Title page

NICE should reconsider its recommendation to withdraw acupuncture from its 2016 guidelines on low back pain and sciatica

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Abstract

In 2009, NICE published guidance on its recommendations for low back pain and which, for the first time in the history of NICE, recommended that acupuncture be considered for episodes of non-specific low back pain. In March 2016, NICE released a draft of its updated guidance in which it states clearly that acupuncture should not be used for non-specific low back pain nor for sciatica. In this opinion piece, the author highlights inconsistencies in the process by which the guideline authors appear to have reached this decision and urges NICE to re-consider their recommendation to withdraw acupuncture from its 2016 guidelines on low back pain and sciatica.

NICE should reconsider its recommendation to withdraw acupuncture from its 2016 guidelines on low back pain and sciatica

In 2009, NICE published guidance on its recommendations for low back pain and, for the first time in the history of NICE, recommended that acupuncture be considered for episodes of non-specific low back pain (1). This March, NICE released a draft of their updated guidance within which NICE states clearly that acupuncture should not be used for non-specific low back pain nor for sciatica (2). In less than 8 years, how come the apparent U-turn?

Representatives from the British Medical Acupuncture Society have examined in closer detail the analysis by NICE (3, 4). They have highlighted a serious scientific error in the analysis and incorrect data was entered for a key meta-analysis that compares acupuncture against sham acupuncture for pain severity within 4 months. This error meant that a clinically significant difference was not shown between acupuncture and sham acupuncture. However, when the correct data was subsequently entered into the meta-analysis, this demonstrated that a clinical significance did indeed exist. The interested reader is directed to the response piece itself where further details can be found (3, 4). This error ultimately led to the panel withdrawing the recommendation for acupuncture and the panel must address this serious error prior to publication of its full guidance and, with this new information to hand, review the evidence on acupuncture once again.

Looking at the draft guidance in more detail, I wish to add to the debate my own questions and concerns.

Within the draft guidance, a change appears to have been introduced by this particular panel of experts in how they have considered comparisons between true acupuncture and sham treatment. The 2016 NICE panel stated that they:

> '*decided to ascertain if the intervention 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 (guideline development group) 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*' (page 495).

Whilst the comparison between true and sham treatment is in itself an interesting area to explore from a research perspective, evidence from placebo-controlled studies is increasingly recognised as being less relevant to patients, healthcare providers and commissioners (5). Contextual effects exist in all healthcare approaches including in conventional medicine. What's more important to the everyday patient, clinician and policymaker is whether a new treatment is better than what is already available in a real-world setting. These research questions typically use trials of a pragmatic nature, comparing real-world active treatments head-to-head such as acupuncture versus oral analgesics.

The requirement by this NICE panel for superiority to be demonstrated in placebo trials before considering cost-effectiveness appears to only have been specified for acupuncture and is not seen in any of the remaining treatments that were analysed in the guideline. Further to this, there was no formal a priori agreement that can be seen in the Methods section of the guideline that this requirement ought to be considered across all interventions considered for this guideline (2). In fact, when looking at the set of review questions that were decided upon pre-consultation, review question number 10 in the document states that the key question of importance was 'What is the clinical and cost-effectiveness of acupuncture in the management of non-specific low back pain and

sciatica?' (6). This means the focus of the acupuncture evidence review was never pre-specified to require efficacy to be proven above clinical effectiveness and before cost-effectiveness data should be taken into consideration. Likewise, in the pre-consultation economic plan, a specific note regarding the health economics analysis of another intervention - radiofrequency denervation – stated that 'studies assessed the change in pain score with the intervention compared to sham; however in the economic analysis usual care was considered to be the most appropriate comparison' (7). This suggests that evidence from pragmatic trials comparing a new treatment against usual care is clearly recognised as the most relevant for economic analysis and yet the cost-effectiveness data for acupuncture appears to be selectively dismissed and considered irrelevant by this panel.

These points strongly suggest that the decisions made by this panel to consider the evidence differently was made post hoc and then selectively applied to the evidence for acupuncture alone. Post hoc decisions are frequently made in research and I expect this to be no different in the development of guidelines such as these. However, what we are required to do as good scientists and as good researchers is to apply post hoc decisions systematically to our data, and to explicitly provide reasons as to why and how decisions have been made. This should be no different in guideline development. In the case of acupuncture, the panel appears to have disregarded the evidence presented on clinical effectiveness and placed undue emphasis on the evidence of efficacy. This is, at best, a serious error in this panel's judgment and a grave misunderstanding of which research approaches have real-life relevance to the everyday healthcare user and clinician and which approaches clearly do not.

The views by this panel regarding the evidence on acupuncture is further illuminated by the following comment within the draft guideline:

> *'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'* (page 496).

This is a deeply troubling conclusion for a number of reasons. Firstly, the recommendations made by this panel are completely at odds with those made by NICE's very own panel in 2009, indicating uncertainty in the interpretation of the present body of evidence. Secondly, this panel's interpretation of the data appears to conflict with an earlier systematic review on acupuncture for chronic pain led by Vickers et al. (8). Vickers et al. compared the effects of true and sham acupuncture for 4 chronic pain conditions by conducting an individual patient data meta-analysis, an approach considered to be the 'gold standard' of systematic review by the Cochrane group. This analysis suggested that significant differences between true and sham acupuncture existed and the authors recommended that acupuncture was a reasonable referral option for the treatment of chronic pain. Given the gold standard nature of this landmark study, it remains unclear why this panel failed to take into account the significance of these conclusions. Finally, the panel's recommendation to remove acupuncture from the guidelines is in complete contrast to the American College of Physicians and the American Pain Society. These groups published clinical practice guidelines specifically recommending that clinicians consider the addition of acupuncture to self-care options for patients with chronic or subacute low back pain (9). This recommendation had been made on the grounds of moderate-quality evidence and the full set of guidelines was further endorsed by the American Academy of Family Physicians. Collectively, these circumstances would have led a reasonable and balanced panel of researchers and clinicians to conclude that the evidence is far from clear cut and that further research would indeed be warranted.

One could accept that decisions made by the guideline experts remain subjective and that these decisions will obviously be based on the experiences and views of those selected for a panel. This subjectivity would lead to different panels of experts considering the same evidence and reaching different conclusions, especially where treatments are new or where evidence is emerging. Looking at the members of the two NICE panels, there is one clear difference that's apparent. The 2009 guideline was organised by the National Collaborating Centre for Primary Care (NCC-PC), consisting of a number of primary care professional associations and panel experts who understood the needs of the primary care profession (10). To my understanding, the 2016 panel appeared to consist of just 2 GPs from primary care whilst the remaining clinical members of the panel consisted of consultants and one consultant nurse, all of whom work in secondary care (2). Whilst I acknowledge that low back pain and sciatica are seen in general practice as well as in secondary care, 90% of all patient contact with the NHS takes place in general practice (11). GPs provide healthcare continuously within the community and are well-placed to understand the needs of a particular individual in the context of their own environment. Their everyday work is to relieve patient suffering in the most clinically effective and cost-effective way and without putting patients at additional risk. At the same time, they respect differences in individuals and recognise the need to weigh-up the pros and cons of different therapies to make an informed decision together with the patient. This consideration for patient choice alongside clinical evidence and safety was clear in the 2009 guideline. In contrast, the process by which the 2016 panel has come to its decision to drop acupuncture altogether from the guidelines suggests that this group of experts are out of touch with the reality of living with back pain, and of providing day-to-day front-line care for these patients.

Although the current evidence as considered by NICE may not be sufficient to recommend acupuncture alone nor as first-line treatment, for NICE to remove acupuncture as a treatment option entirely from its guidance means that patients and providers are certain to lose out on a treatment that is safe and which could offer cost-effective pain relief. This is especially important for patients who have not responded to conventional treatment options. Removing acupuncture from the guidance is a short-sighted move by NICE which restricts patient choice and practitioner autonomy, and a decision which shows that it has failed to put patients and healthcare providers at the heart of their work.

I urge NICE to correct the analytical errors already pointed out by representatives at the British Medical Acupuncture Society and to re-consider the evidence, taking into account the evidence for both clinical effectiveness and cost-effectiveness. NICE needs now to re-consider its recommendation prior to its final publication and which I sincerely hope will be aligned with the interests of the patients, healthcare professionals and caregivers that NICE ultimately serves.

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