

Low back pain and sciatica

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

| <p>Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.</p> <p>We would like to hear your views on these questions:</p> <ol style="list-style-type: none"> 1. Do any recommendations represent a substantial increase in costs, and do you consider that the reasons given in the guideline are sufficient to justify this? 2. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) <p>See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.</p> | | | | |
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| <p>Stakeholder organisation(s) (or your name if you are commenting as an individual):</p> | | <p>The Acupuncture Now Foundation - https://acupuncturenowfoundation.org/about-us/</p> <p>The Northern College of Acupuncture - http://chinese-medicine.co.uk/</p> | | |
| <p>Name of commentator (leave blank if you are commenting as an individual):</p> | | | | |
| Comment number | Document (full version 1, full version 2 short version or the appendices) | Page number Or 'general' for comments on the whole document | Line number Or 'general' for comments on the whole document | Comments |
| <p>Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.</p> | | | | |
| Example 1 | Full | 16 | 45 | We are concerned that this recommendation may imply that |
| Example 2 | Full | 16 | 45 | Question 1: This recommendation will be a challenging change in practice because |
| Example 3 | Full | 16 | 45 | Question 2: Our trust has had experience of implementing this approach and would be willing to submit its experiences to the NICE shared learning database. Contact..... |

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| 1 | Appendix B | p17 | Stephen Ward | <p>EVIDENCE OF CONFLICT OF INTEREST</p> <p>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.</p> <p>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.</p> <p>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.</p> |
| 2 | Appendices K-Q | p153 | Figure 667 | <p>DATA ERROR</p> <p>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.</p> |
| 3 | Appendices K-Q | p153 | Figure 668 | <p>DATA ERROR</p> <p>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.</p> |
| 4 | Appendices K-Q | p72 | Figure 266 | <p>DATA ERROR</p> |

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| | | | | There is an error in this forest plot. The SD for Kell in the biomechanical exercise group was 2.0, not .2 |
| 5 | Appendix H | p216-217 | Group Aerobics versus Usual Care | 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 means that the results in Appendix K, p76, Figure 282 are incorrect. Using the correct data, group aerobic exercise does not outperform usual care. |
| 6 | Appendices K-Q | p63 | Figure 228 | DATA ERROR/REPORTING ERROR Firstly, there is a data error in Goren 2010. 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. |
| 7 | Appendix K | p159 | 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. |
| 8 | Appendices K-Q | p155 | Figure 678 | REPORTING ERROR Figure 678 is mis-labelled - according to the original study, acupuncture outperformed sham in Function in the long-term. |
| 9 | Main draft | p299 | 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'. |
| 10 | Appendices K-Q | p60 | 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). |

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| | | | | Thus, the mean difference is -0.80 [-1.52, -0.07]. So the effect of exercise over sham is not clinically significant. |
| 11 | Appendix K-Q | P151-156 | | 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. |
| 12 | Appendices K-Q | p161-163 | | 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. |
| 13 | Main draft | p 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. |
| 14 | Main draft | p297 | 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. |
| 15 | Main draft | p493 | 13.6 Recommendations and links to | 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, |

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| | | | evidence; Trade-off between clinical benefits and harms. | 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. |
| 16 | Main draft | p571 | 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. |
| 17 | Main draft | p494 | 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 |

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| | | | | <p>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."</p> <p>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'.</p> <p>Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.</p> |
| 18 | Main draft | p196 | Lines 24-26 | <p>INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS</p> <p>"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."</p> <p>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 NICE's 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.</p> |
| 19 | Main draft | p199 | 8.6 Recommendations - Trade-off between benefits and harms | <p>INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS</p> <p>"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)."</p> <p>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-management fails the criteria applied to acupuncture.</p> <p>Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach.</p> |
| 20 | Main draft | p199 | 8.6 Recommendations - Trade-off between benefits | <p>INCONSISTENT APPLICATION OF CRITERIA TO DIFFERENT INTERVENTIONS</p> <p>"There was evidence that healthcare utilisation (consultation for back pain, hospitalisation, physician visits, physiotherapist visits) was reduced by the use of self-management programmes."</p> <p>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.</p> |

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| | | | and harms | Again, declared criteria have been applied inconsistently to different interventions, which suggests a biased approach. |
| 21 | Main draft | p349 | Line 11-13 | <p>ABSENCE OF PARITY BETWEEN DIFFERENT INTERVENTIONS</p> <p>"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.</p> <p>[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.]</p> |
| 22 | Main draft | p349 | lines 14-16 | <p>ABSENCE OF PARITY BETWEEN DIFFERENT INTERVENTIONS</p> <p>"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."</p> <p>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. <i>Complementary Therapies in Medicine</i> 12: 136-140.</p> |
| 23 | Main draft | p495 | Trade-off | <p>DETAILED COMMENT – SHAM ACUPUNCTURE IS NOT AN INERT PLACEBO CONTROL</p> <p>"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."</p> <p>This merits some deconstruction. First of all, the literature demonstrates that verum acupuncture <i>does</i> outperform sham acupuncture in the treatment of</p> |

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| | | | <p>pain where this comparison is done on a large enough scale to detect differences in effect size (Vickers <i>et al</i>, 2012). Next, it should be noted that this detected superiority is ‘relatively modest’ in size (Vickers <i>et al</i>, 2012, p. 1444) because the sham treatments involved are not inert.</p> <p>Furthermore, the GDG is correct to note that acupuncture comprises well-documented non-specific treatment effects (Paterson and Britten, 2001; Linde <i>et al</i>, 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.</p> <p>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 <i>et al</i>, 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 <i>et al</i>, 2009; Takakura <i>et al</i>, 2011).</p> <p>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 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 <i>et al</i> state that ‘...the additional no acupuncture waiting list control was included since minimal acupuncture might not be a physiologically inert placebo’ (Witt <i>et al</i>, 2005, p. 137).</p> <p>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 <i>et al</i>, 2008; Bei <i>et al</i>, 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.</p> <p>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.</p> <p>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 <i>et al</i>, 2012; MacPherson <i>et al</i>, 2013)</p> <p>Mike Cummings of the British Medical Acupuncture Society, who sat on the GDG meetings, has commented:</p> <p style="padding-left: 40px;">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</p> |
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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 Lundberg, 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 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.

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| | | | | <p>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]</p> <p>Paterson, C. and Britten, N. (2004) Acupuncture as a Complex Intervention: A Holistic Model. <i>The Journal of Alternative and Complementary Medicine</i> 10:5, 791-801.</p> <p>Streitberger, K. and Kleinheintz, J. (1998) Introducing a Placebo Needle into Acupuncture Research. <i>Lancet</i> 352:9125, 364-5.</p> <p>Takakura, N., Takayama, M., Kawase, A. and Yajima, H. (2011) Double Blinding with a new Placebo Needle: A Validation study on Participant Blinding. <i>Acupuncture in Medicine</i> 29:3, 203-7.</p> <p>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. <i>Archives of Physical Medicine and Rehabilitation</i> 90:12, 2141-2145.</p> <p>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. <i>Archives of Internal Medicine</i> 172:19, 1444-1453.</p> |
| 24 | Main draft | General comment | Benefit to harm | <p>DETAILED COMMENT - Ethics of Benefit to Harm Ratio</p> <p>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.</p> <p>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.</p> <p>With an emphasis on the ethics of safety, the strength of recommendations of different therapies should follow this order:</p> <ol style="list-style-type: none"> 1. Less harm and greater benefit 2. Less harm and equal benefit 3. Less harm and slightly less benefit |

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| | | | | <ol style="list-style-type: none"> 4. Equal harm and slightly greater benefit 5. Slightly more harm but significantly greater benefit <p>Therapies that would be the most unethical to recommend follow this order:</p> <ol style="list-style-type: none"> 1. Greater harm and less benefit 2. Greater harm and equal benefit 3. Equal harm and less benefit <p>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.</p> |
| 25 | Main draft | P 495 | Paragraph 2 | <p>DETAILED COMMENT - Safety/adverse events</p> <p>‘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 <i>et al</i>, 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).</p> <p>References: Hawkey, C.J. and Langman, M.J.S. (2003) Non-steroidal anti-inflammatory drugs: overall risks and management. <i>Gut</i> 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. <i>British Medical Journal</i> 323, 486-7. 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. <i>Journal of Rheumatology</i> 29, 804–812.</p> |

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- Spell out any abbreviations you use
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You can see any guidance that we have produced on topics related to this guideline by checking [NICE Pathways](#).

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

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