



Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value

Response to Public Comments on Draft Evidence Report

October 4, 2017

Prepared for:



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#	Comment	Response/Integration
Julia C. Finkel, MD		
Children’s National Health System (Sheikh Zayed Institute for Pediatric Surgical Innovation)		
10	<p><u>Recommendation to recognize quantitative pain measurement in Final Report</u></p> <p>I recommend that the final ICER report specifically reference the importance of a comprehensive diagnostic process in managing patients with chronic low back and neck pain, and the value for clinicians to utilize all diagnostic methods, including particularly, quantitative technologies that can enhance pain assessment and pain treatment, using more evidence-based science.</p>	<p>Thank you for commenting on our draft report.</p> <p>No objective measures were used in the studies identified in our literature search. We look forward to future studies incorporating such objective measures.</p>
Acupuncture Now Foundation		
1	We respectfully submit that the draft report underestimates acupuncture’s clinical and cost effectiveness in managing chronic low back and neck pain and that a more comprehensive review of the evidence would support a significantly expanded role for acupuncture services in pain management.	Thank you for these comments.
2	In July of 2017, the ANF published a white paper: “Acupuncture in Pain Management: Strengths and Weaknesses of a Promising Non-Pharmacologic Therapy in the Age of the Opioid Epidemic”. We recommend those interested in acupuncture’s potential in managing pain to review this paper. It addresses issues relevant to the goals in ICER’s draft report.	We have reviewed the white paper. Thank you.
3	Firstly, we believe there are potential issues categorizing acupuncture along with the four other therapies in this report. Acupuncture is a clinical procedure delivered by state licensed and regulated health care providers and carried-out on patients for a limited number of treatments. The other four therapies are essentially self-help techniques taught with the expectation they will be practiced over long periods of time.	We agree that each of the five therapies that we reviewed have unique characteristics.
4	In real world practice, acupuncturists often give their patients “self-care” advice during and after the treatment process so that the patient might better build and maintain their progress. For example, acupuncturists may encourage their patients to practice tai chi and even offer classes in that exercise system or they may teach their patients to do acupressure on themselves. The controlled research studies ICER’s researchers used in their evaluation were of the type that did not allow the acupuncturists to carry-out any additional services often done in practice – no acupressure/massage, no heat therapy and no self-care advice. Neither did those studies allow the number and frequency of acupuncture treatments to be adjusted based	Clinical trials in general do not reflect real world practice, though several of the acupuncture trials that we reviewed studied acupuncture interventions that were not defined by protocol including the one that you cite later in your comments: Haake, et al, 2007 (“GERAC”). In that trial it is noteworthy that there were no significant differences between verum and sham acupuncture. As you note below the study of Cherkin et al has similar findings.

	<p>on the patient’s response as happens in actual clinical settings. These limitations in controlled trials vs real-world settings limit acupuncture’s effectiveness and give an underestimation of its true potential.</p>	
5	<p>Considering these shortcomings in acupuncture trial designs, it is especially helpful to review a recent study that tracked patients’ experience/satisfaction with acupuncture services they received in private practice. The study utilized the “Clinician & Group Consumer Assessment of Healthcare Providers and Systems” (CG-CAHPS®) survey developed by the Department of Health and Human Services’ Agency for Healthcare Research and Quality (AHRQ).</p> <p>These widely used “CAHPS” surveys were designed to provide a standardized tool to measure patients’ experiences with healthcare providers, health plans and health systems. They are administered by independent, accredited contractors, and the results are fed into a national database and compiled to help establish national benchmarks of patient satisfaction.</p>	<p>We are familiar with the CAHPS surveys.</p>
6	<p>This two-year retrospective study was published by American Specialty Health, a company that specializes in the development and management of managed care plans for non-pharmacological physical medicine services. The study reflected the experience of 89,000 acupuncture patients treated in 2014 and 2015 through a credentialed network of 6,000 U.S. acupuncturists. Low back and neck pain were the two most common conditions these patients presented. The survey found that acupuncture providers and their practices scored above national benchmark averages in an array of standardized questions regarding patient experiences with provider communication, office conditions, and staff helpfulness. Of particular interest to the issue of non-pharmacologic pain management was the inclusion of an additional proprietary question built into the survey. This question asked patients if their acupuncturist was successful in addressing their primary complaint. Of the patients in the national survey, 93% responded that they agreed or strongly agreed with that statement.</p>	<p>Thank you. Our primary concern with this study is selection bias. Patients who elect to pay out of pocket to be treated with acupuncture have an expectation of benefit from the therapy and may be more likely to report positive experiences and outcomes, in part because of the very strong placebo effect with acupuncture that has been repeatedly demonstrated in trials of verum acupuncture, sham acupuncture, and non-acupuncture controls. It would be interesting to use the same instrument in a study that randomized patients to acupuncture or to another of the interventions evaluated in our report.</p>
9	<p>Overlooked Studies</p> <p>There were important studies not included in the draft report that could have helped clarify acupuncture’s potential. One study strongly compliments the “key study” on chronic low back pain chosen by ICER’s researchers (Cherkin 2009). The missing study is the 2007 “German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups.” The GERAC trial involved medical doctors performing acupuncture in 340 outpatient practices, and included 1162 patients aged 18 to</p>	<p>The study was not overlooked. Please see the reference list of the Annals of Internal Medicine systematic review that formed the core of the report (Haake et al, 2007) and appendix D1 of our report that lists included trials. Note that the trial reports Von Korff and HFAQ scores, but no VAS pain measure, ODI, RMDQ or other measures that are more commonly reported in studies of chronic low back pain.</p>

	86 years with a history of chronic low back pain for a mean of 8 years.	
10	The Cherkin 2009 trial essentially followed-up on the 2007 GERAC trial and sought to investigate the same questions of how acupuncture compares to usual care in treating chronic low back pain. The GERAC trial is especially relevant to the goal of the ICER’s report to inform health industry decision makers. It was sponsored by the German health insurance industry to help them determine if they should pay for acupuncture in common pain conditions such as chronic low back pain. The researchers were surprised to find that acupuncture was twice as effective as conventional care for both pain and function. The 2009 Cherkin trial found the same thing – acupuncture was 1.5 times to 2 times more effective as conventional care.	We agree, but both trials found that verum acupuncture was not significantly better than sham acupuncture, suggesting that most, if not all of the benefit of acupuncture is through the placebo effect.
11	Like many acupuncture trials, the GERAC researchers included a sham/placebo control arm. Although the “real acupuncture” did not significantly outperform the sham control and despite the absence of a desire to find effective alternatives to opioids, the insurance companies decided to cover acupuncture for chronic low back pain because it was TWICE as effective as the conventional care they were already paying for.	As noted above, much of the benefit appears to be the placebo effect (engaging the mind to control perception of pain).
12	The GERAC researchers reached the following conclusions: “Acupuncture, regardless of the technique, was significantly more effective than conventional therapy at all follow-up points. To our knowledge, this is the first time superiority of acupuncture over conventional treatment has been unequivocally demonstrated for the primary and secondary outcomes, including medication reduction, in contrast to studies with a usual care group.” “The results for conventional therapy were significantly poorer than those in the 2 acupuncture groups. This raises questions about qualitative and quantitative aspects of conventional therapy.”	The conclusion applies to sham acupuncture which the authors describe in the methods section as “avoiding all known verum points or meridians.” Thus, one interpretation of the trial is that no training in acupuncture is required for a provider of needle therapy to achieve the benefits reported in the GERAC trial. Ten 30-minute sessions involving 14 to 20 needles inserted into the back and lower limbs is sufficient to obtain the benefits observed with traditional acupuncture.
13	The 2009 Cherkin trial found much the same thing: “At 8 weeks, mean dysfunction scores for the individualized, standardized, and simulated acupuncture groups improved by 4.4, 4.5, and 4.4 points, respectively, compared with 2.1 points for those receiving usual care (P < .001).	We agree.
14	Participants receiving real or simulated acupuncture were more likely than those receiving usual care to experience clinically meaningful improvements on the dysfunction scale (60% vs 39%; P < .001).	We agree.
15	Symptoms improved by 1.6 to 1.9 points in the treatment groups compared with 0.7 points in the usual care group (P < .001).	We agree.

<p>16</p>	<p>Are the Results Lasting?</p> <p>The ICER’s draft report placed special emphasis on investigating how long the benefits of the therapies under consideration lasted especially looking for studies with one year or more follow up. This is a laudable goal when reviewing therapies for chronic pain. But, here again, a major study on acupuncture that focused on this very issue was not considered in the report.</p> <p>“The persistence of the effects of acupuncture after a course of treatment: A meta-analysis of patients with chronic pain” (MacPhersen) was published in the October 2016 Journal “Pain”. This study found: “The central estimate suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months.” and further -“The effects of a course of acupuncture treatment for patients with chronic pain do not seem to decrease importantly over 12 months. Patients can generally be reassured that treatment effects persist. Studies of the cost-effectiveness of acupuncture should take our findings into account when considering the time horizon of acupuncture effects.”</p>	<p>Thank you. We believe the publication in question is MacPherson et al., Pain 2017, 158:784-793. We did not include this review because it includes a mix of pain conditions including osteoarthritis, shoulder pain, migraine, and tension-type headache in addition to neck and low back pain. There are no stratified analyses reporting just on chronic low back or neck pain.</p>
<p>17</p>	<p>The ICER Table 4.7. “Comparative Clinical Effectiveness for Mind-Body Interventions for Chronic Low Back Pain Added to Usual Care Versus Usual Care Alone Over the Long Term” rated acupuncture’s “Net Health Benefit” as “Small”. Considering we have presented two key studies finding acupuncture to be twice as effective as conventional care for chronic low back pain, an independent patient experience survey finding 85%-93% of patients reporting success addressing their primary complaint, and another study that found 90% of acupuncture’s benefits persists over one year’s time, we believe the evidence shows “significant” net health benefits.</p>	<p>We disagree, in part because of the lack of significant differences in function and pain between acupuncture and sham acupuncture and in part because other randomized trials have reported smaller effect sizes.</p>
<p>18</p>	<p>Cost Effectiveness</p> <p>The draft report table 6.5 (Cost Inputs) lists the cost per session of an acupuncture treatment at \$104 based on a single source (Zhang). This figure is on the upper end of what acupuncturists in the U.S. typically charge and average insurance reimbursements. \$50-\$70 would have been a more accurate figure and resulted in reducing the cost estimates of acupuncture by nearly half. We address this issue and other workforce considerations in our white paper in more detail.</p>	<p>Our threshold analysis indicates that for acupuncture to be cost-effective at \$50,000 per QALY, its per session cost would have to be \$64, given other estimates in the model. This cost falls in the range of \$50-\$70. Additionally, we have conducted one-way sensitivity analyses where we tested the results of incremental cost-effectiveness of acupuncture relative to usual care by varying the cost per session of acupuncture by 20% around its mean estimate used in the base case model. Across the range, incremental cost-effectiveness ratios for acupuncture still fall under the cost-effectiveness threshold</p>

		of \$150,000 per QALY, ranging from approximately \$69,000 per QALY to approximately \$111,000 per QALY. These results are available in section E of the appendix in the report.
19	<p>The U.K.'s "National Institute of Health Care Excellence" (NICE) sets a threshold for the cost of a QALY at £20,000 to £30,000. If a therapy can provide 1 QALY for less than £20,000 to £30,000, it is considered cost effective. In their 2016 draft report of their review of therapies for treating low back pain, they reported the following regarding acupuncture's cost effectiveness:</p> <p>"This within-trial analysis found that the addition of acupuncture to usual care increased costs and improved health (increased QALYs) with an incremental cost-effectiveness ratio of £3,598 per QALY gained. Uncertainty was not reported in the analysis using EQ-5D but in the analysis using SF-6D (which had a similar ICER) the probability of acupuncture being cost effective was around 97%". (page 495)</p>	We have added a comparison to the NICE Analysis in the Evidence Report.
20	<p>Conclusion</p> <p>Space limitations prevent us from addressing other issues of concern we had with the ICER's draft report including implications of real acupuncture vs. sham. We cover that topic in some detail in a blog post found on our website titled: "The Lack of Clinical Quality Guidelines Causes Underestimation of Efficacy in Sham Controlled Acupuncture Trials". We look forward to further dialog on these important issues and thank the ICER again for the opportunity to provide our input.</p>	Thank you. We look forward to additional input and dialogue during the public meeting.
American Academy of Pain Medicine		
1	<p>The major finding from this effort seems to be that we do not have enough information or quality research to draw meaningful conclusions regarding these integrative health approaches. Thus it is problematic to build economic models of these treatment approaches. Additionally, since the impact of many of these approaches are synergistic, it is artificial to look at each modality individually outside of the integrative health model where they are designed to complement patient care.</p>	<p>The primary conclusion was that there was moderate certainty of a small net health benefit for most of the therapies when used for chronic low back pain. Where the evidence was insufficient, we did not model economic outcomes.</p> <p>We agree that there is potential to use these therapies together and that their benefits may be additive or synergistic. We did not identify any randomized trials that tested this hypothesis.</p>
2	<p>The scope of this review focused on five Cognitive and Mind-Body therapies, and as such was quite narrow. There are recently published systematic reviews that demonstrate the efficacy of massage therapy for musculoskeletal pain, cancer pain, and post-surgical pain. If the scope had been expanded to include other integrative medicine treatment approaches,</p>	<p>Thank you. We agree that there are many other non-pharmacologic therapies that could have been considered. The AHRQ/ACP systematic review of non-pharmacologic therapies for back pain includes a much larger set of therapies</p>

	like massage therapy, more data would have been available for assessment.	and interested readers could look to that as a source of information.
3	The description on CBT is lacking. CBT does not equal pain-CBT. There should be clear distinction throughout the document. Pain-CBT includes pain education and specific pain management skills. It is not necessarily the same as CBT for depression or anxiety. There is an opportunity to provide clarity on this important point. CBT often reports on pain bothersomeness as the main outcome vs. pain intensity. This analysis does not use that outcome. The review of evidence is quite narrow for CBT. For instance, CBT has positive effects on depression, pain catastrophizing, and general psychological experience. This report offers a narrow view of its value, even in its overall generally positive assessment of the treatment modality. As such, looking at the bottom line may be most effective because it provides an index for medical service utilization.	In our description of CBT on page 13, we indicated that CBT can be adapted for different indications (initially depression, now many other indications including pain). We have added your suggestions at the end of this description of CBT.
4	This review may also be strengthened by using modern NIH PROMIS instruments to evaluate the biopsychosocial nature of the pain experience. Examples of this would be the Stanford University Choir program or the DoD PASTOR program.	We did not find PROMIS reported consistently in the studies reviewed. Multidisciplinary interventions were beyond the scope of this review.
5	Overall, within its scope and limitations this document is otherwise well-written. The questions are appropriate and fit the content of the manuscript. The draft voting questions seem reasonable and appropriate. There should be emphasis on the need for more high quality research of these treatments approaches in order to provide a more scientifically rigorous assessment of their benefit (or lack there-of).	Thank you. We expect this to be a topic of discussion and in the final report after the meeting we include policy recommendations including recommendations for further research. We will highlight your point in that section.
6	PG (2): Consider adding SNRI's to the list of pharmacologic therapies.	Thank you. We have added SNRIs to the list.
7	PG (6): This is a relatively arcane definition for modern acupuncture. We recommend a more inclusive definition of acupuncture that recognizes that interprets the phenomena achieved with placing needles in the body "according to current understanding of the body's structure and function." - An Introduction to Western Medical Acupuncture by White, Cummings, and Filshie.	We have added this description and cited White et al.
8	PG (14): We agree and support ACP's recommendations. This approach is consistent with the VA/DoD Stepped Care Model for Pain Management as well.	Thank you.
9	PG (22, Table 4.1): Greater than 2.0 improvement in pain intensity does not constitute a "Large/substantial" improvement. A 2.0 improvement is marginally larger than most accepted definitions of the minimal improvement necessary to be clinically significant. The definition of "slight / small" improvement in pain is lower than many accepted definitions of clinically significant improvement and could	As noted throughout the review, we adopted the approach and definitions used in the AHRQ review for the ACP. This Table summarizes their definitions for effect size. We have emphasized the source more clearly with a footnote to Table 4.1 with the reference.

	easily be considered as “no meaningful improvement”. Please consider rewording the top of each column.	
10	PG (39, 40): The comments regarding placebo effect should be reconsidered. Because every treatment in medicine has the potential for placebo effect, the dramatization of the potential for placebo effect applied only to acupuncture in the context of this review seems problematic. If commentary regarding placebo effects is desired, we recommend a more thorough discussion and review of the placebo response in general be provided in a separate paragraph. Important to this discussion would not to discount the benefit of a treatment because a placebo effect may be contributing, but to emphasize the overall impact and benefit (or lack of benefit) of the treatment taken as a whole (including risk and cost in the assessment).	We think that this is particularly relevant for acupuncture based on the data with sham controlled trials. We expect this to be an important topic of discussion at the meeting. NICE decided not to recommend acupuncture because the randomized trial evidence found no difference between acupuncture and sham acupuncture. More invasive interventions (internal mammary artery ligation, arthroscopic knee surgery) tend to have large effects on subjective outcomes (pain and function), but many of them are no different than sham therapy. The other interventions considered in our review are less invasive.
11	PG (44, Table 5.1): The sentence “On the Contrary...” This PP should be reworded as that it seems to be more of an opinion. Who is to say if adding yoga as a daily activity is “complex”? If the treatment is successful perhaps it lowers the complexity of multiple physician return visits and other tests, treatments, etc. This seems to be a subjective answer that may not reflect everyone’s opinion (unless there is a referenced study on patient perceptions of medical complexity).	We clarified our statement to indicate that the interventions do not reduce complexity. We agree that different individuals will interpret the relative importance of this in different ways.