

September 12, 2017

Institute for Clinical and Economic Review
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Comment on Draft Evidence Report on Cognitive and Mind-Body Therapies for Treatment of Chronic Low Back and Neck Pain – Importance of Using Effective Diagnostic Tools, including Quantitative Pain Measurement

Colleagues:

I am pleased to submit this comment on ICER's Draft Evidence Report on Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value (August 15, 2017) (Draft Evidence Report), prepared for the California Technology Assessment Forum. ICER is to be congratulated on its continued commitment to reviewing clinical and economic evidence about pain treatment. This is important in the analysis of cognitive and mind-body therapies for pain, but particularly in the context of the epidemic of opioid addiction which has become a national healthcare priority.¹

As a pediatric anesthesiologist and Director of Research and Development for Pain Medicine in The Sheikh Zayed Institute for Pediatric Surgical Innovation at Children's National Health System and Professor of Anesthesiology, Pediatrics and Critical Care Medicine at The George Washington University in Washington, DC, ICER's Report is important to, my clinical practice and research to advance pain management.

Summary:

1. Current measurement of pain is fundamentally subjective, intensity oriented and "mechanism agnostic" e.g., patient reported in response to long-standing pain measurement questions (i.e., Visual Analog Scale). An objective and quantitative pain measurement technology provides clinicians a better tool to assess pain type and pain intensity, and thus select the analgesic intervention most effective for the patient. Quantitative pain measurement also enables the clinician to monitor analgesic response and improve short and long term patient pain management.
2. The National Institutes of Health (NIH) has recently recognized quantitative pain management as an important adjunct in the diagnosis and management of patients with or at risk of opioid addiction. While the recent NIH initiative focuses on drug development and

- treatment, quantitative pain measurement tools are equally valuable to monitor non-pharmacological interventions such as cognitive and mind body pain therapies.
3. I recommend that the final ICER report recognize the importance of the diagnostic process in managing patients with chronic low back and neck pain, and the value for clinicians to utilize all diagnostic methods, including quantitative technologies which potentially change the landscape for pain assessment and pain treatment.

Detailed Comment

1. Need for Quantitative Pain Measurement Tools

Clinicians have historically used a wide array of patient reported diagnostic tools in the measurement and management of pain. The Draft Report identifies many of these tools, including: Radicular Pain; Visual Analog Scale (VAS) for Pain Intensity; Visual Analog Scale (VAS) for Pain Bothersomeness; Roland Morris Back Pain Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI); Neck Disability Index (NDI); Northwick Park Neck Pain Questionnaire (NPQ); etc. These tools are fundamentally subjective and qualitative, based on the patient’s reported condition. Significantly, the Draft Report states that, “There is no consensus on what change in the measures of pain and function is clinically meaningful....”ⁱⁱ

It is becoming increasingly clear for clinical specialists in pain management that an objective and quantitative pain measurement technology can offer a better tool to assess pain type and pain intensity, and thus select the cognitive, mind-body, or other therapeutic intervention most effective for the patient. Quantitative pain measurement also enables the clinician to monitor analgesic response and improve short and long term patient pain management.

2. National Institutes of Health Recognize the Need for Quantitative Pain Measurement

In 2017, as part of a scientific evidence-based effort to respond to the opioid epidemic, the NIH initiated a public-private partnership to address three major areas for advancement: (1) new and innovative medications and biologics to treat opioid addiction and for overdose prevention and reversal; (2) safe, effective, and non-addictive strategies to manage chronic pain; and (3) neurobiology of chronic pain.ⁱⁱⁱ

At its June 16, 2017 meeting, the NIH recommended the development of an action plan to, among other things:

- Initiate an effort to develop objective measures of pain (e.g. a “pain-meter(s)” grand challenge).^{iv}

More specifically, the NIH summary stated:

- There is a need for objective biomarkers for pain; the visual analog scale (VAS) is not sufficient; there is significant heterogeneity in patient responses on this scale
 - A diverse set of biomarkers is needed for research and clinical practice that reflect:
 - Analgesic target engagement (molecular and circuitry)
 - Functional impairment (e.g. sleep, activity level, quality of life)
 - Mobile health devices can be leveraged
 - Pain sensitivity
 - Severity of pain
 - Predicted and actual treatment response
 - Risk of developing chronic pain
 - Safety (e.g. abuse potential or risk for respiratory depression)
 - Predictors of patients who can discriminate pain and treatment response
 - Relevant biomarkers may vary based on pain condition and need to be validated for diverse modalities including MRI, PET, peripheral imaging, EEG, plasma markers, genotype, etc.

Clearly, quantitative pain management is an important for patients at risk of opioid addiction. Likewise, quantitative pain measurement tools are equally valuable to diagnose, treat, and monitor pain patients receiving non-pharmacological interventions such as cognitive and mind-body pain therapies.

3. Recommendation to recognize quantitative pain measurement in Final Report

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.

I very much appreciate this opportunity to provide input on the Draft Evidence Report and would be available to discuss my recommendation.

Kind regards,



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ⁱ The Draft Evidence Report recognizes this serious public health threat. https://icer-review.org/wp-content/uploads/2017/03/CTAF_Chronic_Pain_Draft_Evidence_Report_081517.pdf. See page 2.

ⁱⁱ The Draft Evidence Report. See page 7.

ⁱⁱⁱ <https://www.nih.gov/opioid-crisis>.

http://www.nejm.org/doi/full/10.1056/NEJMSr1706626?query=featured_home&#t=article

^{iv} <https://www.nih.gov/opioid-crisis/development-safe-effective-non-addictive-pain-treatments>



September 12, 2017

Institute for Clinical and Economic Review (ICER)

Submitted electronically

Re: Acupuncture Now Foundation's input to ICER's draft report: "Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value"

We are grateful for the opportunity to provide input to this timely report. The Acupuncture Now Foundation (ANF) is a U.S. based, international, non-profit organization dedicated to educating the public, healthcare providers, and health policymakers about the practice of acupuncture. We seek to work with mainstream healthcare providers and institutions as well as other complimentary/integrative disciplines in order to further understanding regarding the strengths and weaknesses of acupuncture as a healthcare resource. We applaud the efforts being made in this report to explore the clinical and cost-effectiveness of non-pharmacologic cognitive and mind-body therapies for managing pain. We encourage all interested parties to contact our organization for further information regarding acupuncture.

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.

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.

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.

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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 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.

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).

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.

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.

A subsection of this study looked at the responses of a number of patients that were referred to acupuncture providers by several pain management clinics in California. In order to be considered for referral, these patients were first seen by their primary care provider and then, if deemed needed, referred to pain management physicians. Many of these intractable pain patients had already been treated with multiple “conventional” therapies including opioids, other non-opioid drugs, and physical therapy before receiving treatment with acupuncture. In this subset of

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poor responders, 85% indicated their acupuncturist was successful in addressing their primary complaint. These figures are well above the 50% or so positive response rates found in many controlled acupuncture trials but better reflect real-world results.

Other highlights of this study include:

- 95%-99% of the patients rated their overall quality of care as good to excellent.
- 80%-87% patients rated their acupuncturists at a 9 or a 10 on a 1- to 10-point scale.
- 0.014% (13 out of 89,769) patients reported a minor adverse event and no serious adverse events were reported.

Overlooked Studies

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 86 years with a history of chronic low back pain for a mean of 8 years.

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.

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.

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 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 ($P < .001$).

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%; $P < .001$).

Symptoms improved by 1.6 to 1.9 points in the treatment groups compared with 0.7 points in the usual care group ($P < .001$).

Are the Results Lasting?

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.

“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.”

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.

Cost Effectiveness

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.

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:

"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)

Conclusion

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.

Matthew Bauer, L.Ac., President, The Acupuncture Now Foundation (501c3)

Resources:

ANF's - Acupuncture in Pain Management white paper:

<https://acupuncturenowfoundation.org/wp-content/uploads/2017/07/ANF-FDA-20170712.pdf>

AHRQ CG-CAHPS Acupuncture Experience Survey

<http://files.clickdimensions.com/ashcompaniescom-a70ce/files/acupunctureahps.pdf>

German Acupuncture Trials (GERAC) for chronic low back pain

<https://www.ncbi.nlm.nih.gov/pubmed/17893311>

The persistence of the effects of acupuncture after a course of treatment

<https://www.ncbi.nlm.nih.gov/pubmed/27764035>

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Re: ICER Draft Evidence Report on Cognitive and Mind-Body Therapies for Treatment of Chronic Low Back and Neck Pain

To whom it may concern,

The American Academy of Pain Medicine appreciates the opportunity to submit comments regarding the Institute for Clinical and Economic Review's (ICER) draft evidence review on Cognitive and Mind-Body Therapies for Treatment of Chronic Low Back and Neck Pain. We are the medical specialty society representing physicians practicing in the field of pain medicine. As a medical specialty society, the Academy is involved in education, training, advocacy and research in the specialty of pain medicine.

AAPM supports the Institute for Clinical and Economic Review's (ICER) efforts to review and evaluate the effectiveness and value of integrative medicine approaches to pain management. We thank you for the opportunity to provide this feedback and offer a constructive critique for your consideration.

General comments:

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.

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, like massage therapy, more data would have been available for assessment.

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.

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.

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).

Specific Comments:

PG (2): Consider adding SNRI's to the list of pharmacologic therapies.

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.

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.

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 easily be considered as "no meaningful improvement".

Please consider rewording the top of each column.

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).

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).

Sincerely,

American Academy of Pain Medicine