ICA
International
Chiropractors
Association

6400 Arlington Blvd.
Suite 800
Falls Church, VA 22042

(703) 528-5000
(703) 528-5023 FAX
www.chiropractic.org

Submission of the International Chiropractors Association

To

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Comparative Effectiveness Review
Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review

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Prepared by

Beth Clay, Director of Government Relations, ICA
and
Stephen P. Welsh, DC, FICA, Vice President, ICA

The International Chiropractors Association (ICA) appreciates the opportunity to respond to the Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review Draft entitled, “Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review”.

The ICA is the world's oldest, continually operating international chiropractic professional organization representing practitioners, students, chiropractic assistants, educators, and lay persons world-wide. The ICA was founded in 1926 in Davenport, Iowa by Dr. B. J. Palmer. We are dedicated to the growth and development of the chiropractic profession based on Dr. Palmer’s commitment to professional and clinical excellence and, the fundamental principle of chiropractic as a unique, separate, distinct, and drugless health care profession.

Chiropractic is a non-invasive, drugless form of health care that seeks to maximize the body’s capacity to heal itself by restoring the structural balance and integrity of the human spine and remove any interference to the vitally important nerves it houses. It is estimated that over one million chiropractic adjustments are provided every day around the world.

Our comments on this draft systematic review are not offered as if this report will function in a vacuum; rather we frame our review through the lens of the perspective of the effect of an AHRQ report of this scope may have across health care and insurance systems both in the public and private sector. The report specifically states that it is, “to provide evidence to inform guidelines and health policy”.

We ask several basic foundational questions which form a framework to address potentially fundamental flaws in the design of the analysis itself. Given these flaws, we are obligated to the chiropractic profession and the consumers globally who benefit from it to ask that these flaws be addressed fully and fairly.

Initial Observations

1. The title of the report does not accurately reflect the work product: Given the stated objective to assess the effectiveness of opioid alternatives, being clear and factual is imperative. “Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review” implies that all noninvasive and nonpharmacologic treatments for chronic pain are included in this analysis. Further, it suggests an analysis of the whole body of evidence has been conducted. Neither are factually accurate. In truth, chiropractic care has not actually been reviewed. One cannot with any credibility conduct a systematic review of five conditions with just eight studies.

2. All noninvasive, nonpharmacological treatments are not represented with equal vigor: A review of both the search strategy and the review methods confirm that chiropractic was never a specific search term, while other therapies were included as specific search terms. These include acupuncture, massage, mind-body therapies,

meditation, qi-gong, and yoga. As a result, the term chiropractic only appears once in the text of the report, on page 219. The term appears only in passing, not as part of the review. There are only 8 out of 884 papers listed as part of the appendix bibliography in which the word chiropractic appears in the title. The authors of this report have merged osteopathic and chiropractic research into one category as if there are no distinctions in the professions and practices. Chiropractic is a distinct profession that warrants equal inclusion, equal treatment, and equal mention.

3. Given the chronic pain crisis, the *a priori* determination to conduct a Cochrane style meta-analysis and include only specific clinical trials does not serve the best interest of the public. The current need is not simply to conduct an academic exercise evaluating the quality of certain previous research. The current chronic pain crisis warrants a comprehensive review of all types of evidence in order for the review to build a full picture of the evidence base on opioid alternatives rather than a narrow, one dimensional report that will do more to cloud inclusion and reimbursement rather than bring clarity to the issues. The limited number of chiropractic clinical trials, as well as the specific selection of trials included raises concerns. Our review of the chiropractic and spinal manipulation provisions of this report confirm that the report does not provide a full picture of the body of evidence confirming the benefit of chiropractic care. The detrimental effect of the handling of chiropractic care in this study may result in consumers opting for opioids, rather than finding recovering from pain through chiropractic care. Further it may harm access to insurance reimbursement or expansion of availability through federal health programs for veterans, the military and their dependents, and Medicare and Medicaid recipients.

4. There are numerous research reviews ongoing related to alternatives to opioids for pain management. It is unclear if these various government activities build upon each or not or have been created in stove pipes, devoid of cross agency communication. For example, is the AHRQ conduction of a meta-analysis supportive of the CMS patient centered care activities?

5. The design of the inquiry itself may be biased: Given the failure to search specifically for chiropractic, the limited number and specific selection of a handful of studies, and a rigid drug model style analysis, this report has inherent bias against chiropractic and likely other therapies.

The interventions included in the analysis:

- Exercise
- Psychological therapies
- Physical modalities
- Manual therapies
- Mindfulness practices
- Mind-body practices
- Acupuncture
- Functional restoration training
- Multidisciplinary/interdisciplinary rehabilitation

The key questions for adults covered the following conditions:

- Chronic low back pain
- Chronic neck pain
- Osteoarthritis-related pain
- Fibromyalgia
- Chronic tension headache

Our review of the report focuses on the specific statements and outcomes listed for spinal manipulation. (Given that there is no specific analysis conducted for chiropractic care.) At no point in this report do the authors suggest that a specific review of the chiropractic literature has been conducted. There is not even a specific mention of chiropractic in the Executive Summary.

In Key Messages Text Box, the following statement is included:

Exercise, acupuncture, multidisciplinary rehabilitation, mind-body and mindfulness practices, and psychological therapies such as cognitive-behavioral therapy may improve function or pain outcomes for specific chronic pain conditions.

Manual therapies in general and chiropractic care specifically are not included.

Page vii: Structured Abstract

Results. 205 publications (192 trials) were included in review…Chronic low back pain: Function improved slightly in the short term with massage, yoga, and psychological therapies (Strength of evidence [SOE]: Moderate) and with exercise, acupuncture, low-level laser therapy, mindfulness-based stress reduction (MSR), spinal manipulation, and multidisciplinary rehabilitation (SOE: Low), and psychological therapies (SOE: Moderate). …Improvements in pain persisted into the intermediate term for exercise, massage and yoga (moderate effect, SOE: Low)…as well as spinal manipulation…(small effects, SOE" Moderate)

No further reference to spinal manipulation for other conditions are mentioned in structured abstract.

Page ES-1: Evidence Summary

The section on non-pharmacological treatments for chronic pain includes: exercise and physical therapy, mind-body practices, psychological therapies, interdisciplinary rehabilitation, mindfulness practices, osteopathic and spinal manipulation, acupuncture, physical modalities, and acupuncture.

There is no mention of chiropractic care specifically.

Page ES-2 – Chiropractic not included in the specific strategies considered in the review:

The authors of this report exclude chiropractic from specific mention in detailing the types of therapies included in the review.

Individual pain management strategies considered in the review include exercise and physical therapy, mind-body practices (yoga, tai chi, qigong), psychological therapies (cognitive-behavioral therapy, biofeedback relaxation techniques, acceptance and commitment therapy), interdisciplinary rehabilitation, mindfulness practices (mediation, mindfulness-based stress reduction practices), osteopathic and spinal-manipulation, acupuncture, and physical modalities (traction, ultrasound, transcutaneous electrical nerve stimulation [TENS], low level laser therapy, interferential therapy, superficial heat or cold bracing for knee, back, or neck, electro-muscular stimulation and magnets), acupuncture, and functional restoration training.

It is inconceivable to conclude that a true comprehensive review of more than 20 therapies for multiple conditions can be achieved when less than 200 studies were included total. For Spinal Manipulation, only eight studies were included.

Page ES-7: Manual Therapies for Low Back Pain

- Spinal manipulation was associated with slightly greater effects than sham manipulation, usual care, and attention control, or placebo interventions in short-term function (3 trials, pooled)…and intermediate-term function (3 trials, pooled)…
- There was no difference between spinal manipulation versus sham manipulation, usual care, and attention control or a placebo intervention in short-term pain (3 trials, pooled…) but manipulation was associated with slighter greater effects than controls on intermediate-term pain (3 trials, pooled)…(SOE: low for short-term, moderate for intermediate term).

If the true objective of this report was to provide a true analysis of the evidence related to spinal manipulation, a pooling of just three studies is not sufficient. The National Center for Complementary and Integrative Health at the National Institutes of Health provides an information page online describing spinal manipulation that provides more than the eight studies, including the prior report from AHRQ. (https://nccih.nih.gov/health/pain/spinemanipulation.htm)

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ES-9: Comparative Effectiveness of Interventions for Chronic Low Back Pain

- There were no differences between spinal manipulation versus exercise in short-term function (3 trials, pooled….) or intermediate-term function (4 trials, pooled….) (SOE: Low)
- There were no differences between spinal manipulation versus exercise in short-term (3 trials, pooled…) or intermediate-term pain (4 trials, pooled…) (SOE: Low).

ES-15: Key Question 5: Chronic Tension Headache

Spinal manipulation therapy was associated with small to moderate improvements respectively, in function compared with usual care….and with moderate improvements pain intensity…over the short term (SOE: Low) Approximately a quarter of the patients had comorbid migraine.

ES-23: Findings in Relationship to What is Already Known

Consistent with the prior review, small to moderate effects of exercise, yoga,…..spinal manipulation…were identified. This review suggests that most effects are at short or intermediate-term followup: long-term data are sparse.

ES-24: Implications for Policy and Decision Making

Our review provides evidence that an array of nonpharmacological treatments provide small to moderate improvements in function and pain that are durable for more than 1 month for the five conditions addressed in this review….The evidence synthesized in this review may help inform guidelines and healthcare policy (including reimbursement policy) related to the use of noninvasive, nonpharmacological treatments as alternatives to opioids….and inform policy decisions regarding funding priorities for future research….Importantly, some interventions such as exercise…and some complementary and integrative medicine therapies such as acupuncture and spinal manipulation were associated with some sustained effects on function. At the same time, there was no evidence suggesting serious harms…

As the report acknowledges, this report is likely to have significant policy implications. The ICA is greatly concerned that this limited review of existing data on spinal manipulation in general and absent analysis of chiropractic care specifically will bring a chilling effect to the efforts of the ICA and others to advance the profession, improve access for consumers and improve reimbursement for providers.

Page 57: Detailed Synthesis of Spinal Manipulation for Low Back Pain

A total of eight studies were considered for this review, six reported as of fair quality and two of poor quality.

Page 245: Manual Therapies for Chronic Tension Headache

Just two trials for spinal manipulation were included in this synthesis. One of these was considered of poor quality.

Page 247: Manual Therapies Compared with Pharmacological Therapy

The summary notes that a single poor-quality trial was reviewed, providing insufficient evidence to determine effect of spinal manipulation compared with amitriptyline over the short term.

Summary of Concerns and Recommendations

From the title page throughout the report, it is obvious that the (as yet, unnamed) authors have either consciously chosen to ignore the diversity of professions within the complementary and integrative health community; or have chosen to ignore the chiropractic profession specifically.

With so few studies included, both for the overall review but specifically for spinal manipulation, one must consider if the problem is the availability of scientific data, or if the real problem is with the study design and implementation?

Policy makers and the public are likely better served by a comprehensive review of existing data, both clinical trials, other research styles, and data from real world datasets such as workman's compensation data in states where these exist.

It is important to acknowledge that when designing and evaluating research in nonpharmacologic approaches, trying to retrofit the drug study model into this nonpharmacologic frame is not going to provide the most accurate or useful information. It would appear the authors have attempted to utilize a drug study model to evaluate over 20 non-drug approaches. Doing so, short changes these therapies but also those who are likely to turn to this report as a conclusion of what the policy maker and general public will assume has been a fair and comprehensive analysis.

If the study designs of the existing body of clinical trials are of poor or fair quality, there is an urgent need to address research design quality issues going forward and to stipulate an urgency with federal research agencies in funding well designed, useful studies that can address the management of pain in real world situations.

The ICA requests a meeting with AHRQ to discuss the lack of inclusion of chiropractic in this report, to discuss the existing whole body of evidence on the benefits, and cost saving potential of chiropractic care for the treatment of the five conditions noted in this report.

The ICA actively engages in collaborations domestically and internationally to promote the field of chiropractic, advance research, access, and appropriate regulations and compensation. The ICA is also actively engaged in advancing the broader field of integrative health care; plays a leadership role in the Integrative Health Policy Consortium; and engages in educating policy makers about the value of non-drug options for care for pain management.

The doctor of chiropractic as the primary care provider resulted in a 52 percent reduction in pharmaceutical costs, 43 percent decrease in hospital admissions, and 43 percent fewer outpatient surgeries and procedures. This was the finding in a four-year study begun in 1999 of doctors of chiropractic in a primary care role in a large Chicago HMO. (Sarnat RL, Winterstein J. Clinical and cost outcomes of an integrative medicine IPA. Journal of manipulative and physiological therapeutics. 2004;27(5):336-47. doi: 10.1016/j.jmpt.2004.04.007. PubMed PMID: 15195041.)

There are dozens of other studies that support the safety, benefit, and value of chiropractic care. Upon request, ICA will provide a bibliography of relevant research.