture the only intervention where the GDG make this comment? • You could argue that many treatments can have a "non-specific contextual effect". Why is acupuncture any different? Why has this comment not been made when discussing other interventions (e.g. injection). There is evidence supporting that acupuncture has a biological (neurophysiological) effect: • Functional MRI • Sham acupuncture also a biological effect, but it is weaker. • Acupuncture is effective in pain reduction and the neurochemical basis known since Han JS and Terenius L 1982 paper in Annual Review of Pharmacology and Toxicology, Vol. 22: 193-220 DOI: 10.1146/annurev.pa.22.040182.001205. The criteria to judge acupuncture has been set higher than other interventions. • The forest plots demonstrate reasonable effect sizes in favour of acupuncture compared to other treatments. (E.g compared to analgesia). • Reduction of pain is important. • The headache guideline recommendation is to "consider" acupuncture. • Acupuncture has been shown to be more effective than medication. Why is medication in, yet acupuncture is out? • The effect sizes (forest plots) are larger for acupuncture than injection. • The logic should be the same as for manual therapy, acupuncture should be considered as part of multi modal care. • It is not clear why it is considered differently to the recommendation for oral NSAIDs or the recommendation for weak opioids.	Thank you for your comment. The statement regarding dependency has now been removed from section 13.6. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Where placebo or sham is available, this has been given priority in the review process to first demonstrate a treatment effect separate from the non-specific treatment effects. Since the evidence of acupuncture versus sham was conflicting, the GDG agreed there was insufficient evidence of clinical benefit to recommend acupuncture on the NHS. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. Although there were similar effect levels observed for acupuncture and NSIADs, the GDG noted that these were only from 2 small studies of low and very low quality. Given the more positive results seen in the pharmacological review for NSAIDs compared to placebo, the GDG agreed that the limited evidence for acupuncture versus NSAIDs was insufficient to consider equivalence between them and therefore agreed to have a 'consider' recommendation for NSAIDs. The recommendation for weak opioids was developed as an alternative treatment option for people who could not take NSAIDs which has now been made clear in the recommendation.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• As per medication, acupuncture will similarly facilitate exercise and return to work and function and therefore should be considered as part of multimodal package with exercise +/- manual therapy as per the 2009 GG88 guidelines. Either, both analgesia and acupuncture should be recommended, or neither as they have not been treated consistently. INCONSISTENCY IN USE OF EVIDENCE. 1/ There is no evidence that acupuncture promotes dependence, discourages self-management or participation in activity/exercise any more than any other passive treatment (e.g. injection). 2/ Acupuncture shows superiority over sham in 11 out of 12 outcomes. 3/ Vickers AJ, Linde K Acupuncture for chronic pain. JAMA. 2014 Mar 5;311(9):955-6. doi: 10.1001/jama.2013.285478 supports acupuncture for chronic pain on the basis of significant differences against both sham intervention and usual care 4/ The Scottish Intercollegiate Guidelines Network (SIGN) guidelines in 2013 recommend acupuncture for acute low back pain and in persistent non-specific low back pain. 5/ Systematic reviews such as Lee JH et al 2013 (Clin J Pain. 2013 Feb;29(2):172-85. doi: 10.1097/AJP.0b013e31824909f9), synthesising 11 RCTs with 1139 patients, conclude acupuncture may be more effective than medication for symptom improvement in acute low back pain (5 studies; risk ratio, 1.11; 95% confidence interval: 1.06, 1.16) and may also relieve pain more effectively than sham acupuncture (2 studies; mean difference, -9.38; 95% confidence interval: -17.00, -1.76).	The GDG recognise that evidence for both epidurals and acupuncture are conflicting when compared to placebo/sham. However, when reviewing the evidence for epidural injections the GDG was able to identify a subset of people in whom epidurals showed clinical benefit; people with acute sciatica, whereas this was not possible from the acupuncture evidence review. Therefore the recommendation made for epidural injections is for this subset of people with sciatica only. Furthermore, the GDG were mindful of the limited availability of treatment options for people with severe sciatica, and the various options for people with low back pain with or without sciatica. Acupuncture could not be considered as part of a combined treatment package as there was no available evidence included in this guideline for packages including acupuncture,
Society for Back Pain Research	Full 1	199-201	General	INCONSISTENCY of strength of recommendation: We are not clear why self-management is such a strong recommendation "provide" and why it appears in box 1 of the algorithm. The effect size is negligible and the GDG concluded that: • There was "uncertainty about this evidence". • " no conclusive evidence in favour of self-management provided in isolation" Advice and education are not self-management. Advice and education may facilitate self-management. The terms can't be used interchangeably. It would be helpful if there was guidance about what information to provide. It is important to highlight that this is usually integrated with other intervention throughout the algorithm. It would be helpful if the GDG could support the importance of the consistency of information across the pathway. It would be helpful to highlight that there was no benefit of unsupervised exercise.	Thank you for your comment. The GDG have clarified that the recommendation for self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practice rather than a separate intervention that is offered. They noted that the evidence from the review was weak, however it was also acknowledged that this review did not adequately capture true self-management approaches and that a good practice statement to support self-management was justified. This is further supported by evidence from the review of multidisciplinary programmes where self-management was often included as part of treatment packages demonstrating benefit. The LETR and recommendation have been updated to clarify this. The wording of recommendation 1.2.1 is now the following: All healthcare professionals should provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, at all steps of the treatment pathway. This should include: information on the nature of non-specific low back pain and sciatica; encouragement to continue with normal activities as far as possible. The following interventions were reviewed for the self-management review: self-management programmes (including patient education and reassurance for example, the Back Book); advice to stay active; advice to bed rest; unsupervised exercise (including exercise prescription, advice to exercise at home). While acknowledging the difficulty to define self-management, the GDG considered appropriate to review advice and education under self-management at protocol stage. The effectiveness of unsupervised exercise is detailed in the clinical evidence statements (section 8.5.1) and in the recommendations and link to evidence (section 8.6), alongside the other self-management interventions reviewed in the chapter.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society for Back Pain Research	Full 1	764-766	General	CLARIFICATION: The term "Promote and facilitate return to work": this is not clear. It would help the user if some guidance on what the clinician should offer in the way of advice/support, and what outcomes should be measured. The term "Promote and facilitate return to work": this is not clear. Work Focused Healthcare is a better term than "promote and facilitate return to work. • what it is important is that the principle of promoting and facilitating return to work should be accepted as part of routine clinical practice (which is supported by current guidance and government policy – see below). • We are not sure it would be helpful for the guidelines to be prescriptive about what clinicians should offer/measure • We suggest to refer to the existing guidance and policy, e.g. guidance for GPs on the importance of work to health, and on how they should advise their patients to encourage work participation rather than incapacity. Burton AK, Waddell G, Kendall N: Developing guidance for workplace and clinic - *Work & Health* (guidance leaflet for professionals in and around the workplace). London: The Stationery Office [ISBN 9999072399] (www.tsoshop.co.uk/gempdf/Work_and_Health_Leaflet_1.pdf) *Health & Work* (guidance leaflet for GPs and other healthcare professionals). London: The Stationery Office [ISBN 0-11-703772-4] (www.dwp.gov.uk/docs/hwwb-health-work-gp-leaflet.pdf) and *Tackling musculoskeletal problems: a guide for the clinic and workplace - identifying obstacles using the psychosocial flags framework. London: The Stationery Office* (www.tsoshop.co.uk/flags). This guidance was sent to all GPs in 2010 to coincide with the introduction of the Fit Note which replaced traditional incapacity certification (http://www.dwp.gov.uk/docs/fitnote-gp-guide.pdf) and was incorporated into the related National Education Programme for GPs, run by the Royal College of General Practitioners in 2010-11. The imminent launch of the Fit for Work Service (which means that GPs, individuals and employers can refer into a tele-occupational health case management service) will in essence assist clinicians in terms of 'what to do'. • Current policy calls for 'work-focused healthcare' (which may be a better term than 'promote and facilitate return to work) and the evidence informing this can be found within the government's Health, Work and Wellbeing Strategy 2010-2015. Although this isn't specific to LBP, much of the evidence comes from LBP populations as this is a leading cause of sickness absence and work disability, and it is suggested that the same principles should be applied across all common, work-relevant health conditions. EVIDENCE: • There is a wealth of robust evidence, but it doesn't lend itself to clinical trials methodology or the program focuses on 'stay at work', and therefore wouldn't be deemed eligible evidence here. The RCTs that have been included suffer from the same issue as much of the other clinical evidence included – small effect sizes, largely because most people recover and return-to-work, and they do not need intensive/clinical intervention. This kind of research is essentially social research, and outcomes are generally seen as long-term, public health benefits. • This does then beg the question as to whether return-to-work should have been included in these guidelines, but seeing as though work disability due to LBP is a global health concern then it seems right to. The guidelines do acknowledge this and the policy evidence in this area, and I would agree that this should stay as is. This issue also then has implications for the following suggested recommendations:	Thank you for your comment. The GDG agreed that facilitation of returning patients to work, where applicable, should be encouraged. However, they felt that specific return to work programmes separate from other clinical interventions should not be recommended for the NHS. The GDG prioritised other areas for research recommendations as they believed there was existing evidence for return to work programmes.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				SUGGESTED RESEARCH RECOMMENDATION: Given the importance of work for people's health this is an important research topic. o What is the clinical and cost effectiveness of return to work programmes for people with non-specific low back pain with or without sciatica? o Studies would have to incorporate some kind of stratification as most people do recover and return to work - current evidence suggests that most people do not need intensive, expensive return-to-work programs. o What are the different needs of unemployed vs employed people with non-specific low back pain with or without sciatica, in return to work. o This is an important distinction to make, but the term 'return to work' isn't usually appropriate when applied to unemployed populations as the term is only relevant to people who are already employed and taking sickness absence. It is only relevant to make this distinction in the clinical domain if people have become unemployed due to ill-health. I would be hesitant to make this a specific research recommendation due to the other issues outlined, and the social complexity involved when dealing with unemployed populations – it would mean that the term 'needs' would have to be very clearly defined, and presumably would only be related to clinical/health needs. Additionally, there is separate NICE guidance on long-term sickness absence and incapacity. o Implementation research is needed – we know enough about what works (in the clinic and other settings), and the clinical and cost-effectiveness of keeping people at work can be measured at a societal level, e.g. less dependence on health and welfare services, but we know less about how the evidence can be implemented, or the barriers to implementing it in practice. I would put this forward as a suggestion for further research.	
Society for Back Pain Research	Full 1	15	General	In its current form the algorithm is not sufficiently user friendly: • The boxes are heavy on text content. • Patient choice does not reflect strongly in the algorithm. Based on the strength of evidence we are not clear why: • Self-management appears in box 1. • Supervised exercise does not appear in box 1 • Multi-modal (including manual therapy) does not appear in box 1 It would be helpful if the GDG could bring some direction as to what care is proposed of people at the end of the pathway? • No supporting evidence is provided to support the statement "Additional treatment unlikely to be of benefit". • There is evidence that for a suitable subgroup spinal fusion may be of benefit (but has risks). • There needs to be some direction/support for people at the end of the pathway. Perhaps this should be a research recommendation. Suggested research recommendations: : 1. What is the effectiveness and cost effectiveness of the NICE back pain & sciatica algorithm, compared to usual care 2. For people with persisting back pain impacting on quality of life what is the cost effectiveness of no care versus supported care.	Thank you for your comment. The algorithm has been extensively remodelled for clarity and to better depict the recommendations in the guideline. Additional footnotes have been included to aid in the clarity. An additional section has been added for considerations to take into account if an inadequate response is observed following treatment. Once these considerations have been made, if no further treatment option is suitable, the algorithm shows that those patients who reach the end of the pathway are 'Out of the pathway'. Research recommendations have been drafted relevant to areas within the evidence reviews in which there was uncertainty or a lack of evidence, as prioritised by the GDG.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society of British Neurological Surgeons	Full	General	General	We note that in many key areas the evidence available is not of a high quality. The SBNS will support the guideline recommendations to develop areas of research to produce evidence. However, in some areas, the clinical issues are such that RCTs will not be possible or ethical. *Additional comment: It is interesting to see that though GDG has extensively looked into the evidence but in most places due to lack of evidence, they have taken the opinion of GDG "clinical experts". This expert opinion is valuable but decreases the scientific value of the guideline and also brings in a bias which should be clearly mentioned. I would propose that guideline makes it very clear as to which opinion is based on "expert opinion". Though this information is there in detailed version but this should be made very obvious in the recommendation section.*	Thank you for your comment and support of the research recommendations. It is acknowledged that double blind RCTs may not always be the most appropriate trial designs, and other trial designs will need to be considered, this can still lead to good quality evidence however if well performed. GDG opinion is integral to the guideline in interpreting the clinical evidence. In areas where evidence is conflicting or limited, clinical experience is used to further inform the recommendations, however where evidence is lacking completely, recommendations have not been made.
Society of British Neurological Surgeons	Full	General	general	The definition of Non-specific LBP is based on diagnostic uncertainty of the source of the pain in degenerative disease. Many patients with LBP have a probable specific cause identified, e.g. prolapsed disc, spondylolisthesis based on imaging, clinical assessment and investigations such as Discography. The guideline should recognise that LBP can be due to a 'Specific' condition and to recommend indications for interventions. Additional comments: *The very first thing is definition of NSLBP. This is still confusing and prevents an attempt for specific diagnosis. Some serious pathology like discitis or malignancy may first present as NSLBP. Red flag signs are not always present. Also after failure of initial conservative treatment, further management depends on establishing a diagnosis and thus imaging will be required at this stage. Why this can't be done in a primary care setting minimising expensive secondary care consultations?* The heterogeneity of back pain generators is such that the trial to answer the pertinent questions could never be done	Thank you for your comment. The introduction has been rewritten to clarify that low back pain can be due to specific conditions, and to highlight those that are excluded from the guideline.
Society of British Neurological Surgeons	Full	General	general	Cauda Equina syndrome (CES) – We recommend the guideline to include the clinical pathway, referral arrangements and imaging timelines of this condition. This recommendation was made by the SBNS to NICE in March 2015 and discussed at a meeting between NICE and NHS England when it was agreed that the GDG will be informed to be considered in LBP guideline. The SBNS has in combination with BASS circulated a document indicating the standards relating to the diagnosis and treatment of CES. This condition can potentially cause very disabling long term symptoms and the timelines of diagnosis and treatment are crucial to prevent these complications.	Thank you for your comment. Cauda Equina syndrome (CES) is beyond the scope of this guideline as stated in section 4.1.2 of the scope in appendix A.
Society of British Neurological Surgeons	Full	115	22,23	States that MRI is relatively expensive but compared to other costs given in the documents (like for physiotherapist, GP consultation etc), if the imaging can minimise the number of consultations then it is not expensive. Psychological benefits are difficult to capture.	Thank you for your comment. This introductory paragraph is intended to set the scene of current practice and the need for the review. The cost stated here purely relates to the direct costs, and is not used as a basis for the cost-effectiveness.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society of Teachers of the Alexander Technique	Full 1	331	Boxed text	Evidence base The draft report states: '*Although the GDG acknowledge that the improvement in function, pain and quality of life scores demonstrated in the intervention group of 24 lessons of Alexander technique were clinically significant and represent a very promising finding in favour of the Alexander technique it was felt that to recommend a therapy not currently available on the NHS (and so to recommend a significant change in practice) based on limited evidence was not appropriate. Further, given that a second study did not support these results, and the fact that all evidence came (from) group single studies of a small sample size, it was decided that no recommendation would be given for postural therapies'*. Parts of the statement above are highly problematic, namely: *'A second study did not support these results'* In our view it is not tenable to claim that a second study *did not support* the results of the ATEAM trial. It is also somewhat misleading to state that this second study showed *'no clinically important benefit'* (page 328, lines 29−31). The second study in question was a small, methodological feasibility study (ASPEN) whose design specifically stated that it was not sufficiently statistically powered to be able to show clinical benefit. Thus, in the Methods section of the ASPEN publication it states: 'no formal sample size calculation was appropriate' and 'the analysis of effectiveness was underpowered, we performed an intention-to-treat analysis of covariance to estimate the main effects of the interventions'.[1] The results state 'As expected given the very limited power, most outcomes did not reach significance at the 5% level and so the lack of significance should be interpreted very cautiously...(changes) were nearly always in a beneficial direction, suggesting that type 1 errors are unlikely. The estimates suggest that clinically important improvements were probably occurring'.[1 (page 20)] The study concluded 'The exploratory analysis of clinical outcomes suggests that the estimates of treatment effects are likely to be clinically important....in particular 10 Alexander technique lessons appeared to provide the same order of benefit as 24 Alexander technique lessons did in the ATEAM trial.[1 (page33)] As a secondary point, ASPEN was only a 6-month study (unlike the 1-year ATEAM trial);[1,2] since Alexander lessons are not a treatment for back pain but a method for improving movement coordination and postural support, through self-management it would be anticipated that effectiveness would not diminish over time but may actually improve (as seen in ATEAM).[2] Elsewhere in the report the GDG do acknowledge that ASPEN was only a feasibility study but this has not prevented the above unsupported conclusion being drawn. *All evidence came (from) group single studies of a small sample size* This point is debatable as, for some reason, all the data that the GDG has considered from the ATEAM trial come from the analyses of individual groups.[2 (Table 5)] The main analysis of the study (with its larger group sizes) does not appear to have been considered, namely 6 Alexander lessons plus/minus exercise versus usual care and 24 Alexander lessons plus/minus exercise versus usual care.[2 (Table 4)] The ATEAM trial randomised nearly 600 individuals followed up for a year and thus represents the first substantial randomised controlled trial evidence for the effectiveness of Alexander lessons for people with chronic back pain. We agree that more evidence is needed to confirm the findings of ATEAM and address key gaps in the evidence (see comment number 2 above). *'Based on limited evidence'* We acknowledge that the evidence for the effectiveness of Alexander lessons for people with low back pain is currently relatively limited but do not agree that the evidence base	Thank you for your comment. The GDG are aware of the nature and length of the ASPEN study and took this into account when weighing up the evidence and making recommendations. We have now included the Alexander (6 lessons) + exercise prescription, and Alexander (24 lessons) + exercise prescription versus usual care in the combination section of the postural review. Although both combination arms showed a clinically important benefit on pain, function and quality of life, the GDG agreed it was not sufficient to make a recommendation for the Alexander technique due to the fact that all evidence favouring the Alexander technique still came from just a single study. The GDG have considered the two further studies mentioned however, unfortunately they are not includable in this review; the ATLAS trial consisted of a population with neck pain, rather than low back pain, and therefore is beyond the scope of the guideline.Additionally, the Vickers trial was unpublished at the time the systematic review was undertaken.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				consists of a single trial only (ATEAM trial).[2] Since the time when the literature searching for the draft guidelines was conducted, the ATLAS trial has been published.[3] This large randomised controlled pragmatic trial also shows clinically meaningful benefit of Alexander Technique lessons in primary care patients who have chronic pain associated with the spine and its musculature, in this case at the level of the neck. The ATLAS trial demonstrated significant long term (1 year) reductions in chronic neck pain and associated disability following 20 Alexander lessons (N=517).[3] Since the ATLAS trial provides robust evidence of the effectiveness of Alexander lessons for people with pain associated with the spine and its musculature, it can be considered as strongly supportive of the ATEAM trial findings. Further supportive data come from a small randomised controlled trial that does not appear to have been considered in the current NICE review. This was a small (N=91) randomised controlled trial that reported significant benefit in pain severity and disability following Alexander Technique lessons for patients with chronic non-specific low back pain. The trial has not been published in a peer-review journal and would be considered to be of very low quality, so can only be considered as preliminary supporting evidence. A study report is available and the methodology and findings have also been described in a systematic review.[4,5] References 1. Little P, Stuart B, Stokes M, Nicholls C, Roberts L, Preece S, et al. Alexander technique and Supervised Physiotherapy Exercises in back paiN (ASPEN): a four-group randomised feasibility trial. *Efficacy Mech Eval* 2014;1(2). 2. Little P, Lewith G, Webley F, Evans M, Beattie A, et al. Randomised controlled trial of Alexander Technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008; 337: a884. 3. MacPherson H, Tilbrook H, Richmond S, Woodman J, Ballard K, et al. Alexander Technique lessons or acupuncture sessions for persons with chronic neck pain: A randomized trial. *Annals of Internal Medicine 2015;163:653−62*. 4. Vickers AP, Ledwith F, Gibbens AO. The impact of the Alexander Technique on chronic mechanical low back pain. Westmorland General Hospital, Kendal, UK (unpublished report, 1999); 1–19. [STAT holds a copy which can be forwarded]. 5. Woodman JP and Moore NR. Evidence for the effectiveness of Alexander Technique lessons in medical and health-related conditions: a systematic review. *International Journal of Clinical Practice* 2012;66:98–112.	
Society of Teachers of the Alexander Technique	Full 1	331 312−319 331, 309	Boxed text Tables 132−138	Quality of evidence The draft report states: *'Three pragmatic RCTs met the criteria for inclusion in this review. The quality of the evidence for all outcomes reported by these 3 studies ranged from moderate to very low quality due to high risk of bias and in some cases significant imprecision in the effect estimate. The reason for the high risk of bias included the absence of a description of usual care, a high rate of missing data (>20%), a differential rate in missing data between groups and difficulties surrounding the issue of adequate blinding with such interventions*' [Note: this quote refers to three studies but only two of them evaluated Alexander Technique lessons (ATEAM trial and ASPEN feasibility study[1,2]] One of the stated reasons why Alexander lessons are not included in the draft recommendations is that the evidence is described as not being of high enough quality for	Thank you for your comment. Details about the massage and prescribed exercise interventions in the ATEAM trial, and the usual care arm in the ASPEN trial have been added to the review, and the LETR has been updated to reflect these changes. However, the ATEAM trial did not provide a description on the 'normal care' group (with no exercise) and therefore the statement 'absence of a description of usual care' has been unchanged. When determining quality, including risk of bias assessments and the rates of missing data and loss to follow up, the GRADE process is to do this by outcome, not by study. There the dropout rate is considered per outcome, rather than overall participant numbers. Having reassessed the missing data rates in both trials, we agree that the rate of missing data was similar for most comparisons, although not all. Therefore, we have removed this statement

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		331, 309 331, 309 331	Boxed text, Table 130 Boxed text, Table 130 Boxed text, Table 130	the reasons given above. We challenge the categorisation of the ATEAM trial as being of only low to moderate quality. To address the points raised above in turn: *'Absence of a description of usual care' (p331) and 'Care other than intervention not described' (Table 130, p309) and 'the limited information about the other care, particularly doctor-led exercise prescription received, meant they were unable to be certain of the effects of the Alexander Technique from this single trial' (page 331)* • All patients in all groups in the ATEAM and ASPEN studies received usual NHS care throughout the study duration, as described in the publications.[1,2] • For the ATEAM trial, the published online appendix to the main paper describes in detail the GP-prescribed exercise intervention with follow-up nurse consultations that half of all patients were randomised to (so including half of those in the Alexander lesson groups).[1] • Because of the factorial design of the ATEAM trial, the relative effects of Alexander lessons and exercise could be evaluated, therefore it was very clear what the relative impacts on clinical outcome these two interventions had.[1] • The published appendix to the ATEAM trial also describes in detail the massage intervention.[1] • In addition, usual care in the ATEAM trial is described quantitatively in the economic evaluation publication which details the number of GP visits, other primary care, secondary care and medication costs for each group.[3] • The publication describing the small feasibility study, ASPEN gives this description of usual care 'analgesia or referral for further care according to NICE guidance as appropriate (including orthopaedic or routine physiotherapy assessment)'.[2 (page 9)] *'High rate of missing data' (p331) and 'High rate of loss to follow-up' (Table 130, p309)* NICE defines a high rate of missing data as being an amount *greater than* 20%. Using this criterion, the ATEAM trial does not reach this threshold as the overall rate of missing data was 20% at the final 12-month primary endpoint. At the 3 month endpoint 81% of participants (469/579) completed the self-report outcome measures and at 12 months this figure was 80% (463/579 i.e. 80% to one decimal place).[1] Similarly the label of 'high rate of missing data' has also been incorrectly applied to the ASPEN feasibility study which actually had a missing data rate at the 6-month final endpoint of 19%.[2] Furthermore, as a general point, a missing data rate of 20% at 1 year for a pragmatic trial would usually be seen as acceptable. Given that the rate of missing clinical outcome data / loss to follow-up was *not* high in either the ATEAM or ASPEN studies, we are wondering if perhaps there has been a misunderstanding and confusion caused by the relatively high rate of missing *economic* data in the cost-effectiveness evaluation of the ATEAM trial?[3] *'Differential rate in missing data between groups' (p331)* We assume that this comment in the quote above does not relate to Alexander Technique lessons but refers to the third study which evaluated a different intervention. Our assumption is because in Table 130 (page 309) the comments state that 'there was a low differential rate of loss to follow-up in the ATEAM trial'. No comment is made in relation to the ASPEN study but loss to follow-up was low and similar in all four groups.[2] *'Difficulties surrounding the issue of adequate blinding with such interventions' (p331) and 'No sham or attention control' (Table 130, p309)* The draft report acknowledges that the nature of the intervention precludes designing a placebo-controlled study (p331, boxed text). However, the statement that there was no sham or attention control in the ATEAM trial is incorrect. Firstly, because of the impossibility	from the review and this is reflected in the GRADE quality rating for the relevant outcomes. Regarding massage as an attention control, all of the interventions included in the review were discussed and agreed by the GDG; therefore massage was considered an active intervention, as this is an intervention that is being considered within the manual therapies review in this guideline, rather than an attention control. Therefore, the statements regarding difficulties surrounding the issue of adequate blinding and lack of sham or attention control have not been changed. The overall quality rating of the outcomes for the ATEAM and ASPEN trials have not changed in the review and therefore the GDG's conclusion remains unchanged.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		328	Boxed text 11−16	of devising a placebo/sham for an educational, hands-on method such as the Alexander Technique, the ATEAM study design included a massage intervention as an attention and touch control for the Alexander Technique 6 lesson group. Participants in the massage group received the same amount of individual time and attention as those in the Alexander 6 lesson group.[1] So there was an attention control for the 6 Alexander lesson group and, furthermore, the effectiveness of 6 Alexander lessons was maintained at 1 year whereas massage was found to be no longer effective in the primary outcome measure of Roland Morris disability score.[1 (Table 4)] Secondly, because one of the aims of the ATEAM trial was to evaluate cost-effectiveness, it was essential that the main control group was usual care, otherwise the increments in costs and effectiveness between groups would not have been correctly estimated and would have made any conclusions about cost-effectiveness very limited. In relation to this last point, a further incorrect statement is made in the Quality of evidence section on page 331: *'as this is a usual care comparison it is not possible to tell if it is the technique itself or simply the contact with a therapist that is causing any effects seen'*. Firstly, as mentioned, a comparator group of massage was included to control for non-specific effects of contact and individual attention. Secondly, as the GDG acknowledges, clinical outcomes were significantly superior in the Alexander lesson groups compared with the massage group (Full report, page 328, lines 11−16). Thirdly, the endpoint for the primary outcome measure was at 1 year, several months after the intervention had ceased, so it would be surprising if non-specific benefit persisted to this point. Fourthly, it is important to take into account that pragmatic trials to estimate the effectiveness and cost-effectiveness of interventions are the primary source of evidence needed: the key piece of evidence for any intervention is the estimate of the total effect of the intervention (i.e. the combined specific and non-specific elements of an intervention) since these are the benefits that patients experience. Finally, the current (2009) NICE back pain guidelines describe the ATEAM trial as a *'well-conducted trial with a low risk of bias'*. Even allowing for methodological changes in NICE's review process (using GRADE etc), it seems surprising that the same trial can be categorised as being both 'low risk of bias' and 'high risk of bias'. In light of all the points raised above, there appears to be little basis to conclude that the ATEAM trial was at high risk of bias and the description of being only low to moderate quality is questionable. References 1. Little P, Lewith G, Webley F, Evans M, Beattie A, et al. Randomised controlled trial of Alexander Technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. BMJ 2008; 337: a884. 2. Little P, Stuart B, Stokes M, Nicholls C, Roberts L, Preece S, et al. Alexander technique and Supervised Physiotherapy Exercises in back paiN (ASPEN): a four-group randomised feasibility trial. Efficacy Mech Eval 2014;1(2). 3. Hollinghurst S, Sharp D, Ballard K, Barnett J, Beattie A, et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain: economic evaluation. BMJ 2008;337:a2656. doi: 10.1136/bmj.a2656.	
Society of Teachers of the	Appendix H	344−355	63	There is a typo here: it should read '24 lessons' not '6 lessons' for both interventions 3 and 4. In addition, Alexander lessons are not 'postural therapy'	Thank you for your comment. This typo has been corrected. The GDG discussed grouping of the different interventions included in this guideline and agreed that tor the purposes of this review, the Alexander technique lessons

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Alexander Technique					were appropriately classified as postural therapy. More detailed description of the form of postural therapy is given in the evidence tables and summary of included studies where the specific intervention is detailed.
Society of Teachers of the Alexander Technique	Full 1	General	General	We are disappointed that pain frequency is not considered as an outcome measure worthy of consideration. 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. Because pain frequency is not being considered by NICE, the review of the ATEAM trial ignored one of the two main outcome measures in the ATEAM trial, the number of days in pain.[1] Reference 1. Little P, Lewith G, Webley F, Evans M, Beattie A, et al. Randomised controlled trial of Alexander Technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008; 337: a884.	Thank you for your comment. The priority outcomes were defined in the scope of the guideline, with pain severity specified (rather than frequency). Unfortunately no comments were received at the stakeholder consultation phase for the scope suggesting that pain frequency should be considered. The specific outcomes considered in each review question were subsequently agreed with the GDG, based on this core set, when setting the protocols. These are prioritised according to those the committee believe are the most appropriate to give a representative view of the effectiveness of an intervention. Only a limited number of outcomes can be considered to ensure that the results of the review are interpretable, and consequently not all outcomes reported in individual trials can be captured if they were not prioritised in the review.
South Devon Healthcare NHS Foundation Trust	Full	paragraph 1.2.1 self management	General	We are concerned that this does not recognise the complexities of helping patients to establish self-management and how far beyond "advice and information" this can go. If the support with self management is "tailored" as it says to an individual's needs and capabilities, this is where the bulk of our physiotherapy and psychology input is focussed. also the breadth of barriers (psychological, physical, social and economic) to self-management is not considered.	Thank you for your comment. The complexity of identifying self-management is acknowledged and detailed in the guideline (section 8.6, Recommendations and link to evidence). The objective of the self-management review was to assess the clinical and cost effectiveness of self-management in the management of people with non-specific low back pain and sciatica. The analysis of barriers to self-management was beyond the scope of the review to analyse. However, the GDG acknowledged the existence of other NICE guidance related to this area. This is referred to in section 8.6, Recommendations and link to evidence.
South Devon Healthcare NHS Foundation Trust	Full	Para 1.2.13 psychological therapies	general	Our chief concern is the way it states that psychology should "only" be part of multi modal packages. The point needs to be made about the importance of psychology in dealing with - avoidance - therapy readiness and motivation to change - using values as a motivation to re-engage with activities - extreme distress - managing attachment styles (which may be a barrier to engagement) - helping the high proportion of people with a trauma background for whom their past experience has served to sensitise their pain systems. Many of these patients can benefit initially from input from psychology to enable them to engage further in more multimodal packages, and need this as their entry point into self management. We also have patients seen in our team for only pain psychology who have good outcomes.	Thank you for your comment. The GDG agreed that the reviewed evidence suggests psychological therapies are of limited effectiveness in isolation for low back pain or sciatica. However, the evidence from the combination section of the review and the MBR chapter suggested benefit of psychological therapies in combination with other interventions. The GDG felt it was appropriate to recommend psychological therapies as part of a treatment package including other therapies exercise with or without manual therapy. The MBR chapter also includes evidence suggesting benefits from a package of treatment including a psychological element. Please see section 15.7 (Recommendations and link to evidence) for more details.
South Devon Healthcare NHS Foundation Trust	Full	para 1.2.14 Combined physical and psychological programmes	general	In our opinion this does not take into account the significant proportion of people who would not be suitable for or who would not choose or engage with a group programme.	Thank you for your comment.. The recommendation states that the combined physical and psychological programme incorporating a cognitive behavioural approach should be considered preferably in a group context, that takes into account a person's specific needs and capabilities. Group exercise was given preference in the recommendation in the light of clinical evidence and cost-effectiveness analysis. More details can be found in section 17.5 Recommendations and link to evidence.
Spine Intervention Society	Full	General	General	Evidence Base: The authors did not clearly define study inclusion criteria. Some, but not all, studies aimed at treating facet related pain were included as pertaining to the non-specific low back pain	Thank you for your comment. All study protocols can be found in Appendix C. These protocols outline the inclusion criteria for the review. It was agreed when setting the protocol that study design would be restricted to RCTs in the

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				category. High quality observational studies were omitted that would have shed light on the effectiveness of the different treatment options. The exclusion of high quality observational studies of clinical effectiveness removes important information and context from a synthesis of the literature. While some may argue that there are ample randomized controlled trials (RCTs) for analysis, and examination of observational trials is unnecessary, many of the RCTs included patients selected only by symptoms or failure to utilize image guidance. These failings make such trials irrelevant to current clinical practice and not unexpectedly show poor outcomes. Judging current practice of precise needle placement to a 1 - 2mm target zone in three dimensional space with confirmation of medication distribution by real-time observation of contrast flow by using data from blind injections into an unknown tissue compartment has no validity. There are very few RCTs that utilize current practice standards. Hence, examination of current large observational studies adds important information that is relevant to current standards of practice.	first instance, and then observational studies if there were limited evidence available. If it was felt by the GDG that the RCT evidence was sufficient, then observational studies would not be included. The topic expert members of the GDG are aware of the technical shortcomings of many of the RCTs evaluated by the GDG and these shortcomings were noted when the evidence from individual trials was reviewed. This meant that, although the trials were included in the analysis, we had less confidence in the findings and greater degrees of uncertainty about the outcomes. However, despite this, the GDG felt that there was sufficient RCT evidence available that it was not necessary to include observational studies.
Spine Intervention Society	Full	General	General	Terminology – Sciatica: As explained on Page 18, line 9, the term "sciatica" is in common use: "'Sciatica' is a term that patients and clinicians understand and one that is used widely in the literature to describe neuropathic leg pain secondary to compressive spinal pathology." The problem is that radicular pain may be caused by nerve root irritation, and not compression. Besides, quite often the nature of leg pain that accompanies back pain is somatic referred (non-radicular). There should be some explanation/discussion about the distinctions between radicular pain, somatic referred pain, and radiculopathy. It's not just semantics; the diagnostic and therapeutic options differ for each entity.	Thank you for your comment. We have added further discussion in the introduction to acknowledge the challenge in distinguishing between radicular pain, somatic referred pain and radiculopathy.
Spine Intervention Society	Full	General	General	Diagnosis of Non-Specific Low Back Pain: It is imperative that the guideline promote identification of a proper diagnosis. The term Non-specific Low Back Pain (LBP) implies that it is impossible to diagnose a specific etiology of this condition, which in turn may restrict the ability to treat LBP, depending on its origin. This term is an old misconception that was utterly disproved by a plethora of studies showing that in the majority of cases, the source of LBP (i.e. facet joints, intervertebral discs, SI joints) can be diagnosed. References: 1. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. Spine 1995;20:1878–83. 2. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine (Phila Pa 1976). 1995 Jan 1;20(1):31-7. 3. Maigne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine (Phila Pa 1976). 1996 Aug 15;21(16):1889-92. 4. Schwarzer AC1, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine (Phila Pa 1976). 1994 May 15;19(10):1132-7. 5. Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: an evaluation of prevalence and false-positive rate of diagnostic blocks. J Spinal Disord Tech. 2007 Oct;20(7):539-45 6. Schwarzer AC1, Wang SC, Bogduk N, McNaught PJ, Laurent R. Prevalence and clinical features of lumbar zygapophysial joint pain: a study in an Australian population with chronic low back pain. Ann Rheum Dis. 1995 Feb;54(2):100-6. 7. Laslett M1, McDonald B, Aprill CN, Tropp H, Oberg B. Clinical predictors of screening lumbar zygapophyseal joint blocks: development of clinical prediction rules. Spine J. 2006 Jul-Aug;6(4):370-9.	Thank you for your comment. The introduction to the guideline has been edited to clarify the use of the term 'non-specific low back pain'. Throughout the guideline and in the title, the guideline now refers to 'low back pain' rather than 'non-specific…' as it was agreed this term is poorly defined and misinterpreted. Diagnosis of low back pain and sciatica was beyond the remit of this guideline which focusses on assessment and management; however, some of the specific causes which are excluded are noted in the introduction and in the algorithm for clarity.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				8. DePalma MJ1, Ketchum JM, Saullo TR. Multivariable analyses of the relationships between age, gender, and body mass index and the source of chronic low back pain. Pain Med. 2012 Apr;13(4):498-506. 9. Katz V, Schofferman J, Reynolds J. The sacroiliac joint: a potential cause of pain after lumbar fusion to the sacrum. J Spinal Disord Tech. 2003 Feb;16(1):96-9. 10. Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. Eur Spine J. 2005 Sep;14(7):654-8. Epub 2005 Mar 11. 11. DePalma MJ1, Ketchum JM, Saullo TR. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011 May;12(5):732-9 12. Depalma MJ, Ketchum JM, Trussell BS, Saullo TR, Slipman CW. Does the location of low back pain predict its source? PM R. 2011 Jan;3(1):33-9 13. Laslett M, Oberg B, Aprill CN, McDonald B. Centralization as a predictor of provocation discography results in chronic low back pain, and the influence of disability and distress on diagnostic power. Spine J. 2005 Jul-Aug;5(4):370-80. 14. Hancock MJ, Maher CG, Latimer J, Spindler MF, McAuley JH, Laslett M, Bogduk N. Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain. Eur Spine J. 2007 Oct;16(10):1539-50. 15. Laslett M, Aprill CN, McDonald B, Young SB. Diagnosis of sacroiliac joint pain: validity of individual provocation tests and composites of tests. Man Ther. 2005 Aug;10(3):207-18.	
Spine Intervention Society	Full	General	General	Diagnosis of Non-Specific Low Back Pain: "Non–specific low back pain" presents a symptom, not a diagnosis. A good comparison would be an example of "cough" as a symptom. The actual diagnosis can vary from bronchitis to lung cancer, but both can present with cough, and the treatment approaches for those two conditions would substantially differ. "Non-specific low back pain" should be reserved for patients for whom every effort has been made to identify the pain generator and define the proper diagnosis. Low back pain is not non-specific until appropriate diagnostic testing has been employed and has failed to yield a diagnosis.	Thank you for your comment. We agree that the use of 'non-specific low back pain' is poorly defined and not helpful to readers. We have updated the introduction to clarify its use in the review questions and protocols, but have now otherwise updated the review to refer to 'low back pain'.
Spine Intervention Society	Full	General	General	Inadequate Subgroup Analysis: Stratification of studies according to their technical approach and quality of evidence has not been done. Different types of treatments (e.g. caudal, interlaminar, and transforaminal epidural steroid injections) have been lumped into a category despite the fact that their technical approach may influence outcomes as supported in literature.	Thank you for your comment. The GDG discussed what subgroup analysis and stratification should be undertaken for each review when setting the review protocols. These are detailed in Appendix C. All reviews were stratified by low back pain/sciatica/mixed low back pain and sciatica as agreed appropriate, and further subgrouping was agreed as relevant. For epidurals and spinal injections, the GDG agreed that this review would focus on the effectiveness of what was injected with stratification by diagnosis, primarily (≥70%) disc prolapse/primarily (≥70%) not disc prolapse/mixed population/unclear spinal pathology (no clinical diagnosis); or pathology not confirmed (may or may not have had imaging). There was further stratification according to whether the injection was image guided or not. Pre-specified subgroup analysis was route of injection: caudal, interlaminar, or transforaminal, however, as stated in the methods section of the guideline, this was only undertaken where heterogeneity was observed.
Spine Intervention Society	Full	General	General	Exclusion of Sacroiliac Joint Pain: It is unclear why sacroiliac joint pain has been excluded. It is a well-proven, common cause of low back pain. Investigation of the sacroiliac joint should be included in the algorithm, when there has been an inadequate response to conservative treatment. The data have already been reviewed, and the effectiveness of sacroiliac joint injections was confirmed with a number needed to treat (NNT) of 2 for 50% pain relief. Reference:	Thank you for your comment. The sacroiliac joint has been excluded as it is a pelvic joint, not a spinal joint.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Kennedy DJ, Engel A, Kreiner DS, Nampiaparampil D, Duszynski B, MacVicar J. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. Pain Med. 2015 Aug;16(8):1500-18.	
Spine Intervention Society	Full 1	15	Algorithm	The algorithm suggests that patients with acute low back pain and radiculopathy should go through a very conservative pathway (e.g. group exercise, psychological therapies) before considering epidural steroid injections (ESIs). As a matter of fact, the best indication for ESIs based on current evidence is acute radicular pain, and these injections should be considered before psychological therapies in acute radicular pain cases, in hopes of preventing costly surgical interventions and use of other healthcare resources. Reference: Rathmell JP. The proper role for epidural injection of corticosteroids. Anesthesiology. 2014;121(5):919-21.	Thank you for your comment. The box containing epidural injections for sciatica sits alongside the box containing conservative treatments in the algorithm. This recommendation is specifically for people with acute severe sciatica, and therefore conservative treatments will not need to have been tried first.
Spine Intervention Society	Full 1	15	Algorithm	A major flaw is that leaving box B does not consider discogenic pain or sacroiliac joint pain. It only considers lumbar facet pain- one of the least common sources of axial pain- and "non-specific low back pain". This is in keeping with one of the key recommendations: Do not offer injections for non-specific low back pain. If there is an inadequate response to treatment in box B, then there should be consideration of diagnostic modalities aimed at determining a pain generator, with a selection based on likely etiology. The guideline authors should consider low back pain to be non-specific only if a thorough investigation fails to reveal its cause. Reference: Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.	Thank you for your comment. The algorithm depicts the recommendations contained within this guideline in a graphical format. It has been edited in light of stakeholder comments, however causes of low back pain that are included are listed in section 4.3.1.1.1. of the full guideline, this includes discogenic pain, amongst other causes. However sacroiliac joint pain is not included as it relates to pelvic pain rather than low back pain. We have now added further clarification for what can be considered if there's an inadequate response to the treatments previously tried at the end of the algorithm. If all treatment options have been exhausted and the patient moves to 'out of pathway' of this guideline, this does not exclude further investigation.
Spine Intervention Society	Full 1	15	Algorithm	The American College of Radiology, American Pain Society, and American College of Physicians have developed evidence-based recommendations for the use of imaging in spine pain patients. (1-3) These recommendations are based on risk stratification regarding the likelihood of underlying systemic disease as the cause of the patient's back or limb pain. This stratification is based on signs, symptoms, and historical features (red flag features) which identify risk of neoplasm, infection, traumatic injury or inflammatory spondyloarthropathy. The draft guideline acknowledges this (page 150) but chooses to purposely avoid the discussion. This is to dismiss the crux of the matter. One can include this implicitly, perhaps, in the "will it change management " rubric, but is a disservice to the reading physicians not to provide this established guidance from the literature. Once the criteria for imaging are met, then the utility of imaging in planning subsequent interventional procedures is paramount. Image-guided spinal interventions must be directed toward specific anatomic targets deemed likely pain generators; this is not possible without pre-intervention imaging. References: 1. Davis PC, Wippold FJ II, Brunberg JA, et al. ACR appropriateness criteria on low back pain. J Am Coll Radiol 2009;6:401–7. 2. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007;147:478–91 3. Chou R, Qaseem A, Owens DK, et al. Diagnostic imaging for low back pain: advice for high-value health care from the American College of Physicians. Ann Intern Med 2011;154:181–9.	Thank you for your comment. The red flag features that you mention are outside of the scope of the guideline. This is now detailed within the algorithm for clarity. The recommendation for imaging relates specifically for its use in people with suspected non-specific low back pain and sciatica, once these aforementioned conditions have been excluded.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Spine Intervention Society	Full 1	15	Algorithm	Epidural steroid injections in patients with sciatica should only be performed after adequate imaging of the lumbosacral spine is obtained via magnetic resonance imaging (MRI) or computed tomography (CT). In addition to ruling out other causes, imaging can better localize the site of pathology so that a targeted epidural steroid injection can be performed. A rare but serious complication can be avoided if imaging is performed before epidural injections in cases when spinal tumors (e.g. ependymoma), or spinal hematoma are a cause of the patient's pain. In addition, epidural steroid injections should only be performed with image guidance, as widely documented in literature. This is not addressed in the algorithm.	Thank you for your comment. We recommend that imaging should only be performed if imaging would change management – in the case of epidural injections (in particular transforaminal epidural injection) imaging to determine the site and level of a potential disc prolapse would be consistent with this recommendation. The GDG acknowledge the concerns surrounding spinal tumours and haematoma but are not aware of evidence to suggest that imaging prior to an epidural injection should be mandatory.
Spine Intervention Society	Full 1	15	Algorithm	Surgical decompression should be performed only if mechanical compression of a nerve root by a large disc herniation is proven to be the cause of this pain. Several authors reported significantly worse outcomes after discectomy in those with small, contained disc herniations, and some even excluded from surgical consideration patients with small sized lumbar disc herniations. This recommendation should also caution that surgical results are better if performed within 6 months, as per North American Spine Society guidelines. References: 1. Carragee EJ, Han MY, Suen PW, Kim D. Clinical outcomes after lumbar discectomy for sciatica: The effects of fragment type and anular competence. J Bone Joint Surg Am 2003;85(1):102–8. 2. Dewing CB, Provencher MT, Riffenburgh RH, Kerr S, Manos RE. The outcomes of lumbar microdiscectomy in a young, active population: Correlation by herniation type and level. Spine (Phila Pa 1976) 2008;33(1):33–8. 3. Folman Y, Shabat S, Catz A, Gepstein R. Late results of surgery for herniated lumbar disk as related to duration of preoperative symptoms and type of herniation. Surg Neurol 2008;70(4):398–401. 4. Mysliwiec LW, Cholewicki J, Winkelpleck MD, Eis GP. MSU classification for herniated lumbar discs on MRI: Toward developing objective criteria for surgical selection. Eur Spine J 2010;19(7):1087–93. 5. North American Spine Society (NASS). Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. Burr Ridge (IL): North American Spine Society (NASS); 2012.	Thank you for your comment. We have revised the surgical decompression recommendation to reflect the requirement for concordant imaging prior to surgical treatment. From the trials and data reviewed by the GDG, we were not able to ascertain whether the size of disc herniation had any measurable impact on patient outcomes. The evidence reviewed did not inform a time point to specify within the recommendation.
Spine Intervention Society	Full 1	15	Algorithm	In terms of therapeutic non-invasive modalities, the authors have stripped therapy down to manipulation and exercise therapy. They recommend against traction, ultrasound, transcutaneous electrical nerve stimulation (TENS), and acupuncture. While these modalities do not change long-term outcome, they are palliative and one must remember that initial back pain therapy "is" palliative therapy in many cases.	Thank you for your comment. The algorithm depicts the recommendations that were based on the GDG interpretation of the evidence reviewed in a graphical format.
Spine Intervention Society	Full 1	15	Algorithm	The guidelines make pharmacological recommendations. We agree with using the lowest effective dosage of non-steroidal anti-inflammatories. The guidelines recommend "weak" opioids if non-steroidal anti-inflammatory drugs (NSAIDs) are contraindicated. The guidelines then recommend against selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and anti-convulsants. While the evidence for the use of other medications is not convincing, strong evidence supporting opioid use to treat chronic pain lasting > 3 months is lacking. Offering only an opioid alternative may propagate further expansion of opioid use that has already resulted in accidental overdoses and deaths resulting in an opioid crisis of enormous proportions over the last two decades. In fact, the U.S. Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids emphasize that, "of primary importance, nonopioid therapy is preferred for treatment of chronic pain." (http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm) Physicians need options, and patients require effective treatment with safe therapeutic indices. The guidelines include psychotherapy in their algorithm, but discount the use of other medications for treating pain. Anticonvulsants like gabapentin and pregabalin are known to be very effective in the	Thank you for your comment. The GDG agreed it was appropriate to recommend against the use of opioids for chronic pain, but did recognise the need to provide an alternative pharmacological treatment option for people with acute low back pain who were unable to take NSAIDS. They therefore agreed that weak opioids could be considered only in this context and that short term acute use only could be considered. Pharmacological treatment of sciatica is beyond the scope of this guideline and a cross-referral to NICE CG173 for Neuropathic pain is included in the recommendations.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				treatment of sciatica. Cymbalta is an SNRI shown to be effective in the treatment of musculoskeletal pain. These drugs are opioid alternatives with acceptable therapeutic indices, References: 1. McCleane GJ. Does gabapentin have an analgesic effect on background, movement and referred pain? A randomized, double-blind, placebo controlled study. Pain Clinic 2001;13:103-7. 2. Yildirim K, Sisecioglu M, Karatay S, et al. The effectiveness of gabapentin in patients with chronic radiculopathy. Pain Clinic 2003;15:213-8. 3. Romano CL, Romanò D, Bonora C, et al Pregabalin, celecoxib, and their combination for treatment of chronic low-back pain. J Orthopaed Traumatol 2009;10(4):185-91. 4. Baron R, Martin-Mola E, Müller M, et al. Effectiveness and safety of tapentadol prolonged release (PR) versus a combination of tapentadol PR and pregabalin for the management of severe, chronic low back pain with a neuropathic component: a randomized, double-blind, phase 3b study. Pain Pract 2014;10.1111/papr.12200 5. Baron R, Freynhagen R, Tölle TR, et al; A0081007 Investigators. The efficacy and safety of pregabalin in the treatment of neuropathic pain associated with chronic lumbosacral radiculopathy. Pain 2010;150:420-7.	
Spine Intervention Society	Full 1	16	8	The guideline states, "explain to people with low back pain with or without sciatica that if they are being referred for a specialist opinion, they may not need imaging" but at the same time suggests to "consider imaging in a specialist care setting for people with low back pain with or without sciatica only if the result is likely to change management". This approach may produce negative patient bias towards specialists.	Thank you for your comment. The GDG were concerned that people being referred to a specialist would expect imaging to be performed. The GDG therefore advised that the primary aim of a referral to a specialist service would be a clinical opinion and not necessarily imaging and agreed it was important to state this within a recommendation. However, they further agreed that the situations under which imaging might be considered should be clarified. The GDG do not agree that this would negatively bias towards specialists. The rational for these recommendations is discussed in more details in Section 7.6 (recommendations and link to evidence, 'trade-off between clinical benefits and harms').
Spondyloarthritis GC	Full	25	31	Our guideline is now called 'Spondyloarthritis: diagnosis and management'; this reference should be updated from 'seronegative arthropathies'.	Thank you for highlighting this, we have now amended it.
University College London Hospitals NHS Foundation Trust	Full	303	General for the exercise recommendation	We fully support the guidelines and all the work that has gone into evaluating the current evidence base. We are impressed with the conclusion from the exercise recommendations in terms of establishing that there are no quality papers/evidence that one form of exercise is more effective than another. We are also fully supporting the recommendation to individualise exercises for the patient rather than using an ineffective biomedical subclassification system for which we do not have any evidence. In view of the above, we are writing to comment on the wording of the exercise recommendations: 1. We work with patients who have been told that they "should do pilates because of a biomechanical instability" or "do yoga because of muscle tension" which can increase patient's concerns and fears (Darlow et al, 2014) and can reinforce the idea that engaging in exercises other than the those recommended is "dangerous" and this is not evidence based advice. We believe that the excellent conclusion in the guidelines makes it unnecessary to include different types of exercises in the recommendation. We are particularly concerned that it will be harmful to continue to reinforce the message that it is possible to subclassify the patient's condition and	Thank you for your comments and support of this recommendation. The recommendation does not intend to limit or specify exercise options by specifying the types of exercise, it is intended to indicate what the evidence base covers. The recommendation also makes clear that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise. Definitions and examples of the terms used to categorise the different types of exercise looked at in the review can be found in chapter 9, section 9.1, and section 9.2 in table 68. The GDG felt that these distinctions were important, as different types of exercise have different goals, focuses and may have had different effects on low back pain.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prescribe exercises accordingly when the evidence base is clear in recommending that we encourage exercise and that different exercises have the same evidence base for non-specific low back pain and sciatica. 2. The terms "biomechanical" and "mind-body" are confusing and largely meaningless. Clinicians have an enormous influence on how patients understand and respond to their highlighting the importance of using a simple and evidence based language. Most clinicians do not know what the terms mean; we asked our mutidisciplinary team which includes specialist physiotherapists with 15 years' experience, nurse specialists, consultants and psychologists and nobody was able to explain the terms. We would like to state that ALL exercise IS 'mind-body' and 'biomechanical'. Making this false split may perpetuate an unhelpful dualistic model, and could indeed encourage less experienced clinicians to develop costly services using these terms rather than encouraging activity and movement in the context of our resources and the patients' capabilities.	
University Hospitals Birmingham NHS Foundation Trust	Full	General	General	The scope of this document is much improved from previous guidelines and is welcomed. The full document is extremely long; the short version is very concise. An intermediate length evidence statement would be helpful and aid clinical implementation.	Thank you for your comment. NICE is always interested in better ways to present the information contained within its guidance and will take your suggestion into consideration for future publications.
University Hospitals Birmingham NHS Foundation Trust	Full 1	673-742 15	1 and Figure 1 Algorithm-Section 1.1	This guideline will be challenging to implement where the terminology differs to that used in the NHSE spinal Pathfinder document. This is because our local CCGs are commissioning services specified in Pathfinder and our Trust requires us to strictly implement NICE guidelines. It is recognised that the GDG used the term "Multidisciplinary Biopsychosocial Rehabilitation (MBR) programmes" which has also been used by the Cochrane Collaboration. However, the NHSE Pathfinder document recommends inclusion of low intensity combined psychological and physical programmes (CPPP), high intensity combined psychological and physical treatment programmes (CPPTP) and pain management programmes (PMP). Is the GDG able to describe how "psychological therapies" and "MBR" recommendations equate to Pathfinder terminology?	Thank you for your comment. The concept of MBR was used as a basis to review the evidence, consistent with the Cochrane review. However, the recommendation that results from that review is for combined physical and psychological programmes (CPP) as this is where there was most evidence of benefit, therefore the term CPP is used in the recommendation.
University Hospitals Birmingham NHS Foundation Trust	Full 1	15	Figure 1 Algorithm	The algorithm implies that injections must only be considered after all other conservative options have been explored. However, clinically some patients may be more able to engage in exercise after undergoing injection intervention. Would the GDG consider more flexibility with timing of injection interventions?	Thank you for your comment. The box containing epidural injections for sciatica sits alongside the box containing conservative treatments in the algorithm and is for people with acute severe sciatica. Therefore conservative treatments will not need to have been tried first.
University Hospitals Birmingham NHS Foundation Trust	Full 1	16 147	6-11 Section 7.6 line 23	This guideline will be challenging to implement if the terminology differs to that used in the NHSE Spinal Pathfinder document (reference below). This is because our local Clinical Commissioning Groups (CCG) are commissioning services specified in the Pathfinder document and our Trust requires strict implementation of NICE guidelines. Therefore, clarity and use of same terminology would be helpful in both NICE and Pathfinder documents. Could the GDG define the term "specialist care setting" in relation to requesting investigations; it is understood that commissioners use the terms "specialist" and "non-specialist" services and it is not clear if this is the GDG's intended definition. Also, within the Pathfinder document, "Triage and Treat" practitioners are able to request investigations; would such a role be considered within a "specialist care setting." NHS England National Pathfinder Projects Trauma Programme of Care Pathfinder Project – Low Back Pain and Radicular Pain Report of the Clinical Group National Pathway of Care for Low Back and Radicular Pain (2014)	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. The definition of 'specialist setting of care' has been detailed in the recommendation for clarity as 'for example, a musculoskeletal interface clinic or hospital'.
University of York	Appendix K	153	Fig 667	DATA ERROR RELATED TO ACUPUNCTURE	Thank you for your comment. The data in figure 667 has been checked. Data from Brinkhaus 2006 has been amended. However, no amendments were

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				There is an error in the forest plot (Figure 667) on Pain Severity [(VAS 0-10) ≤ 4 months], whereby the Brinkhaus trial has had the negative sign of the mean difference (acupuncture better) reversed in error to positive (sham acupuncture better), which one can see in Figure 667. When the sign is corrected, the Brinkhaus contribution favours acupuncture over sham. Moreover the Leibing 2002 trial is presented with an error, incorrectly the meta-analysis used mean change scores, but it should have used mean absolute scores. The correct means are 2.1 for acupuncture and 3.2 for sham. A re-analysis of the forest plot, after correcting these two errors, will show that overall acupuncture outperforms sham with a larger effect of: -1.03 (-1.53 to -0.54). Not only will this be shown to be statistically significant (p<0.0001) but now also will become clinically relevant (VAS 0-10 change > 1.0). The quality of this evidence (GRADE), which is currently given as VERY LOW, needs to be re-evaluated (Page 477 of the Full version, Part 1). This fundamental reversal from "not clinically relevant" to becoming "clinically relevant" provides proof of principle that acupuncture outperforms sham, and along with the other statistically significant differences, will support the GDG in considering a recommendation of acupuncture for low back pain.	necessary for data from Leibing 2002 as the change scores reported, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, which were correctly included in the meta-analysis.
University of York	Appendix K	153	Fig 668	DATA ERROR RELATED TO ACUPUNCTURE There is an error in the forest plot, Figure 668, whereby the Leibing 2002 trial has incorrectly used mean change scores, but it should have used mean absolute scores, the correct means are 3.1 for acupuncture and 3.5 for sham, which shows that the Leibing trial actually favours acupuncture instead of sham. A re-analysis of the forest plot will show that overall acupuncture outperforms sham with a larger effect of: -0.38 (-0.66 to -0.11), which will also be found to be statistically significant p=0.006. The GRADE of this analysis may change.	Thank you for your comment. The data in figure 668 has been checked. Leibing 2002 has reported change scores, -2.7 (SD 2.2) and -2.1 (SD 2.2) for the acupuncture and sham group respectively, which have been correctly meta-analysed in this forest plot.
University of York	Appendix K	155	Fig 678	DATA ERROR RELATED TO ACUPUNCTURE There is an error in the forest plot, Figure 678, whereby for long-term function (> 4 months) the Haake trial has had the negative sign (acupuncture better) of the mean function difference reversed in error to positive (sham acupuncture better). When the sign is corrected, such that the acupuncture is better than sham, with the forest plot shows that overall acupuncture outperforms sham for function with an effect of: -4.60 (-7.89 to -1.31). This longer term effect of acupuncture vs. sham on function (>4 months) is a slightly larger than the short-term effect (≤ 4 months), and both are statistically significant. This corrected data provides further proof of principle that acupuncture is more than a placebo, as it is based on statistically significant functional benefits for people with low back pain over both short term (≤ 4 months) and longer term data (> 4 months). The GRADE of this analysis may change.	Thank you for your comment. This figure and corresponding GRADE tables have been amended.
University of York	Appendix K	158	Fig 694	DATA ERROR RELATED TO ACUPUNCTURE There is an error in the forest plot, Figure 694, whereby the Leibing 2002 trial has incorrectly used mean change scores, but it should have used mean absolute scores. For ≤ 4 months, the correct means are 2.1 for acupuncture and 4.4 for sham. A re-analysis of the forest plot is needed as well as a re-evaluation of the GRADE.	Thank you for your comment. Leibing 2002 reports change scores which have been correctly extracted from the study and meta-analysed.
University of York	Appendix K	159	Fig 695	DATA ERROR RELATED TO ACUPUNCTURE There is an error in the forest plot, Figure 695, whereby the Leibing 2002 trial has incorrectly cited mean change scores, but it should have used mean absolute scores. For > 4 months, the correct means are 3.1 for acupuncture and 4.3 for sham. A re-analysis of the forest plot is needed as well as a reconsideration of the GRADE.	Thank you for your comment. The change scores have been extracted from the study and correctly meta-analysed.
University of York	Appendix K	160	Fig 700	DATA ERROR RELATED TO ACUPUNCTURE Page 160, Line 752, Figure 700. The weighting in Figure 700 does not look correct, as all three trials, with numbers of patients ranging between 40 and 2,841, are currently given weightings of approximately one third each. On checking the original paper, it is clear that the Zaringhalam 2010 trial should not be listed in this plot because a different scale was used, a functional scale Roland Morris Questionnaire (RDQ) scoring from 0 to 24. Moreover the Witt 2006 trial, while using the Hanover Functional Ability Questionnaire, presented mean scores at each time point not in	Thank you for your comment. Since Zaringhalam 2010 reports function on a RMDQ scale, this study has now been removed from figure 700 and pooled in the meta-analysis for RMDQ. Witt 2006 has a study population of low back pain with or without sciatica, and has therefore been removed from this figure as well, and added to the evidence for the appropriate population. Haake 2007 is now the only study in figure 700.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				terms of a score between one and a hundred, as in the Haake 2007 trial, but as a percentage change score based on subtracting the actual score from 100, then converting to a percentage reduction. Hence both the way the means and the standard deviations are measured between the Haake 2007 and Witt 2006 trials are fundamentally different, despite both using the HFAQ, which will in part explain the heterogeneity. Along with a re-analysis, the quality of this evidence (GRADE), which is currently given as VERY LOW, needs to be re-evaluated (Page 478 of the main document).	
University of York	Full	general	general	GENERAL COMMENTS 1A) The GDG can be commended on the substantial workload in bringing forward this draft. There is one general point to make regarding the documentation, namely that while the GDG has acknowledged its concern to be equitable in assessing the different interventions, a systematic downgrading by the GDG in its interpretation of the evidence for acupuncture stands out as a major cause for concern. Briefly acupuncture is expected to outperform sham/placebo, and rightly so. However many other interventions in the Draft outperform sham/placebo less well than acupuncture, including several that are recommended as primary or as adjunctive interventions. 1B) In summary, there is more and better evidence on acupuncture beyond placebo effects than say any one of the recommended therapies of exercise, manual therapy, psychological therapies or epidural injections (for sciatica) as follows: 1.) there are more trials on acupuncture vs. sham/placebo than there are for the other interventions vs sham/placebo, 2.) a higher proportion of the sham controlled trials on acupuncture are assessed as lower risk than for the other interventions, 3.) for sham controlled trials, the GRADE scores on quality of evidence of the documented meta-analyses are relatively higher for acupuncture, 4.) there are more forest plots comparing acupuncture vs. sham than the other interventions vs. sham, 5.) there are proportionately more statistically significant meta-analyses of acupuncture than the others, 6.) there is better proof of principle that acupuncture has statistically significant and clinically relevant benefits vs. sham over the short term (≤ 4 months), and statistically significant benefits are also observed over the longer term (> 4 months), benefits that are not achieved by the other interventions mentioned above. [The clinical relevance of the pain data for ≤ 4 months in the comparison of acupuncture vs. sham only becomes apparent on a re-analysis, as the Draft inadvertently has an error for one of the trials – Brinkhaus et al 2006 – which has been incorrectly entered, see Appendix K, Figure 667) and, when correctly entered, will show a clinically relevant improvement in pain with a MCID > 1.0 on a VAS scale of 0-10.] Many other errors relating to the acupuncture data are identified below, all of which when corrected will support a more positive interpretation of the evidence on acupuncture. 1C) The GDG argue that, "there was still not compelling and consistent evidence of a treatment-specific effect for acupuncture." The data presented in this Draft actually shows a more consistent evidence base for acupuncture than for many of the recommended therapies. The main reason for the inconsistency across all therapies is the small sample sizes of included trials. This is an inherent problem across the field of low back pain research. Furthermore, some of the inconsistency has occurred as a result of errors in the Draft (see below for details), which when corrected will reduce the inconsistency, especially for the sham/placebo comparisons. When taking into account that most studies in this Draft are underpowered, it is the acupuncture-related meta-analyses that stand out as providing higher quality data with larger sample sizes, and where sufficiently well powered, statistically significant benefits beyond placebo effects. 1D) The GDG is looking for "a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects". This is exactly what is provided by the	Thank you for your comments. The GDG is mindful of these concerns, and has revisited the evidence base for interventions versus sham comparisons areas where recommendations have been made. Although the GDG agreed to ensure consistency across reviews in giving placebo/sham evidence priority across reviews, for some interventions, sham/placebo comparisons were either not possible to conduct or not available This is reflected in the exercise review. Unlike acupuncture, where a sham intervention is possible (whether penetrating or non-penetrating), the GDG agreed it is much harder to achieve this for exercise. On revisiting the 'sham exercise' evidence that was included in the draft guidance, the GDG agreed that none of the included sham interventions could be considered as true forms of 'sham exercise' (one was a psychological therapy and the other was an alternate form of exercise). Therefore, these have now moved to another comparison or excluded as appropriate according to the review protocol. Therefore, the revised guideline will no longer have any evidence for exercise versus sham. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology). The GDG agreed that there was not enough evidence from the reviews of the interventions offered in isolation for either manual therapies or psychological therapies to base a recommendation on (consistent with acupuncture). However, there was additional evidence for each of these interventions in combination and from the review of 'MBR' interventions which provided enough evidence to warrant these interventions to be considered only as part of a package of treatment. The combinations reviewed did not support the same recommendation to be made for acupuncture. Another reason for the apparent inconsistencies is the differences in available evidence for sham comparisons; this can be seen in the epidural injections review. The GDG noted that there were many studies comparing acupuncture to sham (with multiple outcomes), with relatively few outcomes showing clinical benefit, and fewer outcomes showing large clinical benefit. Despite the mixed evidence seen for epidural injections against sham/placebo, the evidence base was a lot smaller than for acupuncture. This resulted in the GDG feeling more uncertain about the clinical effectiveness of acupuncture over epidural injections. Furthermore, the GDG were aware that epidurals are a clinically approved treatment for patients with sciatica, and were able to use the evidence to identify a subset of people in whom epidurals were clinically beneficial (people with acute sciatica), which they were unable to do for acupuncture. The Vickers IPD meta-analysis was not included in the original review due to it pooling populations with low back pain with/without sciatica and low back pain only, as well as pooling across time points. However, we accept that the data for the relevant studies could have been extracted and used in the meta-analysis. We have subsequently undertaken a sensitivity analysis to

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Acupuncture Trialists' Collaboration who, in an individual patient data meta-analysis of high quality trials, have reported on four separate pain conditions, including low back pain, in top journals (Vickers AJ, et al. Arch Intern Med. 2012;172:1444–53 and Vickers AJ & Linde K. JAMA. 2014;311:955–6). These Acupuncture Trialists' Collaboration studies are the gold standard in the field, as they have involved a major group of statisticians and triallists, and been funded by the US National Institutes of Health (NIH). This collaboration found statistically significant differences in outcome between acupuncture and sham, differences that could not be ascribed to bias, and large differences between acupuncture and usual care. The actual data presented in this Draft (when corrected) generally support those of the Acupuncture Trialists' Collaboration, which provided conclusive evidence that acupuncture for low back pain is associated with specific effects over and above any contextual or placebo effects. 1E) While the comparison of acupuncture vs. sham is a necessary one, evidence on acupuncture vs. usual care is also demonstrated in this Draft. An exemplar is a trial showing statistically significant and clinically relevant long-term benefits at two years, and which also shows acupuncture to be highly cost-effective, as well as being highly generalisable, as it is set in primary care in the UK.(Thomas et al BMJ 2006, 333:623–6, Ratcliffe et al BMJ 2006, 333:626–8). The principles of evidence based medicine, and a commitment to a consistency in their application, is one that NICE has always ascribed to. In the light of the weight of the evidence outlined above, which is elaborated in more detail below, acupuncture compares favourably with several of the interventions for low back pain that are recommended in this Draft. The GDG would be justified in recommending acupuncture as it is strongly supported by the current evidence base.	demonstrate the difference in the review had the data from the IPD meta-analysis been used. This is presented alongside the forest plots in sections K.9.1 and K.9.2, demonstrating no difference to the conclusions made. Whilst the GDG kept in mind the evidence for acupuncture versus usual care, they must give sham/placebo evidence priority where available. In the case of acupuncture, the evidence base was large, and did not consistently show a benefit in favour of acupuncture, as the differences that were deemed to be clinically important were only observed in short term follow up, and were not maintained in the long term; therefore, the GDG did not agree that this inconsistent evidence of effect was great enough to recommend acupuncture.
University of York	Full 1	16	20-24	EXERCISE 2A) While the evidence base provides some useful support for the recommendation of group exercise for low back pain, it is noted that the Draft's evidence on the quality and benefits of acupuncture vs. sham is equivalent to or exceeds that of exercise vs. sham in many ways: • the total number of trials, total participants and mean number of participants for acupuncture vs. sham are documented in the Draft as 11 trials and 1971 participants with a mean of 179, whereas exercise vs sham comprise of 5 trials and 374 patients with a mean of 75; • of the 11 trials of acupuncture, 7 are assessed as "low risk of bias" and 4 are "high risk of bias", whereas of the five trials of exercise vs. sham, one is "high risk of bias" and four are "very high risk of bias"; • in a summation of quality of evidence GRADE scores, when comparing acupuncture vs. sham, 16 out of 48 meta-analyses are assessed as HIGH GRADE, whereas for exercise vs. sham, none of the meta-analyses are assessed as HIGH GRADE and only one as MODERATE, the rest as LOW or VERY LOW. • none of the meta-analytic forest plots involving exercise vs. sham in Appendix K involve more than a single trial, whereas in contrast there are many forest plots that include a cluster of trials of acupuncture vs. sham; • in the meta-analyses, 12 comparisons on acupuncture show benefits that are statistically significantly better than sham over the short and longer term, whereas for exercise vs. sham only two comparisons show that exercise outperforms sham; • short term benefits (≤ 4 months) of acupuncture vs. sham are supported by a meta-analysis of 7 trials with 1359 patients with a statistically significant reduction in pain greater than the MCID of 1 point on a VAS 0-10 scale (based on a correction to one of the errors in Figure 667, Page 153, Appendix K, see below for details of this error), whereas is no meta-analytic evidence at this level for exercise vs. sham;	Although the GDG agreed to ensure consistency across reviews in giving placebo/sham evidence priority across reviews, for some interventions sham / placebo comparisons were either not possible to conduct or not available. This is reflected in the exercise review. Unlike acupuncture where a sham intervention is possible (whether penetrating or non-penetrating), the GDG agreed it is much harder to achieve this for exercise. On revisiting the 'sham exercise' evidence that was included in the draft guidance, the GDG agreed that none of the included sham interventions could be considered as true forms of 'sham exercise' (one was a psychological therapy and the other was an alternate form of exercise), therefore these have now moved to another comparison or excluded as appropriate according to the review protocol. Therefore the revised guideline will no longer have any evidence for exercise versus sham. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology).

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• the evidence on longer term benefits (> 4 months) of acupuncture vs. sham is supported by a HIGH GRADE meta-analysis of four trials with 1159 patients showing acupuncture is statistically significantly superior (Appendix K, Figure 668), whereas none of the exercise trials provide this quality of evidence. [For the Albert 2012 trial on exercise vs. sham over the period > 4 months, sham exercise actually outperforms true exercise.] 2B) In summary, given the need for consistency of interpretation across interventions, and that exercise has been recommended, the level of evidence that exists for acupuncture vs. sham/placebo is now sufficient (given the corrections to the data) for the GDG to be in a strong position to consider recommending acupuncture for low back pain.	
University of York	Full 1	16	33-35	MANUAL THERAPY 3A) The trial and meta-analytic data on manual therapy compared to placebo/sham is more limited than the trial data on acupuncture compared to sham in many ways: • the total number of trials, total participants and mean number of participants for acupuncture vs. sham are documented as 11 trials, 1971 participants and mean sample size of 179, whereas manual therapy vs sham comprise of 7 trials, 697 patients and mean of 97; • of the 11 trials of acupuncture, 7 are assed as "low risk of bias" and 4 are a "high risk of bias", whereas, of the 7 trials of manual therapy vs. sham, 2 are assessed as "low risk of bias and 5 as "high risk of bias" or "very high risk of bias"; • in a summation of quality of evidence GRADE scores, when comparing acupuncture vs. sham, 16 out of the 48 meta-analyses that are assessed as HIGH GRADE, whereas for manual therapies vs. sham, 4 of the 19 meta-analyses are assessed as HIGH GRADE. • in the meta-analyses, 12 show benefits that are statistically significantly better than sham over the short and longer term, whereas for manual therapy (excluding traction) vs. sham, only 5 show that manual therapy outperforms sham; • short term benefits (≤ 4 months) of acupuncture vs. sham are supported by a meta-analysis of 7 trials with 1359 patients showing a statistically significant reduction in pain greater than the MCID of 1 point (based on a correction to one of the errors in Figure 667, Page 153, Appendix K, as set out below) on a VAS 0-10 scale, whereas the meta-analytic evidence for manual therapy vs. sham involving five trials of 533 participants shows a borderline statistically significant reduction in pain of -0.26 (CI: -0.53 to -0.00); • the evidence on longer term benefits (> 4 months) of acupuncture vs. sham is supported by a HIGH GRADE meta-analysis of four trials with 1159 patients showing acupuncture is statistically significantly superior to sham (Figure 668, Appendix K), whereas for manual therapy, there is no long-term (> 4 months) data on soft tissue massage, and data from two trials involving 229 participants of manipulation/mobilisation vs. sham trials provide only a non-significant longer-term benefit (Appendix K, Figure 520). 3B) If manual therapies are considered sufficiently evidence-based to be recommended by the GDG, albeit as part of multi-modal treatment packages, then there is as strong a case for acupuncture to be recommended given the current state of the evidence as set out by the Draft, and that the corrections will provide an even stronger case.	Thank you for your comment. The GDG discussed that there was some albeit limited evidence of benefit of soft tissue techniques and mixed modality manual therapies compared to sham treatments in terms of improving pain and quality of life. These benefits were observed in the short term follow up and somewhat inconsistent, but were not maintained in the longer term. They agreed that there was insufficient evidence to recommend the use of manual therapies in isolation. However, evidence from their use in combination with other treatments, and as part of multidisciplinary biopsychosocial rehabilitation programmes provided more evidence of benefit and therefore the GDG agreed a recommendation to consider manual therapies as part of a package of treatment was warranted. Since there was no evidence of acupuncture being used in similar treatment package, the recommendation for acupuncture was restricted to evidence included in chapter 13. The amended mean differences for figures 667 and 668 in the acupuncture review are 0.80 and 0.26 respectively, which still do not meet the MID criteria, and therefore are not clinically significant. Furthermore, a sensitivity analysis was carried out using individual patient data which impacted these forest plots (and others, please see appendix K.9) which further highlighted the lack of clinical benefit seen for acupuncture over sham. The wording of the manual therapies recommendation has been edited to the following: Consider manual therapy for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy.
University of York	Full 1	16	33-35	ACUPUNCTURE 4A) With regard to acupuncture, "The GDG first discussed the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects."(Page 493, Line 7) Unlike many of the other interventions recommended by the GDG, such as exercise, manual therapies, psychological programmes, and epidural injections for sciatica, the draft documentation provides clear proof of principle that acupuncture is more than simply a contextual or placebo effect.	Thank you for your comment. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. A mean difference of -0.33 does not meet the MID (1 on a scale of 0-10) used in this guideline for pain severity, as agreed by the GDG (please see chapter 4 for details). The data error for Brinkhaus 2006 in figure 667 has been

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				4B) The evidence on longer term benefits (> 4 months) of acupuncture vs. sham which is provided by a meta-analysis of four trials with 1159 patients shows acupuncture is statistically significantly reduces pain compared to sham [-0.33, (95%CI: -0.60 to -0.06)].(Page 153, Line 720, Figure 668). In terms of the quality of this evidence, this meta-analysis is defined as HIGH GRADE (Page 472), which by definition means that "Further research is very unlikely to change our confidence in the estimate of effect". (Page 50, Line 7) 4C) For short term reductions in pain (≤ 4 months), acupuncture is also statistically significantly better than sham (Page 153, Line 719, Figure 667). However the Brinkhaus 2006 trial in this Figure is incorrectly signed (the sign should be switched to show a positive effect), a re-analysis will find that not only is the difference between acupuncture and sham that is statistically significant, it also exceeds the minimum clinical difference of one point [new analysis: -1.03, (95%CI: -1.53 to -0.54)] . This correction will also improve the quality of the evidence as defined by the GRADE. None of the other therapies mentioned above that are recommended by NICE provide such strong evidence of specific intervention effects over and above contextual or placebo effects. 4D) The GDG has "agreed that if placebo-controlled evidence (or sham acupuncture) is available, this should inform decision making in preference to contextual effects, but that the effect sizes compared with usual care would be important to consider if effectiveness relative to placebo, or sham, has been demonstrated."(Full version - Part 1, Page 493, Line 7) The effect sizes of acupuncture compared to usual care are statistically significant for pain reduction in both the short and longer term. Based on 7 trials and 1334 patients, the short term (≤ 4 months) reduction exceeds the minimum clinically important difference, the pain reduction is -1.61 (95%CI: -2.23 to -0.99) on the VAS 0-10 scale (Appendix K, Figure 694). Based on three trials and 950 patients, the long-term (>4 months) benefits are also statistically significant, currently at -0.97 (95%CI: -1.20 to -0.73) (Appendix K, Figure 695). These data provides evidence of a larger clinic effect than is provided by many of the therapies recommended in this Draft. 4E) Additional independent evidence on acupuncture for chronic pain, including low back pain, comes externally from the individual patient data meta-analysis (Vickers et al, Archives of Internal Medicine, 2012). This study only incorporated high quality trials and found a standardised mean difference of 0.5 between acupuncture and usual care (with P<0.001). Significant differences were also found between acupuncture and sham (P<0.001). By only including high quality trials (lower quality trials tend to be more positive), and by testing for publication bias, Vickers et al concluded that the result could not be due to bias. These data support the data presented in this Draft, and also provide support not only for the proof of principle that acupuncture is more than the sum of the context effects, but also in a real world context acupuncture outperforms usual care with a difference that exceeds the minimum clinical difference. 4F) When the cost-effectiveness data is added to this evidence base, with key data from the Ratcliffe et al (BMJ, 2006) trial which showed acupuncture to be highly cost effective (£4,241 per QALY gained) in the UK primary care context (Full version - Part 1, Page 490, Line 1), then a robust evidence-based view is that a recommendation of acupuncture for low back pain would be justified.	amended, and the meta-analysis updated. The updated mean difference is -0.8 (95% CI -1.29, -0.32) which does not meet the MID for clinical benefit. Although the GDG recognise the benefits of acupuncture seen in some outcomes, the overall evidence for acupuncture compared to sham was conflicted. The GDG therefore agreed there was insufficient evidence to recommend acupuncture in an NHS setting. The Vickers IPD meta-analysis was not included in the original review due to it pooling populations with low back pain with/without sciatica and low back pain only, as well as pooling across time points. However, we admit that the data for the relevant studies could have been extracted and used in the meta-analysis. We have subsequently undertaken a sensitivity analysis to demonstrate the difference in the review had the data from the IPD meta-analysis been used. This is presented alongside the forest plots in sections K.9.1 and K.9.2, demonstrating no difference to the conclusions made. With regards to cost-effectiveness evidence, the GDG noted that while Ratcliffe et al. 2006 provided evidence of a clinically important difference in EQ-5D quality of life, the trial did not show a benefit for pain, function or distress, and this therefore led them to question the mechanism by which quality of life would be improved. Nevertheless, overall the GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not considered relevant. This is documented in 'Recommendations and link to evidence' for this review.
University of York	Full 1	17	33-35	EPIDURAL INJECTIONS FOR SCIATICA 6A) The GDG recommends epidural injections of local anaesthetic and steroid in people with sciatica. When comparing this intervention with acupuncture, there is substantially more evidence for acupuncture:	Thank you for your comment. The GDG recognise that evidence for both epidurals and acupuncture are conflicting when compared to placebo/sham. However, when reviewing the evidence for epidural injections the GDG was able to identify a subset of people in whom epidurals showed clinical benefit;

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• the total number of trials, total participants and mean number of participants for acupuncture vs. sham are documented as 11 trials, 1971 participants and mean of 179, whereas epidural vs sham for sciatica comprise of 4 trials, 443 patients, and mean of 111; • of the 11 trials of acupuncture, 7 are assed as "low risk of bias" and 4 are a "high risk of bias", whereas, of the four trials of epidural vs. sham for sciatica, two are assessed as "high risk of bias" and two are "very high risk of bias"; • a summation of quality of evidence GRADE scores, when comparing acupuncture vs. sham, 16 out of 48 meta-analyses are assessed as HIGH GRADE, whereas for epidural for sciatica, none of the meta-analyses are assessed as HIGH GRADE and only one as MODERATE, the rest as LOW or VERY LOW • none of the meta-analytic forest plots involving epidural for sciatica vs. sham in Appendix K involve more than a single trial, whereas in contrast there are many forest plots that include a cluster of trials of acupuncture vs. sham; • in the meta-analyses of acupuncture, 12 show benefits that are statistically significantly better than sham over the short and longer term, whereas only two sham-controlled comparisons show that epidurals for sciatica outperforms sham; • short term benefits (≤ 4 months) of acupuncture vs. sham are supported by a meta-analysis of 7 trials with 1359 patients showing a statistically significant reduction in pain greater than the MCID of 1 point (based on a correction to one of the errors in Figure 667, Page 153, Appendix K) on a VAS 0-10 scale, whereas there is no meta-analytic evidence at this level for epidurals vs. sham for sciatica; • the evidence on longer term benefits (> 4 months) of acupuncture vs. sham is supported by a HIGH GRADE meta-analysis of four trials with 1159 patients showing acupuncture is statistically significantly superior Figure 668, Appendix K), whereas no epidural vs. sham for sciatica trials provide evidence of longer term benefit. 6B) Given the GDG's position on "the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects"(Page 493, Line 7), if epidurals for sciatica are to be recommended, then GDG would be justified in recommending acupuncture.	people with acute sciatica, whereas this was not possible from the acupuncture evidence review. Therefore the recommendation made for epidural injections is for this subset of people with sciatica only. Furthermore, the GDG were mindful of the limited availability of treatment options for people with severe sciatica, and the various options for people with low back pain with or without sciatica.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of York	Full 1	17	21-22	COMBINED PHYSICAL AND PSYCHOLOGICAL PROGRAMMES The GDG has noted, "that there was very little evidence for usual care comparisons (with combined physical and psychological programmes) and no studies were identified that could be classified as a placebo/sham comparison."(Full version – Part 1, Page 736, Line 1) Furthermore, "no clinical benefit was observed for people with low back pain with / without sciatica when cognitive behavioural approaches was compared to sham or usual care or waiting list controls for the majority of reported outcomes"(Page 601, Lines20-22) This recommendation is therefore in marked contrast to the expectation of the GDG that an intervention should demonstrate evidence beyond context effects, as stated, "The GDG first discussed the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects."(Page 493, Line 7) Therefore for consistency when interpreting the evidence, if the recommendation of combined physical and psychological programmes is sustained, then acupuncture should also be considered as a recommendation, as there is clear proof of principle, as documented elsewhere, that acupuncture outperforms sham/placebo, as well as delivering a minimum clinical difference that is cost-effective when compared to usual care.	Thank you for your comment. The GDG placed more weight on the comparison between an intervention and placebo/sham whenever a placebo/sham was available and it was feasible to do so. In the case of MBR the GDG agreed a sham was not feasible. The GDG had therefore to base the recommendation on the best evidence available. Although the GDG acknowledged that the evidence was mixed, the GDG felt that MBR; specifically CPP programmes should be recommended on the basis of MBR showing benefit over waiting list, single and combined interventions, alongside evidence from single intervention chapters. In the case of psychological therapies, there was evidence of benefit for behavioural therapies over placebo/sham for pain, with low quality evidence coming from a single small study, and no evidence of benefit for cognitive behavioural approaches compared to placebo/sham. However the GDG discussed that cognitive behavioural approaches were unlikely to be provided in isolation and that the improvement of pain and function are not primary aims of this type of interventions. These factors would explain why meaningful effects were not seen in these outcomes. The evidence supporting the psychological therapies recommendation came from the combination section of the review, alongside the single intervention section and the MBR chapter. This is detailed in section 15.7 Recommendations and link to evidence.
Warwick Clinical Trials Unit	Appendices K-Q	General	General	While it is explained in section 4.3.3.1 that in the case of marked heterogeneity (i.e. I^2>50%) predefined subgrouping would take place, in some cases the predefined subgroup analyses still yield very high I^2 values. In such cases it is stated that DerSimonian and Laird random effects models would be fitted. However, in some cases (e.g. Figure 695, where heterogeneity in the fixed effects model is 64%) it is not clear where these random effects models are? Additionally, in the cases of acupuncture and manual therapy, predefined subgroup analyses included grouping by chronicity (acute/chronic), yet chronicity is dichotomised at more/less than or equal to 4 months, rather than 3 months (as defined in Table 11). Section 4.3.1.1.1 does not sufficiently explain this decision.	Thank you for your comment. The random effects model has now been applied to all forest plots with an I^2 value of 50% or above. Regarding time cut-offs, the cut-off of 3 months was applied for chronicity as pre-specified in the protocols for subgroup analysis if heterogeneity was observed. The definition of acute and chronic pain has now been added to the glossary. However, the data presented in the reviews were stratified according to two time-points: equal to or less than 4 months and greater than 4 months. Reference to this cut-off in the review reflects to the time point at which the outcome was measured in the study and not to the chronicity of pain. This is detailed in section 4.3.1.1.3 of the Methods chapter.
Warwick Clinical Trials Unit	Appendices K-Q	General	General	Throughout the Forest Plots the chirality of favours sham/control and favours treatment keeps swapping from left to right. This presentation makes for confusing reviewing.	Thank you for your comment. Conventionally on a forest plot, the outcome represented is negative, so that a risk ratio greater than 1 is undesirable, or, in other words, the experimental intervention gives a worse result than the control intervention. This is reflected in the axis labelling: to the right of the line of no effect, the RR is greater than 1 and the label says 'favours control', or whatever the control intervention is. If the outcome is positive, a risk ratio greater than 1 is desirable and the labelling should be reversed so that the label to the right of RR=1 says 'favours experimental' (or equivalent). Hence the chirality will change accordingly, the axes are labelled to enable the reader determine the direction of effect and help avoid confusion.
Warwick Clinical Trials Unit	Appendix B	General	General	We are concerned that the GDG's approach to conflicts of interest may fall below the standard set by NICE. We refer here specifically to version 2.5 of the NICE policy on conflict of interest that has been current since September 2014. These, therefore apply to all meetings from GDG eight onwards. Paragraph 16 of this NICE conflict of Interest statement recognises the special position of chairs of advisory committees who should not have any conflicts of interest for the matters under discussion. We suggest that, in addition to the declared personal pecuniary and personal non-pecuniary interests, it should have been declared that the committee chair's private practice involved providing interventional	Thank you for your comment. Because GDG members were recruited in 2013, the DOI policy that was followed for the purposes of this guideline was the 2007 policy (updated October 2008). This was stated in appendix B and has now also been added to section 3.4 of the full guideline for clarity.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				procedures, including radio-frequency ablation, which we interpret as a personal pecuniary interest. Alternatively, we seek reassurance that NICE do not consider this to be a personal pecuniary interest or reassurance that the chair is not, in fact, providing interventional pain procedures for low back pain or sciatica in private practice. (See https://www.nuffieldhealth.com/consultants/dr-stephen-ward) Appendix B records that the Chair did not withdraw for any discussions. Taken together these conflicts, and failure of the chair withdraw, mean that the probity of the decision making on interventional procedures, particularly from, GDG 8 onwards is open to question. This includes GDG 12 where a decision was made on radiofrequency ablation. There is a risk that this may leave some aspects of the guidance open to criticism.	The Chair and all GDG members were recruited in accordance with this policy. All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and it was agreed that no member unduly influenced the decision of the committee.
Warwick Clinical Trials Unit	Appendix B	General	General	We are concerned that the GDG's approach to conflicts of interest may fall below the standards expected leaving some aspects of the guidance open to criticism. The GDG will be well aware of that the 2009 guidelines on management of persistent low back pain attracted substantial comment. It is therefore most surprising that GDG chair did not choose to request GDG members with possible pecuniary and some specific personal non-pecuniary interests to withdraw from relevant decision-making. The decision-making about withdrawal from decision making because of personal non-pecuniary interests was also inconsistent in that on one occasion only a GDG member was asked to withdraw from decision making because of such an interest (SS on stratified care) but on other occasions GDG members with conflicts were not asked to withdraw. We suggest that; BA should have withdrawn for decisions on spinal surgery, and for all discussions of spinal surgery, if he provides the spinal procedures under discussion in private practice (this can easily be clarified) PH should have withdrawn for decisions on psychological treatments. N O'C should have withdrawn from decisions on acupuncture SV should have withdrawn from the decisions on manual therapy. DW should have withdrawn from decisions on facet joint injections (an undeclared conflict is that he is a co-applicant for a research project on intra-articular facet joint injections based here at Warwick CTU) CW should have withdrawn for any discussion regarding services of the type provided by Pain Matters Limited; a company for which he is a director. We are concerned that an apparent failure to address these potential conflicts will lead to the perception of bias in the recommendations. Members of the GDG will recall, and some were part of, the debate following the publication of the 2009 guidelines. Part of this debate was focussed on the possible bias of the then GDG members. To set a lower standard for managing conflicts for the 2016 guidelines than that used in the 2009 guidelines is, in our view, a shortcoming in the development of the current guidance. For the record, although it is not clear from the records on the NICE website, members of the previous GDG did withdraw from decision making in similar circumstances when they had personal non-pecuniary interest, and so were not involved in decision making on their speciality or on subjects upon which they had published relevant research. We suggest that the National Clinical Guideline Centre arranges of an independent assessment of the adherence to the relevant NICE conflicts policies in the development of these guidelines and whether the concerns we have identified may have affected the development of this guidance. Without such an independent assessment to give	Thank you for your comment. We were mindful of the comments that were received following consultation and publication of CG88. At the beginning of development, discussions were held with the GDG regarding conflicts of interest and the appropriateness of declaring work in private practice. It was agreed in accordance with the conflicts of interest, policy relevant at the time of development, that this was not viewed as a conflict that would require members to withdraw from decision making. Members of committees are recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (appendix B). The GDG member's undeclared interest regarding facet joint injections has now been added to the register in Appendix B.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				reassurance that the process of guideline development has been to an adequate standard these guidelines are unlikely to be generally accepted. If it is considered that the guideline development process has fallen below an acceptable standard then it may be unwise to proceed with publication of the final guidance.	
Warwick Clinical Trials Unit	Appendix K	72	Figure 266	The SD for Kell has been incorrectly entered as 0.2 rather than 2. This will result in the precision for the trial being estimated as ten times too large. The Kell trial is having far too much influence in the model. Also it is not clear that the comparison in Kell is Usual Care? It is stated that the control group must maintain previous levels of activity. This does not equate to Usual Care. We recommend that the GDG reconsider whether Kell should be included in this category.	Thank you for your comment. The SD for the Kell study has been corrected, and the meta-analysis was redone, however, this did not alter the outcome of the review. The GDG agreed that maintaining previous levels of activity should be defined as usual care rather than self-management as no exercise prescription or advice was given. This approach has been applied throughout the guideline as described in the methods.
Warwick Clinical Trials Unit	Appendix K	270	Figure 1117	The decision to support the use of radiofrequency ablation is, we think, dependent on the meta-analyses in this figure 1117. We have identified several serious concerns about the validity of these analyses that need addressing before the findings, and the economic model they inform are re-presented to the GDG. Our attention was drawn to this as in the four months analysis the direction of change in the Leclaire study has been entered in the wrong direction. Additionally, the SE for the Van Kleef study is wrong. The relevant confidence interval in Van Kleef is 2.46 (0.72 to 4.20). However, note that this is a 90% CI, and not a 95% CI. The width of this 90% CI is 3.48 points. Since a 90% confidence interval is (assuming normality) calculated as +/- 1.645 x SE (not 1.96 x SE, as for a 95% CI), then the SE is calculated as one-half of this width divided by 1.645, i.e. 1.74/1.645=1.0578 and NOT 1.74/1.96=0.8878 (as stated in the figure). This large underestimate of the SE results in too much weight being given to the Van Kleef study. A further serious problem with interpreting this figure is the data in the four month analysis from the Tekin study are the immediate post-treatment data collected six hours after the intervention. These immediate post-procedure data are meaningless when pooled with data collected several months after the procedure and cannot be safely used to inform a decisions on longer term benefits. We suggest that the six month outcome data are more relevant and that the six our follow up data should be used. There are also further numerical problems with using Tekin in the analyses. We cannot see how it is possible to calculate an exact SE from Tekin. There are no reports of between group difference SE or CIs for change from baseline that we can find to use, and so we seem to be limited to imputation from p-value. For example, in the <4m data, all we can do is impute an SE using the p-value for the between group comparison (in accordance with section 16.1.3.2 of the Cochrane handbook, part of a section we are told was observed by GDG), which we are told by Tekin is <0.001. Given the between-group difference (which must be calculated from Table 2 – we also assume an error here: the difference should be -1.7 rather than -2?), it follows (since the Tukey test refers to a t distribution on 39 degrees of freedom, two-tailed, at 0.001 the test statistic is approx. 3.558, and therefore SE=|-1.7/3.558|=0.4778, or <0.4778 since p<0.001) that all we can glean from the paper is that the SE was less than 0.478; we cannot calculate it exactly. Please could the technical team revisit how they have obtained the 0.3847 estimate of SE for this study? (and how they calculated a difference of -2 if they believe this to be correct?) In the >4m data from Tekin, we can impute an SE using the p-value for the between group comparison, which we are told by Tekin is <0.05. Given the between-group difference in	Thank you for your comment. The Leclaire and Van Kleef errors have been corrected however; this did not lead to significant changes in the outcome of the meta-analysis. The post procedure data from the Tekin study was used because, when setting the protocol for the review, the GDG agreed that results reported at any time before or equal to four months (including post procedure) should be pooled. However in the economic model conducted for this guideline, the pre-procedure pain score was used to inform the baseline score (and the usual care arm) while the pain score at one year was used to inform the effectiveness of the procedure as the longest effectiveness data from each study were selected for the modelling purpose. The SE in the Tekin analysis was calculated using the final values and SD reported in the paper, rather than the p-value. The values presented in the review are correct using this method. The GDG considered the Gallagher paper and agreed to only look at patients who had a good response to the diagnostic block. This is because radiofrequency denervation would only be carried out in patients who have had a good response to the diagnostic block. The changes made to the analyses were presented to the GDG for consideration and did not impact the recommendation.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				change from baseline (which must be calculated from Table 2 – we assume another error here – the difference should be -1.2 rather than -1.5?), it follows (working omitted - but t on 39 df here is 2.0227) that all we can tell from the paper is that the SE was less than 0.593, but again, we cannot tell exactly what it was. Please could the technical team revisit these analyses to clarify how they have obtained the 0.3847 estimate of SE for this study? (and also how they calculated the difference of 1.5 if they believe this to be correct?) Inspection of the Gallagher paper shows that the data used in this meta-analysis come from, what appears to be, a post-hoc subgroup of those randomised. What has been presented are just from the 30 subjects who had a good response to the diagnostic block. Data from another 11 subjects who had an equivocal response to diagnostic injections have not been included. In this group the intervention was detrimental with a point estimate for harm of 3.5 at four months and 3.2 for > four months. It is not clear to us why these relevant data have been omitted. We note that the original authors used non-parametric tests suggestion that these data re not normally distributed. We suggest that his may make it unsafe to include these data in a meta-analysis. Other commentators have previously questioned the validity of the studies by Gallagher, Leclaire and Wijk and suggested that they should not be used to inform decision making https://www.britishpainsociety.org/static/uploads/resources/files/members_articles_bupa_nov09.pdf We suggest that this whole analysis needs re-visiting by the technical team	
Warwick Clinical Trials Unit	Appendix L	General	general	We note that some studies have been excluded because pain distribution was bounded by gluteal fold rather than buttock crease. We suggest these are checked to ensure they do not contain material germane to the guideline	Thank you for your comment. However, we are not sure which specific studies you are referring to. The excluded studies for this review were double checked and we can confirm all were appropriately excluded.
Warwick Clinical Trials Unit	Appendix N	General	general	We were very pleased to see an economic model with some useful sensitivity analyses. We read this with considerable interest. We do have some concerns, however, that this is not arriving at an accurate answer because of some assumptions about what needs to be included in the model and how the base case has been parameterised. 1. The base case assumes that those people in the usual care arm of the study will show no improvement. This assumption is not robust. On aggregate people seeking care for low back pain tend to improve on subsequent measurement due to regression to the mean. This is because people tend to consult (or join trials) at a point when their symptoms are relatively (to them) more severe. The effect of this is that on subsequent assessment their measurements are more likely to have dropped back towards their own average, notwithstanding the natural history of their condition. A systematic review of cohort studies of people with persistent pain found that mean pain was 51 out of 100 (95% CI 44 to 59) and that at six weeks (closest value to four months) it was 33 (95% CI 29 to38), and at 12 months it was 23 (95% CI 20 to 33).[1] A systematic review of outcomes in the control arms of randomised controlled trials of people with low back pain found an SMD for disability at 13 weeks when compared to baseline of 1.03 (95% CI 0.82 to 1.25) and at 52 weeks of 0.88 (95% CI 0.61 to 1.1).[2] There is good systematic review evidence to show that the decision to have a base case of 'no improvement' in the usual care arm is not robust. We suggest that the base case should assume an improvement in the usual care arm. Using the other assumptions in the model in the deterministic analysis this generates a cost per QALY of £16,896	Thank you for your comment. We will respond to each of your points: 1. The population represented in the model is made of people who already had usual care and have exhausted all the possibilities in the non-invasive care. The GDG advised that longitudinal studies show that these patients do not improve with time; they could be different from the population in the RCTs where a regression to the mean could be observed. Therefore, we do not think we need to change our base case. However, we have also accounted for this possibility in a sensitivity analysis which shows that even when the placebo arm effect is used the intervention is cost effective. 2. The radiofrequency denervation arm in the model already includes an outpatient appointment, which is followed by a separate cost for the diagnostic block. Therefore, we believe the referral part of the pathway is covered; no other imaging tests are required so we believe the model starts at the right point. We realised that Figure 1387 in the model appendix could be the source of the misunderstanding as it may look like the initial consultant appointment is not factored in. We have amended the figure to reflect the actual costing in the model. 3. We have edited the meta-analysis but it had no impact on the economic model. After careful consideration we decided that none of the included studies had to be excluded.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. The model, as currently constructed, has its first decision node the decision to perform a diagnostic block in an individual with suspected facet joint pain. The guidance, however, is *'consider referral for assessment for radiofrequency denervation for people with chronic non-specific low back pain with suspected facet joint pain …'.* The current model cannot directly inform this recommendation. The first decision node needs to be a step further upstream at the point that this decision is being made. The current model assumes that everyone referred for consideration of radiofrequency denervation receives a diagnostic block. This does not recognise the limitations of our diagnostic processes or the natural history of the disorder. The approach to clinical diagnosis of suspected facet joint pain, identified by the GDG, was developed for use in secondary care by physiotherapists familiar with treating low back pain. Even in this environment, we have no data on its validity, including inter-observer variability or its test re-test reliability. It may be premature to recommend use of this approach. We also have no information on the stability of the symptom pattern over time. We do know, however, that people living with back pain commonly improve between referral and clinic assessment. Thus, between the GP (or other professional) decision to refer and the first specialist consultation apparent eligibility for radio frequency denervation will change; either pain will have improved sufficiently that invasive treatment is not justifiable or they do not have the pattern of suspected facet joint pain when seen for assessment. We suggest that the base case is changed to include this. We suggest that, at best, only about half of those referred will actually be considered for a diagnostic block. This would then, by our estimate, in a base case that includes a realistic control arm clinical trajectory and uncertainty about stability of diagnosis of suspected facet joint pain in the model in the deterministic analysis, produce a cost per QALY of around £18,651. 3. We have identified some errors in the meta-analysis of the effect of Radiofrequency Denervation on pain that affect the precision of the estimate for efficacy (Appendix K figure 1117). We also have some concerns that data from some of the RCTs have fundamental flaws meaning they should be excluded from the analyses. We suggest the model should be re-run once our concerns on these two points have been considered. 4. The potential harms of the procedures have not been considered in the model. Each procedure will create radiation exposure from screening. Whilst at an individual patient level this is not of great concern the potential long-term costs and loss of utility from radiation induced malignancy is predictable should be considered; even if only in a sensitivity analysis. 5. There are other risks that are less predictable such as increased pain after a diagnostic block and the known complications of nerve root blocks and ablations. Whilst not directly analogous we note here that Carette in a study of facet joint injections found that 7/110 people with a positive diagnostic facet joint injection declined to join the RCT as the experience of diagnostic blocks was too painful. [3] More serious complications of these procedures are rare in experienced hands. Nevertheless, these need to be part of the decision making process and it would be nice to see a sensitivity analysis that included an allowance for these less predictable adverse events. 6. Use of the clinical effectiveness evidence in the base case model. Lines 182 to 185 and Table 23 (page 426) seems to suggest that the pain score assigned the usual	4. No evidence was available on the harm of the procedure so this could not be incorporated into the model. However, the GDG have considered potential harm from the procedure, including radiation, and thought this was low and unlikely to affect the ISA. We have added some considerations in the model write up to explain this. 5. The model does take into account the possibility that people decline the procedure after experiencing pain from the diagnostic block. No evidence of complications was found and, as explained above, the GDG considered this to be negligible. 6. We carefully considered alternative approaches, including using the effectiveness of the placebo arm as reported in our meta-analysis; however, we concluded that the aim of the economic model is to reflect what would be observed in real practice. Therefore, as a sham intervention would never be offered instead of usual care, and therefore no placebo effect would be observed in usual care, we concluded that using the baseline pain score was appropriate for the economic model. In the model we could have used the scores from the two arms separately, using the baseline score in the placebo arm for the usual care and the follow up score in the RFA arm for the RFA intervention, as the baseline scores in the two arms is similar (5.6 for placebo and 5.7 for RFA). This would keep the randomisation as we are still evaluating the scores in two randomised groups. This would not have made any difference as the mean scores are virtually the same (5.6 and 5.7). Additionally, it is acceptable in an economic analysis to use non-randomised data if these data are from an acceptable source. We have added some considerations to the limitations of the model to explain that we used randomised studies but we may have not kept the randomisation. We have conducted an additional sensitivity analysis where we used the placebo score but it did not make any difference. The GDG had no reason to believe that the average pain score reported in the RFD trials would be different from the average scores reported in other studies, for example, on people receiving conservative management. We have added a sensitivity analysis to account for a different baseline pain score, where the baseline score is varied and the difference in pain score observed in the RFD arm is kept constant. Unfortunately, no UK data was available on the utilities therefore we could only acknowledge this limitation. We do not think the CEAC would be useful for decision making as they represent the probability of interventions being cost-effective at different values of willingness to pay threshold. We think this could be misleading as it implies that this threshold can be chosen by the GDG while the threshold is fixed.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				care cohort equals the weighted average of baseline pain score reported in the RFD arms (weights equals 1/study size) of the RCTs included in the effectiveness evidence. Similarly the pain score for the RFD cohort is assumed to be the weighted average observed score in the RFD arms at end of follow-up. There are 3 potential issues with this approach. a. The first is that pooling evidence this way (i.e. within individual arms rather than the study-specific contrasts between arms) would undo the benefit of randomisation (or even non-randomised but parallel group comparisons) within individual studies. This has the effect of reducing randomised comparisons to observational studies with all the problems associated with observational evidence. b. The second is that only data from the RFD arm of studies included in the effectiveness evidence was used to inform the base case results. This is clearly not ideal since not all the available effectiveness evidence is included in the cost-effectiveness evaluation in addition to the observational nature of such approach just noted. c. The third concerns the fact that most comparative effectiveness studies (RCTs in particular and non-RCTs to a lesser extend) can be quite strict in terms of selection of patients into the study. Hence the pain scores from these studies might not reflect experience of the patients which the cost-effectiveness model seeks to inform. This can be pronounced if for example studies conducted in countries with different patient characteristics to that of the target population are included in the effectiveness evidence. Perhaps it would be better (as was done in sensitivity analysis two based on the data in Table 24) to pool study-specific relative effects using standard meta-analytic techniques to obtain a summary estimate of RFD versus Sham. Then look for evidence from external source on the average pain score for patients in the untreated population (*i.e*. patients in receiving conservative management) and apply the relative risk reduction (mean difference in pain scores, e.g. as in Figure 1319 on page 427) to derive the absolute score in the RFD cohort. If no external evidence is available to inform baseline pain scores, then use the baseline scores from the effectiveness evidence. Concerns about the placebo effect and whether or not sham equals best usual care would still remain but we consider these would probably come second compared to ignoring the benefit of randomisation or parallel group comparison. The utilities used in model may not directly apply to the UK population because the value sets are from an American study. This is a major limitation as the model is meant to inform decisions in the UK NHS context. This limitation has been acknowledged in the report (Line 259 on page 429). We were disappointed that the only probabilistic analysis presented was that for the base case and that no CEACs were presented for the sensitivity analyses. Given the importance of the economic model to this decision we suggest that scatterplots and CEACs should be presented for each analysis [1] Menezes Costa L, Maher CG, Hancock MJ, McAuley JH, Herbert RD, Costa LO. The prognosis of acute and persistent low-back pain: a meta-analysis. CMAJ 2012; 184(11): E613-24	

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				[2] Artus M, van der Windt DA, Jordan KP, Hay EM. Low back pain symptoms show a similar pattern of improvement following a wide range of primary care treatments: a systematic review of randomized clinical trials. Rheumatology (Oxford). 2010 Dec;49(12):2346-56. doi: 10.1093/rheumatology/keq245. Epub 2010 Aug 16. [3] Carette S, Marcoux S, Truchon R, Grondin C, Gagnon J, Allard Y et al. A controlled trial of corticosteroid injections into facet joints for chronic low back pain. New England Journal of Medicine. 1991; 325(14):1002-1007	
Warwick Clinical Trials Unit	Full	general	General	We suggest it is problematic that only follow-up scores by group (eg Fig 266) have been used in meta-analysis models. We assume this has been done because SE for between-group differences were unobtainable. However, this seems to be the case above (in relation to our comment on Tekin figure 1117). Using data that are unadjusted for baseline differences can be problematic, especially in small trials. Whilst in Kell (where there were only 9 participants in each compared group) the baseline difference in ODI was only 1.2 points, in other small trials where the GDG has taken this approach, it is feasible that by chance, baseline scores were more different than this. So baseline should be accounted for (*e.g.* by basing on between group differences derived from change scores and the accompanying SE). Where this is not possible, we suggest that the GDG consider whether trials have been reported with sufficient quality to permit their pooling in meta-analysis, or at least, discuss the limitations of doing this, and interpret results from such models in this context.	Thank you for your comment. The extraction of either final scores or change scores from baseline is based on what is reported by the study. However the GDG is always given details of the baseline scores (where reported), which you can find in the clinical evidence tables in appendix H. The GDG have taken into consideration the baseline scores as well as the final scores when discussing the evidence and determining treatment effect.
Warwick Clinical Trials Unit	Full 1	40	26-38	The examples given here of what may be considered to be above non-standard care are confusing. The suggestion here is that NSAIDs are not standard care for people with low back pain. We suggest that a better example is used as many would consider the provision of pain relieving medication to be usual care. More worryingly, this approach has led to part of the complexity of trying to interpret the data meaning the GDG have not been in position to make properly informed judgments.	Thank you for your comment. The challenge of defining usual care within the guideline was acknowledged by the GDG, however this approach was agreed as a consistent way of managing this throughout the reviews. The example provided does not suggest that NSAIDs are not standard care, it relates to epidurals being above standard care, and is included to illustrate how the challenge of usual care treatments also being treatments reviewed within the guideline has been addressed. This has been reworded to clarify.
Warwick Clinical Trials Unit	Full 1	40	16-19	The wording here does not seem to be consistent with the questions set which are just for low back pain with or without sciatica. Also this approach excludes any data on people with radicular pain in the absence of back pain.	Thank you for your comment. The strata for all reviews are detailed within the protocols, therefore this wording is consistent. People with sciatica without back pain were included within the strata of 'low back pain with sciatica'. This has now been amended to clarify.
Warwick Clinical Trials Unit	Full 1	40	22-24	Some more justification for this decision would be helpful as this may have excluded relevant studies of therapist delivered interventions where an inactive, or ineffective, controls of a different modality has been used.	Thank you for your comment. The GDG agreed this as the most appropriate approach to remain consistency across reviews. If a control of a different modality was used as a control, that would be considered as a comparator intervention rather than a sham, if relevant to the review protocol.
Warwick Clinical Trials Unit	Full 1	41	36-40	Although not available to the GDG at the time this decision was made there is evidence to suggest pooling of measures in this way is not robust. Morris T, Hee SW, Stallard N, Underwood M, Patel S. Can we convert between outcome measures of disability for chronic low back pain? Spine (Phila Pa 1976). 2015 May 15;40(10):734-9. doi: 10.1097/BRS.0000000000000866. PMID: 2595509	Thank you for highlighting this study. At the time of developing the guideline, standard methodology at the NGC was to pool continuous outcomes on different scales where the GDG agreed it was appropriate. This was agreed for RMDQ and the ODI, which were pooled together and presented as standardised mean difference. This was followed throughout the guideline as stated in the methods (section 4.5.1.1.3).
Warwick Clinical Trials Unit	Full 1	42	15-16	The evidence base that requires synthesis here is very large and complex presenting a major challenge for the techical team. So far as we can see no evidence syntheses from systematic reviews have been used to develop this guidance. There is not an explicit statement in the methods that these were to be excluded. Many systematic reviews have been excluded because their methods were inadequate/unclear and for many reviews the reason for exclusion is given as 'Source of references' On nine occasions Cochrane reviews are excluded for these reasons and on four occasions the reason for exclusion is	Thank you for your comment. The technical team considered existing systematic reviews however, due to differences in protocols between the published systematic reviews and those developed for this guideline; it was

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				simply given as 'Cochrane Review'. We do not consider that these are adequate reasons for the exclusion of existing evidence syntheses. We note that the NICE Guidelines manual states; *'Well-conducted systematic reviews (such as Cochrane intervention and diagnostic test accuracy reviews) may be of particular value as sources of evidence.*' The NICE guidelines manual also suggests considering *' Whether the use of existing high-quality reviews will be sufficient to address the guideline review question if the evidence base for the guideline topic is very large.'* We suggest that failing to use existing evidence syntheses has put the technical team in the unenviable position of trying to synthesise almost the entire body of relevant literature on diagnosis of, and treatments for, low back pain and sciatica. The consequences of this are that the job has been done poorly with multiple errors of omission at both the paper level and for data extracted from papers (too numerous to list here). This is remediable, but far more seriously, there is a consequence that the data have been presented in such a fragmented manner that it is impossible to sensibly interpret the data presented. To reject the combined efforts of the back pain research community, over the last 25 years, to synthesise data on back pain may be misguided. Clearly there will still be occasions when original research needs to be synthesised but this should only need to be for a minority of questions. Our view is that the GDG have not been in a position to judge the best available evidence syntheses and that this has hampered their ability to come to unbiased guidance. We consider this to be a potential flaw in the process of guideline development.	not possible to include any. However all were checked for included studies and consistency. We have now added a statement to the relevant clinical introductions to highlight where Cochrane reviews or other high quality systematic reviews were identified and the reasons they could not be incorporated. We apologise that there were some errors identified in some reviews, however do not agree with the statement that there were multiple errors of omission. All suggested errors have been checked, amended where these were incorrect, and reasons provided where these were misunderstandings. There are no significant changes to the outcomes of the relevant reviews, and we also note this only applied to a small number of the total reviews in the guideline. Consequently we do believe the conclusions made and guideline recommendations are based on the best available evidence.
Warwick Clinical Trials Unit	Full 1	49	3	Attention is needed to ensure all of this section is in the past tense.	Thank you for your comment. This change has been made.
Warwick Clinical Trials Unit	Full 1	49	3	It is difficult to follow here, and page 51 lines 14 onwards how the GDG have decided on a clinically important difference. Here the minimally important difference, when there is not an agreed value is given as a standardised mean difference of 0.5 but on page 51 absolute values agreed by the GDG consensus are used for several key outcomes. Clarity and consistency is needed on this point. Based on either set of criteria few, if any, studies of effectiveness will achieve the pre-set minimally important difference. It is stated that the default MID may be changed following discussion with the GDG. However, it is not clearly described in what circumstances this would be altered. Whilst clarity and consistency are needed on this point we suggest that what is the minimally important difference here is context specific and that this need explicitly considering for each intervention in the context of the financial and opportunity costs of accessing, and the risks of harm from, the intervention.	Thank you for your comment. We have amended the text on page 49 and 51 to clarify the process that was followed. MIDs were agreed at the protocol setting stage. If there were published accepted MIDS, agreed by the GDG, these were used in preference of other options for both imprecision and clinical importance. However, in the absence of established MIDs, the GDG were asked to determine MIDs for each continuous outcome for assessment of clinical importance and the GRADE default values are used to assess imprecision (0.5 x standard deviation for continuous outcomes). This is the agreed approach followed by the NGC when published MIDs aren't available. Clinical importance, is determined using these agreed MIDs based on the point estimate, taking into account the baseline values for continuous outcomes. The MIDs set at the protocol stage use used consistently throughout the guideline and are not changed, but a discussion was had amongst the GDG regarding the relation to the control group event rate or baseline values as appropriate.
Warwick Clinical Trials Unit	Full 1	108	29	Recommendation 1 The GDG is here suggesting use of the STartTBack tool as part of shared decision making. As far as we can see the GDG did not examine the available literature on shared decision making in low back pain. Some of our own work; although only a pilot study, actually suggested shared informed decision making to inform back pain treatment choices might be harmful. The suggestion for shared decision making does not seem to be supported by the evidence. Patel S, Ngunjiri A, Hee SW, et al. Primum non nocere: shared informed decision making in	Thank you for your comment. Shared decision making was not reviewed as a specific intervention, however, in alignment with the NICE guideline on Patient Experience (CG138) that shared decision should apply across all choices of investigations, treatment and care.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				low back pain--a pilot cluster randomised trial. BMC Musculoskelet Disord. 2014 Aug 21;15:282. doi: 10.1186/1471-2474-15-282.	
Warwick Clinical Trials Unit	Full 1	108	29	Recommendation 1 The GDG have appropriately identified that the STarTBack tool has good measurement properties for assessing risk of poor prognosis. The evidence they have reviewed does not, however, support its use in the manner suggested in the draft guidance. Indeed, it appears impossible to apply it appropriately within the draft algorithm. The main STarTBack paper tested the combination of risk stratification and bespoke treatment packages compared to 'standard' physiotherapy. Positive results were obtained on the primary outcome at four and 12 months. It is not, however, clear to what extent these benefits were derived from the use of a stratification tool and how much were from the improved physiotherapy approach. Thus any recommendation of the STarTBack approach should support the use of the whole package and not just parts of the package. We note here that the mean difference between groups in RMDQ at one year is 1.06 (95% CI 0.25 to 1.86). This effectively excludes the GDG's pre-set minimally important difference of 2.0 points on the RMDQ . If such a smaller difference is accepted there should be an explicit discussion from GDG as to why this is not consistent with planned methods. Since the comparator is another physiotherapy package, such a small difference may well represent worthwhile added value; but only if it is the whole package that was used. The GDG appear, in fact to be advising that the STarTBack tool should be used to inform stratified management without providing the STarTBack interventions. Neither 'standardised individual physiotherapy addressing symptoms and function' for the medium risk group or the 'individual psychologically informed physiotherapy' for those in the high risk group are recommended in the guideline. Indeed, evidence to support these approaches has not been specifically sought. Since the recommendation here does not appear to be grounded in the evidence, or to be implementable, we suggest that this recommendation is dropped. Other work we have done at Warwick CTU has also sought to identify baseline factors to inform decisions about treatment choices for people with low back pain. In a large IPD network meta-analysis of randomised controlled trials of therapist delivered were we able to define sub-groups of individuals who might gain more benefits from different treatments. The size of the sub-group effects were in fact modest, and thus unlikely to be useful clinically. Although it does suggest that people with more severe symptoms may gain greater benefit from treatment. This has not tested the value of the prediction tools evaluated by the GDG, but it does lend some additional weight to the argument that risk stratification is unlikely to be helpful. This work is awaiting publication in the NIHR journal library and would be available to the GDG on request from the NIHR. Patel *et al*; identifying back pain subgroups; developing and applying approaches using individual patient data collected within clinical trials. [RP-PG-0608-10076]	Thank you for your comment. The GDG recommended a risk stratification tool should be considered, with the STarTBack tool as an example to inform stratified management. The GDG felt there was not enough evidence to recommend a specific tool, nor specific sets of interventions for stratified management. However, the recommendation has now been edited for clarity and the following has been added: Based on risk stratification, consider simpler and less intensive support for those likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach).
Warwick Clinical Trials Unit	Full 1	148	23	Recommendations 2 & 4 We agree with the general message of these recommendations, and that they are grounded in the data, but wonder if they could perhaps be a bit more specific, such that there is a distinction made between imaging for back pain and sciatica in non-specialist setting; *e.g.* 1. Do not offer imaging in non-specialist setting for low back pain 2. Consider imaging in a non-specialist setting for low back pain with sciatica after failed conservative treatment only when special referral is being considered.	Thank you for your comment. The GDG reviewed the evidence and found that it was the same for both populations. Recommendations 2 and 4 apply to people with low back pain with or without sciatica.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The point here is that in some cases onward referral can be avoided if radiological changes are not congruent with symptoms.	
Warwick Clinical Trials Unit	Full 1	203	9.3.1	We note with interest that the UK BEAM study appears listed as being excluded from the clinical evidence on exercise on the grounds that the wrong intervention was being tested in Table 5 of Appendix L. These data are not presented in the Forest Plots in Appendix K or in the included studies table (69); although they are included in Appendix H. However, in the health economic analysis, the UK BEAM trial is included (and discussed specifically in 9.6) with the intervention being described as a group bio-mechanical intervention. There is a clear inconsistency here. Either UK BEAM needs to be completely excluded from the exercise question including from the cost-effectiveness analysis; or alternatively the clinical data should be included in the comparison of group biomechanical exercise vs. Usual care. The GDG will then need to revisit their discussion on exercise with updated analysis to consider if this might change their advice.	Thank you for your comment. The excluded study in appendix L refers to a cost effectiveness study and therefore was correctly excluded. The UK BEAM study has been added to appendix H and the clinical data for exercise and self-management (best practice) versus self-management (best practice) have now been included in the review. The additional outcomes show no clinically significant difference between the 2 groups, except for short-term clinical benefit of exercise plus self-management for function,
Warwick Clinical Trials Unit	Full 1	303	9.6	In link between evidence and recommendation we are not convinced by the GDG's view that there is evidence of benefit for all exercise types against sham, usual care or other active comparators. So far as we can see, for the sham comparison from the Forest Plots, there is one trial of individual exercise (n=170, Albert 2012) that found a benefit on a VAS at four months, but not one year; one trial of group biomechanical exercise vs sham that found a harm on psychological distress,(Smith n=26) and one trial of group mixed exercises versus sham (Machado n=139) that found a benefit on RMDQ at 4 months, but not on pain or psychological distress. This does not provide a robust evidence base to support conclusion that exercise is superior better than sham/placebo. It is difficult to judge the effect sizes for exercise against usual care because of the larger number of different comparators and outcomes. However, if we look at group mind-body exercise, a comparator for which there are several relevant studies and cost utility data from within a trial, the VAS at 4 months does not show a benefit (Appendix K figure 303;data not pooled for one year), the standardised mean difference for the RMDQ/ODI is 0.34 (0.17 to 0.52) at four months and 0.30 (0.11 to 0.50) at one year (Appendix K figure 307). Expressing these results as SMDs makes interpretation harder. Using the baseline data for the standard deviation of the RMDQ from the Tilbrook study (the largest study contributing to this analysis) the point estimates equate to around 1.5 and 1.3 RMDQ points respectively. This does not suggest that either of the GDG's pre-specified minimally important difference in SMD of 0.5, or 2 points on the RMDQ, has been achieved and no explanation has been given as to why the GDG chose a lower threshold to conclude that exercise should be considered as an effective intervention. Overall the failure to show a meaningful effect against sham and the small effect size when compared to usual care would, for some other interventions, lead to the GDG advising against its use. A clear justification is needed for this inconsistent approach to appraising the evidence.	Thank you for your comment. On revisiting the 'sham exercise' evidence, the GDG agreed that none of the included sham interventions were true forms of 'sham exercise'. Therefore the revised guideline no longer has any evidence for exercise versus sham including the Albert 2012 study which was subsequently excluded due to the sham arm comprising of another form of exercise. The Smith 2001 was also excluded as the exercise arm actually comprised of a breathing, relaxation and movement audio tape, and sham arm consisted of a story audio tape. This therefore did not fit in the protocols for any of the interventions and was excluded. The Machado study was moved to the exercise versus cognitive approaches comparison due to the sham arm consisting of non-directive counselling. Although the group mind-body exercise versus usual care comparisons does not reach clinical significance for pain or function, several of the other comparisons, including individual and group biomechanical exercise and group mixed exercise, reach clinical significant for pain, function and quality of life. Therefore, the GDG agreed that there was enough evidence showing a benefit of exercise compared to usual care to warrant a recommendation for exercise.
Warwick Clinical Trials Unit	Full 1	451	14-16	We take it here that is the UK BEAM study that is being referred to. It is incorrect to state that no difference was seen in short or long term outcomes for pain and disability. Inspection of Forest Plots 637, 638, 641, and 644 show this to be incorrect. On all of these outcomes modest but statistically significant benefit was gained. This error appears to have been transmitted into the link to evidence and recommendation on page 453. We seek reassurance that the GDG were correctly appraised of these data at the time that they were formulating their recommendations on manual therapy. If not this recommendation needs to be revisited as this may be sufficient evidence to justify the use of mixed modality manual therapy as a stand-alone treatment.	Thank you for your comment. The decision of whether or not a difference is meaningful is based on an MID rather than statistical significance, as described in the methods chapter. None of the values in forest plots 637, 638, 641 or 644 meet the minimal important difference (MID) for determining clinical significance, as determined by the GDG, and therefore it is correct to state that there was no clinically important benefit. (see table 6 section 4.3).

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Warwick Clinical Trials Unit	Full 1	493	7	Recommendation 13. The GDG have identified here the controversial nature of recommendations for, or against acupuncture. They are considering here largely the same body of evidence that the previous GDG considered. Thus, it does need to be recognised that on both occasions that the perspectives of the individual GDG members will have an important influence on the recommendation. This is part of a wider discussion of the merits, or otherwise, of acupuncture treatment. We note here that the GDG have commented that 'the experience of adverse events may outweigh the possible benefits from acupuncture. We are not aware of any systematic reviews of safety of acupuncture but there are some large observational studies that indicate a very low rate of serious adverse events. See for example MacPherson BMJ 2001; 486-7 that the GDG could have consulted We agree with the GDG that there is a large amount of evidence available and that further research us unlikely to be helpful. We also agree with the interpretation that there is a good body of evidence showing modest superiority to usual care/waiting list controls but the evidence does not consistently show superiority over sham/placebo controls. Nevertheless, some evidence of efficacy is presented. Forest Plot 667 shows a benefit of verum over sham acupuncture at four months of 0.8 (95% CI 0.25 to 1.36) for pain. This does not meet the pre-specified minimally important difference, but then none of the recommended treatments reach the pre-specified minimally important difference. The effect size is better than that of exercise or manual therapy when compared to sham and is derived on data from 1,359 participants in seven trials, suggesting that this is a robust funding. The GDG incorrectly state that there is no evidence for benefit on pain in sham controlled studies. We suggest that a true sham for acupuncture treatment is not possible. A patient receiving any sham treatment will have had the sensation of needling and as such there may be central neurophysiological effects that are in addition to the contextual effects of the consultation. Furthermore, since the research question is 'What is the clinical and cost-'effectiveness' (…) comparisons to sham may be of relatively less importance. Sham comparisons would be relevant only to questions of efficacy whilst the NICE guidelines manual advises that is evidence of effectiveness that should be sought. The key point at issue is how the contextual effects, and any central effects of the perception of needling, are valued by those making recommendations. An approach to consistently accept that contextual effects are an important part of how many of our therapist delivered interventions have their effects is reasonable; indeed this is consistent with the GDGs decision to recommend multi-modal therapies. It is also reasonable to consistently reject the importance of these effects and only accept evidence for therapist delivered intentions when the modality being assessed has been shown to efficacious in sham/placebo controlled studies. However, in cases where the latter is preferred, the research question must necessarily be modified such that it is conditional on demonstrated efficacy; *e.g. 'What is the clinical and cost-'effectiveness' (…), of treatments for which efficacy is demonstrable…'* This is the approach suggested by the GDG for considering acupuncture and is consistent with NICE OA guidance. Finally, if this approach is used, it should be applied consistently across all interventions considered by the GDG. We are concerned that the GDG is using an inconsistent approach here when considering the evidence within this guideline. We suggest that application of the decision-making processes used for acupuncture consistently across the guideline should also have led to	Thank you for your comment. The GDG composition included professionals from a range of expertise and view points and interpreted the evidence taking all factors into account and made a balanced decision on the recommendation in all reviews on the evidence that was presented. The GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Since a large number of RCTs were identified for this review, the observational studies mentioned would not be included. However, the GDG do state in the linking evidence to recommendation section that acupuncture is considered a relatively safe procedure. Although some evidence of benefit for acupuncture was observed for SF-36, HADS, healthcare utilisation and responder criteria, the GDG felt these was small short-term effects , along with the many outcomes which showed no benefit of acupuncture over sham, the GDG concluded acupuncture did not prove clinically effective. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. Effectiveness is used in the guideline as a broad term to include efficacy and we have clarified this in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. With respect to inconsistency across interventions, the above approach has been applied across all reviews and the evidence for these have been revisited to ensure consistency has been maintained.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				rejection of all of the other therapist delivered interventions. Or alternatively that acupuncture should be accepted as one of the treatment options in-line with other therapist delivered treatments.	
Yawye	Appendix J	12	29-29	It is not quite difficult to accept GDG still used Thomas cost effective analysis which Prof Thomas found the Qaly was under £20000 threshold of NICE. Although her study was made 10 years ago but NICE threshold is still £20,000[1]. Although several serious limitations such as studies based on the questionnaire with recall bias, and miss data due to many young patients who do not have persistent NLBP, and although QALY should be not recommended in health decision making[2] , but we consider that there is no equal study has been done to criticize her study directly. Therefore, we do not accept criticizes from our colleague, which NICE has used older standard to measure new life since there is no evidence to say objecting Prof Thomas study. We also not accept criticize from GDG which they criticise Thomas study did not have sham or placebo control and therefore, effective analysis is irrelevant. We think that is misleading by previous wrong equation sham =placebo=real acupuncture=dishonest. Thomas and his colleague do not agree with this and they have recently published another cost effective study in 2014 and they did not include any sham or placebo [3].[4]	Thank you for your comment. The quality assessment of the study is conducted using standard checklists, as described in the Methods section of the guideline (Chapter 4.4.1). Our literature review includes both papers from the same group, Thomas et al (2005) and Ratcliffe et al (2006). As you mentioned in the footnote of your comment, no study from the same authors was published in 2014. The other study by Hopton mentioned in your comment was on people with depression and comorbid pain, therefore this study was not retrieved in our searches as it did not match the population of this guideline.
Yawye	Full	General	General	About Dr John And Grace Wu Both are medical qualified Chinese medicine doctors in Western and Chinese medicine and daily practiced in the largest hospital in Hunan province before immigrated in the UK almost 30 years ago. From 1988 both worked in Moorfields Eye Hospital and Institute of Ophthalmology. Dr Wu received several degrees included PhD for public health from University of London and Master Degree for Epidemiology from London School of Tropic Hygiene and Medicine(LSTHM). Dr Wu has involved several national surveys and community trials funded by MRC, charities and WHO. From 1997, both left NHS and started to run private business for Chinese medicine. According to epidemiological knowledge they have immediately realised great increasing of demand for alternative medicine. They decide to open the first Chinese medicine clinic in shopping centre (Northampton). Shortly, they and their business parterres created a Brand: Dr&HERBS and occupied more than 160 units in all of largest shopping centres cross the UK and Ireland within 10 years. Due to economic crises in 2008, the national chain crashed and their companies wound up but both of them continue to see their patients up to day. They have provided great effective treatments to local people and received near thousand or good comments from public.[5] Both of them are not just in medical field experience and business but have good records in academic and social welfare. Except title: practitioner as self employment, they have refused to join any association and take any response to other than themselves. They have given NHS and our Government many responses to different consultations independently. For instance they had refused the proposal for setting statuary regulation for Chinese Medicine and Acupuncture because they considered too early to introduce premature medical system into UK since not many people understood what Chinese medicine was ten years ago. They had given NHS several proposals for setting up wellbeing system: National Wellbeing System. In comparison with all sorts of expertises on the back pain issue, experiences from both of them should be very important to share with others since they have enough skill understanding all different issues: Chinese medicine, acupuncture in clinic, clinical trial, data analysis, bias, confounding factors, meta analysis, public management police etc. In	Thank you for your comment.

[1] https://www.nice.org.uk/advice/lgb10/chapter/judging-the-cost-effectiveness-of-public-health-activities
[2] European Commision Project. ECHOUTCOME http://www.echoutcome.eu/
[3] We have tried to contact her to ask her any new developments but she did not reply. We assume that Thomas 2006 paper is best for NICE to considered
[4] Hopton A et al:, Acupuncture, counselling or usual care for depression and comorbid pain: secondary analysis of a randomised controlled trial. http://bmjopen.bmj.com/content/4/5/e004964.full.pdf+html
[5] There is comments book with 1200 customer comments. That book has been used as market research by public media.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Chinese acupuncture society, there are no similar persons as them to involve all of the above fields at the moment. Due to acupunctures society requested, both of them decide to take part of this consultation because they realise they can help NICE to make better guideline for people with low back pain. PACHA would like to take this opportunity introducing Dr Wu to NICE and their comments will be supported by our members of society although they are not member of our society yet. PACHA hold several meetings to help Dr Wu and Mrs Wu finishing their responses.	
Yawye	Full	General	General	Introduction We are glad to have the opportunity to offer comments on the draft NICE guideline on NLBP. We hope that our comments will be helpful. Our consultation response was informed by 5 half day internet workshop with over hundreds Chinese medicine doctors, acupuncturists and health social care professionals who have a special interest in Acupuncture and LNBP cross international countries China, German, France, USA and Australia . A clear consensus was sought on all issues but more specific on quality of acupuncture and sham acupuncture: for inclusion in the scope; from study design whether with or without sham/placebo, whether considering Nocebo[6] or hidden treatment in placebo , whether modifying acupuncture treatments were inadequate treatments or acupuncture should not be alone from acupuncture practice and whether experiences of acupuncturists had been considered as important issue.[7] After we reviewed most of 25[8] trial case relevant with acupuncture intervention, we realize that there is no quality of control for both arms of intervention or control such as Acupuncture and sham needling. There is also no quality of control for placebo needling. To simplify our comments, we consider that we focus on both quality of the intervention arm and control arm in our responses. We have also sought the views of independent epidemiologic advisors and acupuncturists who have extensive expertise, experience and knowledge of using acupuncture to treat back pain, as well as more than 1500 members from several internet social media communities which are made up of exchanging knowledge of Chinese medicine and other alternative medicine. From those communications, we would like to give you our suggestions to enhance the guideline. Furthermore, there was a great angry from our communities because the new guideline is proposing to withdraw acupuncture from list of recommendations. We have received a great confusions, blaming negligent, bias criticises, and even unfair or conspiracy. We fully understand their bad feeling coming from but we have taken a first step to persuade them not to make any public gathering or demonstrations until we have had chance to look those data independently. Many thanks PACHA[9] organised those public meetings on internet social media. For this reason, our second part for this response is to answer all questions for our community: Whether is unfair for NICE to make U turn decision? We think it is very important to report this at this response and it is very relevant for policy makers to know. I	Thank you for your comment and this information. We have responded to all of your separate comments below. The GDG considered all of the evidence reviewed for acupuncture in light of the stakeholder comments, however it was agreed that there is no evidence of benefit compared to sham or placebo and therefore agreed that acupuncture should not be recommended as a treatment for people with low back pain or sciatica on the NHS.
Yawye	Full	General	General	Executive Summary The NICE Guideline on Low Back Pain with or without sciatica proposes to make U turn: withdrawing acupuncture from list of recommendation.	Thank you for your comment. Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. However, the GDG agreed that the evidence was still conflicting for acupuncture versus sham.

[6] Vincent C and Lewith G:Placebo controls for acupuncture studies . Journal of the Royal Society of Medicine.1995 88(4) 199-202
[7] Acupuncture Today: The STRICTA recommendation: Improving Standards in Acupuncture Research. Acupuncture Today 2002,3(6)
[8] We are unable to get all original papers.
[9] PACHA: Professional Acupuncturist and Chinese Herb alliance

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• There is no evidence that because NICE U turn decision was resulted from unfair to deal with all of RCTs information. • There is no evidence that NICE has serious bias or serious error to affect the decision. If they had and all of those biases and entry errors would be avoided, it would not change the consistent finding that No clinically significant results from benefit of Acupuncture. • It is no doubt that acupuncture under the guideline is acupuncture practice inside NHS but not for standard acupuncture practiced outside of NHS • NICE does not recognise that there is no real sham needling or placebo needle to test acupuncture since acupuncture is never worked as alone, such as tablet[10] [11].[12] [13] • NICE does not recognise that quality of acupuncture in the randomized trial with intended to test placebo has damaged since blinding procedures restrict acupuncturist freely acting best way to treat their patients as daily practice.[14] • We accept that there is no significant difference between real and sham needling but that were resulted from inadequate acupuncture performance and sham placebo needling. The similarity of results from sham and real acupuncture cannot be directly treated that real needle is placebo needle before examining whether placebo needle is real placebo one. • Before final version in September published it would be essential for NICE to make great effort to determine all of qualities of Acupuncture interventions and to make new analysis after excluding poor quality of intervention. We believe the results will have significantly changes. • There is no simple criteria to establish such as qualification to determine what it is good or not good acupuncture. We have demonstrated there are 12 essential factors which can affect the quality of acupuncture. After considering of those factors, there are 30% of 30 trials have been in good acupuncture practice, but rest of them are in question. We would like NICE to re do analysis based on good quality of acupuncture. • We absolutely accept NICE point there is no point to need for other well-funded trials to explore further. Regardless NICE reason, we consider that although using placebo or sham as control is fundamental mistake for acupuncture trial because it is impossible, but previous studies information can be used to understand what it is acupuncture. Those existing RCTs data should be very useful to have further analysis. Therefore we advice GDG that it is time to stop any sham or placebo trial for acupuncture. But it is time to re-do meta analysis after quality of acupuncture is reached optimal situation. . • It is time to consider that all of sham needle control are as inadequate acupuncture treatments • Since impact of withdrawing acupuncture could be as U turn, we do not consider UK is ready to accept this wake up call and confused everyone that acupuncture is dishonest treatment and alternative medicine is rubbish. Furthermore, question to the NICE was for acupuncture in the NHS or NHS related society which called western medical acupuncture. Before NICE to resolve the above quality problem and find all of types of acupuncture whether within or not in NHS are useless, NICE should not make announcement e moment that acupuncture is not working.	The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. We are unable to advise people to seek acupuncture through the private sector, as these recommendations only inform NHS practise.

[10] Vincent C and Lewith G:Placebo controls for acupuncture studies . Journal of the Royal Society of Medicine.1995 88(4) 199-202
[11] Vickers AJ:Placebo controls in randomized trials of acupuncture: EVALUATION & THE HEALTH PROFESSIONS, Vol. 25 No. 4, December 2002 421-435
[12] Colagiuri B and Smith CA: A systematic Review of the effect of expectancy on treatment responses to acupuncture :Evidence Based complementary and alternative medicine 2012 : http://dx.doi.org/10.1155/2012/857804
[13] Ernst E, White AR. Acupuncture for back pain: A meta analysis of randomized controlled trials. Arch Intern Med 1998;20:2235–2241.
[14] See Forest plot figure 691-701

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				NICE should consider such not working statement is serious nocebo for people using alternative medicine and people should not be discouraged from looking alternative medicine as they are used. • In the worst situation if NICE cannot accept to recommend acupuncture, we would therefore suggest that in the absence of further research into this area at present, the recommendation should be altered to read " *There is currently no conclusive evidence that western medical aAcupuncture can be effectively treated NLBP, but research into this is on-going. People with NLBP should be advised that with server condition or who used to acupuncture treatment, they should remain to look benefit from acupuncture they have used and, if situations under such …. prove this to be the case, acupuncture should be offered or if NHS has no facility for acupuncture in certain area, people should be advised to look private section and giving them the guide to find local practice for acupuncture."* • If NICE decides not make U turn, we welcome the decision. However, the guideline requires clarity around access to acupuncture specialists. In particular, it should include a definition of differences between "Western medical acupuncture[15]" and traditional medical acupuncture in order to clarify which acupuncture specialists should be responsible for different areas of care and treatment, for example who should treat those difficult cases and who should lead the annual review of people with NHS *or out* NHS.	
Yawye	Full	General	General	Acupuncture therapies are an important part of the delivery of health care within the NHS, voluntary and private sector since 2000. The proportion of using acupuncture treatment has significantly increased over last 15 years. Based on our own records from Dr&HERBS chain operation across the UK, it has shown that more and more people would like to choose acupuncture rather than herbs alone now. Before year 2000, there were less than 15% patients to take acupuncture as a relaxing treatment, but today almost 80% of our customers would like to acupuncture with herbs together or other cupping or assistant treatment for their unstopped symptoms. Over last 20 years our previous company alone had recruited more than 300 outstand Chinese medicine specialists from China. Proximately 50% have already settled in the UK as residents to provide local people daily practice for acupuncture. Today, it is estimated there are more than 3000 acupuncturists who practice both Chinese medicine and acupuncture in the UK[16]. Almost all of them are self employment and have opened their own clinic and see more than 20 to 30 patients a week, in high street, shopping centers or their private houses across the whole of UK. They have substantial different ways from western medical acupuncture. For them, acupuncture is rare used alone. Most of acupuncture done is inside their clinics and their clinics open from 9:30am to 9:30pm. People can pop in and receive services straightway	Thank you for your comment and this information. However, NICE guidance is based on the best available evidence for each intervention, and on the basis of the systematic review for acupuncture, the GDG do not agree that there is sufficient evidence to recommend acupuncture as a treatment for low back pain or sciatica on the NHS.
Yawye	Full	General	General	Every week, almost 100,000 of potential GP clients have turned to see those specialists outside of GP clinic. More than 5 millions clinic appointments were made in this private sector per year. Almost 45% of their clients are taken acupuncture as well as other intervention. Today there is over 4 millions acupuncture sessions done in those acupuncturist outside of NHS or by those not referred in the guideline as western medical acupuncture. According to BCcA there have over 1800 member[17] and one practitioner can have 60 session per month and total of acupuncture session from BCcA per year is 1.3 millions. In comparison, sessions outside of BCcA is more than 3 millions. Therefore, we advice NICE should consider that guideline impact is going to affect not just BCcA but also thousands of practitioners outside of BCcA.	Thank you for your comment. The original guideline for low back pain published in 2009 (CG88) recommended that a course of acupuncture should be considered. However, as you highlight, this recommendation was poorly implemented within the NHS, and this formed part of the decision to update the guideline. In updating and re-reviewing the evidence, the GDG do not believe there is sufficient evidence to maintain this recommendation and therefore no longer recommend acupuncture in an NHS setting.

[15] The Guideline 13.1 introduction No 9 line
[16] We do not know exactly but it estimated based on overall total number of Chinese doctors how holding working permits divided 2 to meet nearly 50% of them settled in the UK. The Chinese doctors are included all of TCM doctors and other medical professionals from China or East Asia. There is evidence many of Chinese medical professional who worked in NHS but later altered into Chinese medicine. Just like ourselves.
[17] http://www.welwynacupuncture.co.uk/files/MacPherson_AiM_2001.pdf

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Yawye	Full	General	General	Our own experiences over last twenty years, have shown a strong increasing demand for alternative medicine in our working populations. For example, due to great demand, our clinic has withdrawn all advertisement from internet and yellow page 5 years ago. In comparison 20 years ago, some days, there were only two patients or even less. Great demand for alternative medicine is partly contributed by NHS encouragement for using acupuncture but most important contribution is effective treatment for all sort of pain reliefs, especially for no specific pain such as NLBP. Pain has been confirmed the best effective treatment by using acupuncture from several meta-analyses[18]. If even NLBP could not be considered as recommendation for acupuncture, NHS would have been expected to withdraw all of acupuncture services soon. All of millions pounds investments to set up acupuncture clinic in NHS over last 16 years will be liquidated and wasted. That is not just all. If acupuncture could not be approved as effectively treated for NLBP, people in favour acupuncture would reduce a great confidence to alternative medicine. That is because to encourage people to take acupuncture is not just to relief pain or other illness, it is more important to encourage people looking alternative ways or DIY by efficiently using their own resources rather than from NHS.	Thank you for your comment. In updating and re-reviewing the evidence, the GDG do not believe there is sufficient evidence to maintain this recommendation and therefore no longer recommend acupuncture in an NHS setting. The GDG recognise the importance of encouraging self-management of low back pain and sciatica and have included a recommendation to highlight that information should be provided to help people self-manage their pain.
Yawye	Full	General	General	Used inadequate definition for acupuncture from GDG, it does not suggest GDG made everything wrong. In contrast, we have found that GDG team for acupuncture has made great efforts to be fair for public by collecting all of good studies into their analysis. Due to difficulty to read original paper and original cases notes[19], we only collect 25 full papers. We took particularly attention to look quality of acupuncture in each study. Like RCTS data quality control as Grade, we ask us: What is best way to enhance effective treatment from acupuncture? After a survey and collecting many academic research papers, we define there are 12 elements to influence quality of acupuncture treatment. We put 12 elements together as quality scoring too to test 30 RCTs[20]. We found 15 trials are reasonable with good quality on acupuncture treatment because they have allowed other interventions involvement. Among of them, there is 9 studies reached highest score(>8/12). The best case is from Dr Coan 1980 which included 50 cases. However, the original paper did not give detail. We looked the another paper. We understood that Dr Coan told us this study was collected completely by blinding methods[21]. All parties were not informed and all data were secreted collecting in the same clinic with 5 Chinese medicine doctors. In order to make secreted observation, he allowed doctors practiced intervention as usual at daily practice and patients would have no nocebo or placebo effect because he followed them for 52 weeks[22]. The score for Dr Coan study is 12/12. There is also another 7 studies with bad score quality of acupuncture. Among them, there are two studies : Brinkhaus 2006 and Haake 2007. Both of them have been frequently cited by many systematic reviews. But it is not surprised for us. The qualities of acupuncture intervention are poor because both of them were to try to find effect of acupuncture alone and restrict other interventions.	Thank you for your comment. The review protocol, including the inclusion criteria for the review was discussed and agreed with the GDG, including input from a co-opted acupuncturist as an expert for this question. Any queries regarding appropriateness of the intervention to the review protocol were checked with the GDG / co-optee as required.
Yawye	Full	General	General	In terms of the placebo effect, our experiences in clinic have also demonstrated there are serious nocebo and even more than placebo effects from acupuncture practices. GDG should take a balance between placebo and nocebo. Especially in populations have multiple choose for their healthcare. We have never seen anyone feeling happy immediately if you tell him to have needle inserted his body. There is great populations who do not want see the needle. They have treated using needle as last resources and if there is alternative way they would not take acupuncture again. For the above reasons, today people working in the acupuncture services have be very care to avoid any pain from needling. That is why dry needle or	Thank you for your comment. We are aware of, and have acknowledged the potential for placebo effects in acupuncture. However the GDG have taken the position that an intervention must produce important effects when compared to placebo control conditions. As such placebo effects alone were not considered sufficient to warrant a recommendation for acupuncture. Since the GDG have made a recommendation of "do not offer" for acupuncture, further discussion of specific issues related to the nature and delivery of appropriate acupuncture is not considered necessary in this guideline report.

[18] Madsen MV et al: Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. BMJ http://www.bmj.com/content/bmj/338/bmj.a3115.full.pdf
[19] We do not have any academic position in UK school. More than 70% papers required to pay £ 35 for each. To apply school library cards for public member is taken 3 weeks process. Even you pay for day rate, no one would allow you using web search paper. Fortunately Dr Wu is previous students in LSTHM and the school allowed him to assess part of database. Here, NICE should be advised to delivery those papers for free analysis in future.
[20] See comments NO 15
[21] Fan AY et al:Dr Ralph Coan: hero in establishing acupuncture as a profession in the United States. 2013 J integr Med 11(1):39-44
[22] It is common agreement that either nocebo or placebo effect cannot go beyond certain short period.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

<table>
<tr><th>Stakeholder</th><th>Document</th><th>Page No</th><th>Line No</th><th>Comments
Please insert each new comment in a new row</th><th>Developer’s response
Please respond to each comment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Japanese needling are very welcome and popular because they do not intend to cause de qi and make people feeling painful.</td><td></td></tr>
<tr><td>Yawye</td><td>Full</td><td>General</td><td>General</td><td>We notice that most of trial have made de qi as criteria for quality of acupuncture. We do not agree that. There are many good reason why de qi is good indicator for acupuncture working. From our own experiences, anything can cause our clients felt uncomfortable during the treatment or un-expectation, nocebo is happen and real treatment will be failed. For new patient, because they are very nervous and any incidence of pain by needling can cause uncomfortable feeling and effective of treatment will be reduced. For instance, for old patients, there could be: room was not quiet or warm, not same practitioner, not same instrument, not same locations, not same number of needling, or not same feeling reached. According above, today our practice not just ourselves but also many our colleagues have intended not cause any de qi and reducing number needling. In our clinic we have reduced number of needling to three or even only one if that is good enough to reach effective treatment. At the same time we have brought massage, cupping and other heating treatment to add more benefit. It is absolutely no case to the more needle the more effective. It is absolutely another direction. The more needle the more nocebo. Perhaps, we can easy find that nurse is most people unlike to needling to put into their body. It is same true that our patients with more needling they are more unlikely to take treatment unless they have to. In summary, we agree there are placebo effect from population but there are also nocebo effect in our population. Nocebo should be found especially in the population with multiple services, in the old people and in repeated treatment. Placebo should be found for young population, difficulty to have medical services and first time to have needling in their life. Again, GDG should be balance placebo and nocebo at the same time.</td><td>Thank you for your comment. The study inclusion was specified in the protocol which was agreed with the GDG and co-opted acupuncturist.
The inclusion criteria of the trials are stated in the evidence tables for information, but all were considered relevant to consider as part of this review. The effects of each intervention included in the studies are assessed according to the pre-specified outcomes in the protocol where both positive and negative outcomes were considered. The trade-offs between benefits and harms of each intervention is detailed in the ‘linking evidence to recommendation’ section of the review section 13.6.</td></tr>
<tr><td>Yawye</td><td>Full</td><td>General</td><td>General</td><td>When we start to look question what is most important effect to enhance acupuncture treatment, we received many different suggestions but most majorities of us have agreed that acupunctures are never used alone. Following 12 conditions have been considered by acupuncturists:
<table>
<tr><th></th><th>Factors for enhance acupuncture</th><th>Reasons</th></tr>
<tr><td>1</td><td>No Sham/No placebo needling</td><td>Educated clients just like a simple treatment only and not inserted any other purpose. As long as people told uncertainty in the treatment, nocebo can happen</td></tr>
<tr><td>2</td><td>population with acupuncture experience</td><td>It is true that return patients can always received longer term effective than new patients</td></tr>
<tr><td>3</td><td>Acupuncturist with outstand experience</td><td>That is everyone agreed condition for acupuncture. Since acupuncture just likes a music instrument, all of important effective is based on player to reach effective treatment.</td></tr>
<tr><td>4</td><td>Acupuncturist in daily practice</td><td>It is also true to play a nice music we need a nice concert hall. It is essential to have quiet room or comfortable services for practitioners to reach longer term effective. Of course, there is many showing demonstration in the public but professional acupuncturists think that is rare case.</td></tr>
<tr><td>5</td><td>Established manual by individual practitioners</td><td>It is also widely accepted that there is no better or worse method for acupuncturists. It is all depended on their own established skills. In China, central minister of health cannot set up a best procedure for</td></tr>
</table></td><td>Thank you for your comment. The review protocol, including the inclusion criteria for the review was discussed and agreed with the GDG, including input from a co-opted acupuncturist as an expert for this question.</td></tr>
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Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row			Developer's response Please respond to each comment
						acupuncture treating any single disease. However, it is always true that each practitioner has their own established skill	
				6	Individual points	There is no evidence that certain pattern acupoints are best for NLBP. Points from acupuncture text book are only giving an example, *Yaotong* but not criteria. Professional acupunctures can use only single needle to cure back pain.	
				7	no de qi required	It has gradually become acceptable concept that to account of *de qi* is not from when a needle is inserting in but it is from needle taking out at end of treatment. Therefore ,de qi is not cause of effective treatment but it is result of effective treatment. Most time it is impossible to have de qi if needle is inserted less than 1 cm depth. To require de qi can cause serious pain.	
				8	Session > 30 Minutes	It has already established to have long term effective, the needle must kept in the body for more than 30 minutes. No matter single or multiple. This is especially for needling in distance control out of pain area. Due to NLBP pain in Chinese medicine have several categories. For instance, for those patients holding high recurrence of NLBP in next few weeks by Chinese medicine, the effective treatment has to be included distance needling and session must have more than 40 minutes.	
				9	other treatment included: massage, cupping	It is essential that no professional acupuncturists use acupuncture alone. That is because acupuncture is only carrier to bring the treatment to the patients. Each individual practitioner has their own intervention to enhance acupuncture treatment. In the UK, it is very common to use heat lamp, hot stone, massage and herbs together.	
				10	Allowing communication during session	There are many types of way to perform acupuncture. One of types is called dynamic needling which is practitioners taken responses from his client and then decided next needle. In our practice, we have found it is essential to communicate with patient when it is needed. For instance, we have always spent 10 or 15 minutes to take pre-treatment communication in order to give indication what they should be expected and what they should not expected. There are statistic study comparison with acupuncturist with good communication and poor communication. There is no doubt that a good communication can enhance the treatment but bad one can cause nocebo. .	
				11	Advice given after session	All of TCM practitioners have been trained to treat patients for preventive as a top grade medicine doctor. All of our patients after acupuncture session, we have always given them different advice. For instance, 50% NLBP can be one off treatment[23]. After acupuncture session to relief pain immediately clients are able to do body movement exercise outside of clinic without visiting clinic again. It is clearly if no advice given after session, recurrence of pain will shortly happen	
				12	No intention to treat analysis	All of TCM practitioners have been trained that treated each patients should be wholeheartedly or single-minded without any second purpose or other purpose. For ourselves, we have published our paper to against any clinician to take two job: Doctor	

[23] We have a survey of the effective of NLBP by Chinese medicine or acupuncture. Most of answers is that almost 50% of NLBP with single location pain, can be one off treatment to stop pain completely or cure the problem if patients also followed advice after session. 25% of NLBP will need more than 3 sessions and another 15% will need 6 sessions. If 6 session is not cured the pain, it should not be case for NLBP. The latter case is rare to see.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and Scientist at the same time. That is un-ethics. It is true that if someone involved some standard procedure to favour research purpose, he has to ban his own skill which he knows that is best for people, but he will lose his confidence and to practice his skill as best performance.	
Yawye	Full	General	General	Carefully examined 30 cases, there are 13 studies with placebo or sham needle. There is another error that GDG has frequently treated placebo needle as sham needle. Clearly, that is not case. From our view or from international academic view, sham needle is not same as placebo needle. Sham needle can be used for looking nocebo treatment such by lower or inadequate treatments or hidden treatment by denied no treatment at all. For example Dr Coan has not had a sham acupuncture group but he has inadequate acupuncture group. That group has only taken one session of Acupuncture which is 10% dose of acupuncture. At end of following up(52 weeks) they had worse results than delay treatment group.	Thank you for your comment. The GDG recognise that there is controversy over the plausibility of sham acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those sham comparisons. This was the case for both penetrating and non-penetrating shams. Since non-penetrating shams did not demonstrate acupuncture to be clinically effective, the GDG were of the view that the sham comparisons included were essentially credible.
Yawye	Full	General	General	We have found as long as a sham or placebo control introduced into trial, acupuncturist will be restricted to perform as daily practice. Because they cannot communicate the people, they have to follow certain points to insert needle even they are allowed to add few individual needle. Furthermore, they are not allowed to give individual other intervention such as massage, cupping. For example, since Haake used sham needle partial blinding stopping communication with patient, excluding people who received acupuncture within one year , must make *de qi* experience et al, all of those additional requirement were used to enhance detecting placebo effect but at same time destroy the characters of real acupuncture arm. Therefore it is not surprised that effective from sham needle(inadequate needling) was almost equal another type of needling (he thought that is best one). That is exactly what Vickers points in his study 15 to 20% over a placebo," was not a real placebo, just a weaker version of acupuncture "	Thank you for your comment. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.
Yawye	Full	General	General	Guideline: *One cost–utility analysis found that acupuncture plus usual care was cost effective compared with usual care alone for treating low back pain (with or without sciatica) (ICER: £3,958 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations"* . We should believe that is correctly but should be added. The limitations are mainly resulted from optimal number of session at 10 which may not be case for generalised in whole. Prof Thomas study 2006[24] is good study because using our quality of acupuncture score her study had 8/12 which is satisfied for quality of acupuncture. Prof Thomas is also one of researchers who does not like to use Placebo or sham as control group and she insisted the practitioners must have Traditional Chinese medicine knowledge and her selected practice places were done in the daily practice. She did not completely exclude anyone who had acupuncture experiences. She intends to keep what it was more practical in the UK rather than to meet for study. However, one thing caused us difficulty to accept why they patients need to have a 10 session for three months treatment course? We expect a trade off of sessions for NLBP at a 6 session is best efficient to use. Our own experience in Luton is that 60% one off, 30% 3 sessions and 10% 6 or more sessions[25]. Average is less than 4 session for NLBP. Therefore total cost should be £459-4*£24=£336. Increment cost=£336-345=18. Overall the incremental cost effectiveness ratio for acupuncture in the treatment of low back	Thank you for your comment. More details about the quality assessment of this study are reported in the economic evidence profile table prior to the quoted economic evidence statement. The cost analysis reported in the study is based on the number of sessions that were actually provided in the study (which was up to 10 sessions, so not 10 on average) and therefore the cost and cost effectiveness analysis cannot be edited. In the LETR section relative to the acupuncture section we do acknowledge that number of sessions vary across RCTs.

[24] Thomas KJ, MacPherson H, Thorpe L, Brazier J, Fitter M, Campbell MJ et al. Randomised controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain. BMJ. 2006; 333(7569):623

[25] Our experiences from company Dr&HERBS Ltd in North of UK is slightly different that they have average about less than 5 session for NLBP. The differences between North and South of UK is mainly due to age population and type of NLBP. In south, we saw majority of NLBP with young labour people and the pain was normally located only one position. Because they are working people. They felt great psychological depress and worried too much to keep them as normal people or even to quite job. In contrast, people from North of UK were more retired people and they considered NLBP as life trouble with pain from different locations in their life but not threaten issue. It is clearly that majority of LNBP can be 6 weeks self- resolved. Only small proportion of NLBP might be taken longer. Therefore 6 session at 6 weeks is good option.

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				pain was positive with a mean of £667 at 24 months. Under £667, we assume that an implicit threshold of a maximum willingness to pay of £15,000 for a QALY which the probability of the cost per QALY can be over 95%[26].	
Yawye	Full	General	General	We have received many complaints about poor quality and wrong entries from GDG. After we have already decided not to look too much about those directions, we will go much detail to find errors but It will be worth to let GDG member to correct errors before the final published. And also it might be important to tell many Chinese medicine doctors who do not have much time or good command for English language to go through the guideline. We would like to give them some kind independent assessments. However, since NICE has not put any efforts to determine whether the sham acupuncture is real sham or might have hidden treatment or nocebo, any further cleaning entry error could not make any difference for the final result. For instance, GDG was too focusing placebo control that they excluded all of studies without placebo control for meta analysis. For another instance, we have discovered two serious errors: last two studies from Yun. One is from China army population which it is not good quality for included here because the soldiers could be very bias for any research study and no representatives for UK. The second one was done in Lebanon when Yun was peacekeepers but GDG treated as in China. Not just this, GDG treated Zaringhalam 2010 study done in Japan but it is in Tehran University of Medical Sciences (TUMS) in Iran, Again, those errors should not change the no significant differences between sham and real needle.	Thank you for your comment. We apologise for any inconvenience caused by the errors in the evidence review. All suggested errors have been checked, and amendments made where needed. The GDG has re-reviewed the updated evidence and agreed that the evidence was still conflicting for acupuncture. Therefore, no changes were made to the current recommendation. The GDG recognise that there is controversy over whether it is possible to effectively deliver an inert sham treatment. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. All RCTs in the English language were considered for inclusion in this review as (please see review protocol for inclusion criteria). Study details for Jun 2012A have been edited to state Lebanon instead of China as the country the study was carried out in. As you mention, the Zaringhalam 2010 study was carried out in Iran, which is what has been stated in the data extraction in appendix H.
Yawye	Full	General	General	Finally , we would like to answer the question: Can inadequate acupuncture treatment test placebo or decebo or hidden effect? Because if we can approve it can be done, GDG will have opportunity to have meta analysis from existing database. Our answer is yes. We advice GDG should collect all of RCTs studies regardless what kind of languages. Then from them GDG category quality of acupuncture for all RCTs such as our example using 12 factors. We assume the placebo effect should be equal in all category quality of acupuncture but gap between normal and acupuncture should become bigger and bigger as long as higher and higher quality of acupunctures applied for. If that is approved, except the top quality one, the rest of them should be treated as inadequate acupuncture treatments. The following figure show a good example to fit our above assumption.(both Witt and Molsberger studies were good quality but Brinkhause was not. Table 2 shows all of scores of 30 studies. The meta analysis is from Madsen [27]	Thank you for your comment. Unfortunately, we are unable to include studies which are not in the English language into our evidence reviews. This was stated a-priori in all review protocols which are available in appendix C.
Yawye	Full	General	495	There is also evidence that GDG has had only chance to check if there is inadequate acupuncture treatment or there is over dose of acupuncture treatment with 10 sessions. Here, in order to find out placebo effect GDG says: " *It was considered that if there is inadequate patient, therapist or outcome assessor blinding, there is a risk of studies demonstrating inflated effect sizes, particularly on subjective outcomes when the patient is not blinded to the treatment group. The GDG considered that blinding within the studies reviewed was not equally effective, and therefore this was taken into account when the quality of evidence was reviewed."* There is no evidence that GDG has had considered that because Prof Thomas cost analysis was serious limited and it is essential to take other studies to find further evidence. What have they made: "*The economic evaluation was judged to be partially applicable with potentially serious limitations. The latter was largely due to the fact that this analysis is based on only one of a*	Thank you for your comment. As we explained in the recommendations and link to evidence section, before considering the cost effectiveness of acupuncture compared to usual care, the GDG decided to ascertain if acupuncture has treatment-specific effects over and above the contextual or placebo effects, and the best comparator to prove this would be a placebo or sham. The GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not considered relevant. A new economic analysis was not prioritised in this area for the reason above. The study by Thomas et al (2005) did use EQ5D and was included in the economic literature review; the limitations of this study are reported in the economic evidence profile table in chapter 13.4.

[26] Detail calculation is not included
[27] Madsen MV et al: Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. BMJ http://www.bmj.com/content/bmj/338/bmj.a3115.full.pdf

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				number of RCTs that contribute to the evidence base for the clinical effectiveness of acupuncture " The most important question is that if GDG did not consider acupuncture doing any cost effective, the update of economic study for acupuncture is definitely essential to have one. We advice for that reason NICE should have study to evaluate cost effective and also look optimal trade off what number of session should be recommended. At the moment, there is no study to assess this issue. Furthermore, GDG did not consider Thomas study was good enough because there is no EQ5D. However, correct us, EQ5D was not initially question for GDG search outcome of trial. And no of acupuncture trial had EQ5D. There is some reason acupuncture trials do not test EQ5D[28] but Hopton study is coming from the same population of Thomas in York and with the same acupuncture clinic. GDG should realise that if Thomas used EQ5D there would be more benefit than only looking simple pain or physical function separately.	
Yawye	Full	General	496	Initially, we thought a real clinic trial for acupuncture needed. After reviewing all of available studies, except a cost effective study should be done, we partially agree NICE decision: *"The GDG considered that there was a substantial body of evidence relating to acupuncture in this review and that further research was unlikely to alter conclusions*." It is true not that not have more study with sham and under placebo, because there is useless since there is no real placebo or sham needle. There is no point spending money to carry out such kind of study any more. However, we advice GDG that a study for quality control for intervention by acupuncture is definitely necessary. We are no doing a study (time restrict), which we will like to see relationship between quality of acupuncture intervention and effective of treatment. We advice GDG should have same one to set up quality acupuncture score first and then re-do meta analysis. Furthermore, we consider that there is possible great opportunity to look hidden effect of sham or placebo acupuncture by using retrospective following up study. If we can demonstrate hidden effect from acupuncture, it is same important evidence to prove specific effect from acupuncture. So far, there are more than 3000 acupuncture trials, it should be able to have enough cases for detecting hidden effect.	Thank you for your comment. Unfortunately it is beyond the scope of the guideline to undertake research studies. The remit is to assess the best available published evidence to base recommendations on. The research recommendations made are based on the systematic reviews that are undertaken rather than exploratory research. However, further research you are undertaking may inform future updates of the guidance. It was agreed by the GDG when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Since a large number of RCTs have been included in the acupuncture review, retrospective non-randomised studies have not been included.
Yawye	Full	13	457	As early discussed, if NICE make U turn , it is not just affecting BCcA member or registered acupuncturists under NHS, it can also serious damage reputation of acupuncture in pain management services and brings serious confusing among all of patients who are currently under the treatment or who will like to take the treatment ? We have seen lots of media to give people impression acupuncture is useless and waste our money to look acupuncture so on and so on. The NICE proposed suggestion to U turn on acupuncture has been spread the whole of the world. . Clearly, public does not consider the NICE decision is only to the NHS and clearly the U turn is going affecting acupunctures treatment outside of NHS. We immediately felt that something was wrong and NICE should reconsider the decision carefully because it is not just simple to include or withdrawing a drug or a technique but it is going to have a wake up call which tells everyone born again and something has been done wrong in their mid-life. Is Britain ready for a mass u-turn? Is NHS ready to take all of acupuncture funs back to NHS? Is Britain ready to ban acupuncture? Is everyone in UK would like Prof Ernst	Thank you for your comment. As stated in the setting detailed in the scope, this guidance applies to all settings in which NHS care is received. We are unable to assess how it will impact on non-NHS settings as that is beyond the remit of NICE guidance.

[28] **Hopton H et al:** Acupuncture, counselling or usual care for depression and comorbid pain: secondary analysis of a randomised controlled trial: http://bmjopen.bmj.com/content/4/5/e004964.full

Low back pain and sciatica
Consultation on draft guideline - Stakeholder comments table
24 march 2016 – 10 may 2016

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and Emeritus Prof David Colquhoun to celebrate NICE U turn and to approve what they have considered acupunctures just as dishonest tricks [29]? All of those different views have caused us to put one question what wrong caused difficulty to detect significant effectiveness by international academic institutes.	
Yawye	Full	13.1	general	The draft states that "*In the UK, doctors, physiotherapists and manual therapists are increasingly using acupuncture on the basis of neurophysiological mechanisms, known as 'Western medical acupuncture'*." We agree that is true but it seems NICE has not considered real acupuncture from private sector such as Chinese medicine practitioners. To ignore them, perhaps that is because the previous recommendation is only considered for professional acupuncturists in terms of certainly acupuncture societies. We also understand that many of Chinese practitioners were not unhappy or do not bother why NHS will withdraw acupuncture from list of recommendations because that western acupuncture is irrelevant with them. They believe withdrawing will bring more clients from NHS. However, we realize that if U turn happened it would seriously impact not just western acupuncture in NHS and also the whole of acupuncture services in private patients since NICE does not make definition what type of acupuncture it is related and public have no capacity to different two types of acupuncture. From currently meta analysis, there are three studies from UK, except Thomas 2007 was done following Chinese medicine, rest of two did not and they are more like dry needle. However, rest of trials are majority based on Chinese medicine outside of UK. We are really confused that if GDG is looking for assessment of western acupunctures they should have taken more dry needle cases into their review.	Thank you for our comment. The acupuncture review was not restricted to western acupuncture and Chinese acupuncture was not excluded. All available RCTs in the English language were included if they met the inclusion criteria (see review protocol in Appendix C).
Yawye	Full	13.1	general	From technique point of view, Wikipedia has recently modified their definition for dry needling: "Acupuncture is a broad category of needling practices with solid filiform needles... Modern acupuncture notably includes both traditional and Western medical acupuncture; dry needling is arguably one subcategory of western medical acupuncture".[30] According above different definition of acupunctures, there is therefore a serious confusion from the Guideline. On one side NICE seems to consider to stop recommendation for western modern acupuncturist as dry needling for those doctors, medical staff used in NHS. On the other side, GDG reviewed 28[31] RCTs original paper and except Gunn 1980 was using dry needling, none of rest of studies used dry needling. In other words, the assessment of RCTs are made from acupuncture rather dry needling. We advice GDG should modify the definition from dry needle to acupuncture. We also advice that because GDG may misled themselves by using dry needling, this might result to wrong start points to evaluate rest part of selecting RCTs studies	Thank you for your comment. When setting the protocol, the GDG, included a co-opted acupuncturist, agreed that all forms of acupuncture would be included and pooled in the review. All RCTs were included if they were in the English language and met the inclusion criteria (please see review protocol in Appendix C).

[29] https://www.theguardian.com/science/2013/jul/26/acupuncture-sceptics-proof-effective-nhs?commentpage=1
[30] https://en.wikipedia.org/wiki/Dry_needling
[31] Several study papers we cannot collect from pubmed or medline.