

January 12, 2016

**FROM: Joint Acupuncture Opioid Task Force, Acupuncture Now Foundation and the American Society of Acupuncturists**

**TO: Centers for Disease Control**

**RE: Federal Register Notice: Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain Docket CDC-2015-0112**

The Joint Acupuncture Opioid Task Force thanks the CDC for soliciting public input for consideration in the development of the “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016.”

Our task force is comprised of experts in the field of acupuncture including a national membership organization, an international non-profit educational foundation, and concerned authorities. We seek to provide the CDC with research findings to help improve the quality of information currently found in the draft of this guideline, specifically the sections dedicated to “Contextual Evidence Review” of “non-pharmacologic alternatives.”

Research is showing that acupuncture can effectively stimulate the production of the body’s own “endogenous opioids” as well as natural anti-inflammatory compounds [34,35,38]. In other words, acupuncture can facilitate the better usage of the body’s own natural chemistry creating the potential for similar or sometimes better benefits than synthetic drugs, without the risks of addiction or side effects. This being the case, acupuncture has the potential to reduce or even in some cases eliminate the need for opioids and non-opioid drugs while also helping to treat opioid addiction [42,43,44,45].

Before detailing the relevant research, we want to acknowledge three important statements contained within the current guideline draft as they relate to the contextual evidence review. First, that the guideline is not meant to “provide detailed recommendations on the use of non-pharmacologic and non-opioid pharmacologic treatments for chronic pain.” Second, that you recognize that, “reviewing the effectiveness of such strategies as alternatives to opioid therapy provides important contextual information to providers considering opioid therapy and available options for their patients.” And third, that due to time constraints, “a rapid review was required for the contextual evidence review for the current guideline.”

We strongly believe that the CDC is undervaluing the best chance we have as a nation to address this crisis: non-pharmacologic alternatives. Our healthcare system has become overly dependent on the use of drugs as the primary means of addressing health issues including chronic pain. While it is useful to refine guidelines on how these drugs are prescribed, we feel it would be fruitful and to the public benefit for policymakers to consider the significant potential of non-drug alternatives. Of these, acupuncture is a highly promising and increasingly researched tool.

The tendency to rely on pharmacologic rather than non-pharmacologic approaches is in part influenced by the disparity in the financial interests promoting them. In light of this, support from philanthropic and governmental sources is needed to work with experts in non-pharmacologic alternatives to investigate and develop their potential. We ask the CDC to

seek the input of such authorities in the development of guidelines for the use of non-pharmacologic therapies, and not leave this important topic to solely a rapid review of contextual evidence within a drug prescribing guideline.

While acupuncture has consistently been found to provide significant improvements in common, chronic pain conditions, a frequent criticism is that “real” (verum) acupuncture often does not statistically outperform the sham control. This criticism has been debunked in a landmark meta-analysis undertaken to reduce some of the common disparities found in acupuncture trial reporting standards [1]. This study found that when key reporting data were standardized, verum acupuncture outperformed sham.

Critics fixated on how much of acupuncture’s clinical benefits may be due to placebo effects are overlooking perhaps the most important point: the risk to benefit ratio of acupuncture for common chronic pain conditions is clearly superior to opioid medications and often better than other non-opioid therapies, regardless of mechanism. A very recent systematic review and network meta-analyses of 21 different interventions for sciatica found that acupuncture produced better outcomes for global effect and pain reduction than all other therapies except a Cytokine-modulating procedure still in experimental stages [5].

Considering the magnitude of the opioid crisis, non-opioid alternative approaches to the management of chronic pain that are shown to be safer, while of equal or superior clinical effectiveness to opioids, should not merely be categorized as a “possible option”. The research presented below demonstrates these positions and we urge policy makers to carefully consider this information and contact us with and questions.

Sincerely,

The Joint Acupuncture Opioid Task Force

Member organizations:

The Acupuncture Now Foundation

[www.AcupunctureNowFoundation.org](http://www.AcupunctureNowFoundation.org)

The American Society of Acupuncturists

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**Research Findings on Acupuncture**  
**Compiled by The Joint Acupuncture Opioid Task Force**

**1. Acupuncture is an effective, safe, and cost-effective treatment for various types of pain. Acupuncture should be recommended for the treatment of pain before opiates are prescribed.**

**1.1 Effectiveness/efficacy of acupuncture for different types of pain**

There is growing research evidence to support the effectiveness and efficacy of acupuncture for the relief of pain, especially chronic pain (See Table 1). Acupuncture has been shown to be effective for treating various types of pain with the strongest evidence around **back pain, neck pain, shoulder pain, chronic headache, and osteoarthritis** [1]. In an individual patient meta-analysis of 17,922 people from 29 randomized controlled trials (RCTs), it was concluded that the effect sizes in comparison to no acupuncture controls were 0.55 SD (95% CI, 0.51-0.58) for back and neck pain, 0.57 SD (95% CI, 0.50-0.64) for osteoarthritis and 0.42 SD (95% CI, 0.37-0.46) for chronic headache (1). No meta-analysis was performed on shoulder pain as there were only three eligible RCTs. In all analyses true acupuncture was significantly superior to no acupuncture and sham acupuncture controls ( $p < 0.001$ ) [1].

In the largest study of its kind conducted to date, 454,920 patients were treated with acupuncture for headache, low back pain, and/or osteoarthritis in an open pragmatic trial. Effectiveness was rated by the 8,727 treating physicians as marked or moderate in 76% of cases [2].

In a network meta-analysis comparing different physical therapies for pain in knee osteoarthritis, acupuncture was found to be superior to sham acupuncture, muscle-strengthening exercise, Tai Chi, weight loss, standard care, and aerobic exercise (in ranked order) Acupuncture was found to be statistically significantly better than muscle-strengthening exercise (standardised mean difference: 0.49, 95% credible interval 0.00-0.98) [3].

A systematic review and meta-analysis on acupuncture for **sciatica** concluded that acupuncture was superior to standard pharmaceutical care (such as ibuprofen, diclofenac, and prednisone) in reducing pain intensity (MD  $-1.25$ , 95% CI:  $-1.63$  to  $-0.86$ ), and pain threshold (MD:  $1.08$ , 95% CI:  $0.98$ – $1.17$ ), however some of the included studies had a high risk of bias [4].

A systematic review and network meta-analyses of 21 different interventions for sciatica found that acupuncture was second in global effect only to biological agents, and superior to all other interventions including non-opioid medications and opioid medications [5].

A systematic review on acupuncture and moxibustion for **lateral elbow pain** found that acupuncture and moxibustion were superior or equal to standard care, however again most of the included studies had a high risk of bias in at least one domain [6].

A systematic review on acupuncture for **plantar heel pain** found that evidence supporting the effectiveness of acupuncture was comparable to the evidence available for standard care interventions, such as stretching, night splints or dexamethasone [7].

The use of acupuncture to relieve **pain associated with surgical procedures** captured the world's attention when journalist James Reston (who was accompanying President Richard Nixon on a trip to China) underwent an appendectomy using acupuncture analgesia. Since then, acupuncture has been used before, during and after surgery to manage pain and to improve post-surgical recovery in a variety of contexts [8-16]. It is noteworthy that acupuncture has been reported to be effective in pain relief during and after surgical procedures on children and animals [10, 16-18].

A Cochrane systematic review on acupuncture or acupressure for **primary dysmenorrhea** found that both acupuncture and acupressure were more effective in reducing pain than placebo controls [19]. Five other systematic reviews and/or meta-analyses on various forms of acupoint stimulation including acupuncture, acupressure and moxibustion for primary dysmenorrhea have reported similar outcomes [20-24].

The effectiveness of acupuncture for **labor pain** is still unclear, largely due to the heterogeneity of designs and methods in studies which have produced mixed results, with some studies reporting reduction of pain during labor, reduced use of opioid medications and epidural analgesia and a shorter second stage of labor, while other studies reported no reduction in analgesic medications [25-27].

A systematic review on acupuncture for **trigeminal neuralgia** suggests that acupuncture may be equal or superior to carbamazepine, but the evidence is weakened by the low methodological quality of some included studies [28].

A Cochrane systematic review on acupuncture for **fibromyalgia** found low to moderate-level evidence that acupuncture improves pain and stiffness compared with no treatment and standard therapy. Furthermore, electroacupuncture is probably better than manual acupuncture for pain in fibromyalgia [29].

## **1.2 Safety of acupuncture for pain management**

The strongest evidence for the safety of acupuncture in chronic pain management comes from an open pragmatic trial involving 454,920 patients who were treated for headache, low back pain and/or osteoarthritis. Minor adverse events were reported in 7.9% of patients while only 0.003% (13 patients) experienced severe adverse events. Minor adverse events included needling pain, hematoma and bleeding, while serious adverse events included pneumothorax, acute hyper- or hypotensive crisis, erysipelas, asthma attack and aggravation of suicidal thoughts [2].

## **1.3 Cost-effectiveness of acupuncture for pain management**

In a systematic review of 8 cost-utility and cost-effectiveness studies of acupuncture for chronic pain the cost per quality adjusted life year (QALY) gained was below the thresholds used by the UK National Institute for Health and Clinical Excellence for "willingness to pay". The chronic pain conditions included in the systematic review included low back pain, neck pain, dysmenorrhoea, migraine and headache, and osteoarthritis [30].

#### **1.4 Can adjunctive acupuncture treatment reduce the use of opioid-like medications?**

Some studies have reported reduced consumption of opioid-like medication (OLM) by more than 60% following surgery when acupuncture is used [31, 32]. A pilot RCT also showed a reduction of 39% in OLM use in non-malignant pain after acupuncture, an effect which lasted less than 8 weeks after acupuncture treatment ceased [33].

### **2. Acupuncture analgesic mechanisms have been extensively researched and include the production and release of endogenous opioids**

Mechanisms underlying acupuncture analgesia have been extensively researched for over 60 years. In animal models acupuncture and/or electroacupuncture has been shown to be effective for the alleviation of inflammatory, neuropathic, cancer, and visceral pain. Ascending neural pathways involving A $\delta$  and C sensory fibres have been mapped, the mesolimbic loop of analgesia in the brain and brain stem has been identified and descending pathways have also been mapped. Numerous mediators have been identified including opioid and non-opioid neuropeptides, serotonin, norepinephrine, dopamine, cytokines, glutamate, nitric oxide and gamma-amino-butyric-acid (GABA). Acupuncture analgesia has been shown to involve several classes of opioid neuropeptides including enkephalins, endorphins, dynorphins, endomorphins and nociceptin (also known as Orphanin FQ). Among the non-opioid neuropeptides, substance P (SP), vaso-active intestinal peptide (VIP) and calcitonin gene-related peptide (CGRP) have been investigated for their roles in both the analgesic and anti-inflammatory effects of acupuncture [34-38].

Given that acupuncture analgesia activates the production and release of endogenous opioids and activates  $\mu$  and  $\delta$  opioid receptors, it is feasible that acupuncture, used in conjunction with OLM, might alleviate pain with a lower OLM dose for patients already taking OLM [34]. For patients not yet prescribed OLM, acupuncture should be recommended prior to OLM prescription commencing. This would be in line with exiting guidelines which recommend non-opiate alternatives which are safe and effective should first be exhausted before resorting to OLM.

### **3. Acupuncture is effective for the treatment of chronic pain involving adverse neuroplasticity**

Adverse neuroplasticity can present a challenge in pain management as neuroplastic changes can be associated with chronic severe pain which is resistant to treatment. There is evidence that acupuncture has the capacity to reverse adverse neuroplastic changes in the spinal dorsal horn as well as in the somatosensory cortex in chronic pain [39-41]. This suggests that acupuncture may have an important role in treating chronic pain which involves adverse neuroplastic changes.

#### 4. Acupuncture is a useful adjunctive therapy in opiate dependency and rehabilitation

In 1973 Drs Wen and Cheung from Hong Kong published an accidental finding that ear acupuncture treatment for respiratory patients had apparently alleviated opioid withdrawal signs and symptoms [42]. These findings were replicated by others around the world including in New York and Sydney in the mid-1970s. In 1985 Dr Michael Smith and colleagues in New York went on to establish the National Acupuncture Detoxification Association (NADA) which today operates in over 40 countries with an estimated 25,000 providers [43]. In a recent RCT, in 28 newborns with Neonatal Abstinence Syndrome, laser acupuncture plus OLM significantly reduced the duration of oral morphine therapy when compared to OLM alone [44]. The mechanism for acupuncture in opiate withdrawal was found to be mediated by the endogenous opioid dynorphin binding to  $\mu$  opioid receptors [45].

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**Table 1. Effectiveness and harms of acupuncture**

Author, Year	Topic/Intervention	Participants/Population	Primary Outcomes	Key Findings	Study Quality
Vickers et al, 2012	Acupuncture versus sham acupuncture and no acupuncture in back, neck, shoulder pain; chronic headache, osteoarthritis	Systematic review of 31 randomized controlled trials (17,922 subjects) and meta-analysis of individual patient data from 29 of these 31 RCTs in back, neck, shoulder pain; chronic headache, osteoarthritis	A variety of pain severity and disability scores such as VAS, WOMAC, Roland Morris Disability Questionnaire	Acupuncture was superior to sham acupuncture and no acupuncture for each pain condition	High quality evidence
Weidenhammer et al, 2007	Acupuncture for headache, low back pain, osteoarthritis	Open pragmatic trial of 454,920 subjects with headache, low back pain, osteoarthritis	Treating physician rating of “marked, moderate, minimal or poor improvement (which included no improvement and worse)”	Physician ratings: 22% marked, 54% moderate, 16% minimal and 4% poor improvement	Low quality evidence - Open pragmatic trial with no blinding and no external assessors
Corbett et al, 2013	Comparison of 22 physical therapies for knee osteoarthritis pain	Review of 152 trials and network meta-analysis of 12 randomized controlled trials with low risk of bias comparing 22 physical therapies in knee osteoarthritis pain	Knee pain	Acupuncture was equal to balneotherapy and superior to sham acupuncture, muscle-strengthening exercise, Tai Chi, weight loss, standard care and aerobic exercise (in ranked order)	110 of 152 studies analysed were of poor quality. Network meta-analysis included 12 RCTs with low risk of bias.
Ji et al, 2015	Acupuncture versus standard pharmaceutical care in sciatica	Systematic review and meta-analysis of 12 randomized controlled trials in sciatica	Effectiveness, pain intensity, pain threshold	Acupuncture was superior to standard pharmaceutical care in effectiveness, reducing pain intensity and pain threshold	Low to moderate quality evidence
Lewis et al, 2015	Comparison of 21 different interventions for sciatica	Systematic review and network meta-analyses of 122 studies including 90 randomized or quasi-randomized controlled trials comparing 21 different interventions for sciatica	Global effect, pain intensity	In global effect and reduction in pain intensity, acupuncture was second only to biological agents (cytokine modulating drugs), and superior to all other interventions tested including non-opioid and opioid medications	9% of studies had a strong overall quality rating; 7% of studies had a strong overall external validity rating; 21% of studies used both adequate randomization and adequate or partially adequate allocation concealment
Gadua et al, 2014	Acupuncture and/or moxibustion versus sham acupuncture, another form of acupuncture, or conventional treatment in lateral elbow pain	Systematic review of 19 randomized controlled trials	Pain, grip strength	Acupuncture is more effective than sham acupuncture (moderate quality studies) Acupuncture or moxibustion is more effective than conventional treatment (low quality studies)	Low to moderate quality evidence
Cho et al, 2015	Real versus sham acupuncture in acute post-operative pain after back surgery	Systematic review and meta-analysis of 5 trials	24-hour post-operative pain intensity on VAS; 24-hour opiate demands	Real acupuncture was superior to sham in reducing pain intensity but not opiate demand at 24-hours	3 of 5 trials were high quality
Levett et al, 2014	Acupuncture, standard care, sham acupuncture, acupressure and mixed	A critical narrative review of 4 systematic reviews in labor pain	Pain intensity, analgesic use, length of labor	Acupuncture reduces pain intensity, analgesic use and	Conflicting evidence

	controls in various combinations in labor pain			length of labor	
Clark et al, 2012	Acupuncture versus various comparators including standard care, sham acupuncture and other forms of acupuncture in plantar heel pain	Systematic review of 5 randomized controlled trials and 3 non-randomized comparative trials	Various pain and disability scales (morning pain, walking pain, tenderness)	Acupuncture for plantar heel pain is supported by evidence which is equivalent to evidence supporting standard care (stretching, night splints, dexamethasone)	"Evidence at level I and II supporting the effectiveness of acupuncture for heel pain, leading to a recommendation at Grade B"
Deare et al, 2014	Manual and electroacupuncture compared with sham acupuncture, standard therapy and no treatment in fibromyalgia	Cochrane systematic review of 9 randomized controlled trials in fibromyalgia	Pain, stiffness, sleep, fatigue and global wellbeing	Acupuncture improves pain and stiffness compared to standard therapy and no treatment, but not compared to sham acupuncture	Low to moderate quality evidence
Smith et al, 2011	Acupuncture or acupressure versus placebo control, usual care or pharmacological treatment in primary dysmenorrhea	Cochrane systematic review of 10 randomized controlled trials (944 subjects) on acupuncture (6) or acupressure (4) for primary dysmenorrhea	Pain relief, analgesic use, quality of life, improvement in menstrual symptoms, absenteeism	Acupuncture was superior to placebo and Chinese herbs in pain relief, and superior to medication and Chinese herbs in reducing menstrual symptoms. Acupressure was superior to placebo in pain relief and reducing menstrual symptoms.	Low risk of bias in 50% of included RCTs
Abaraogu et al, 2015	Acupuncture or acupressure versus placebo control, wait list or pharmacological treatment in primary dysmenorrhea	Systematic review of 8 randomized controlled trials (>3,000 subjects) and meta-analysis of 4 RCTs	Pain intensity (VAS, McGill), quality of life, blood nitric oxide	Acupuncture and acupressure reduced pain, while acupuncture also improved quality of life	Moderate quality evidence
Chen et al, 2013	Acupuncture or acupressure at acupoint SP 6 versus minimal stimulation at SP 6 or stimulation of another point in primary dysmenorrhea	Meta-analysis of acupuncture (3) and acupressure (4) randomized controlled trials in primary dysmenorrhea	Pain intensity (VAS)	Acupuncture is effective and acupressure may be effective at SP 6 for pain relief	Acupuncture trials had low to moderate risk of bias Acupressure trials had high risk of bias
Cho et al, 2010	Acupuncture versus sham acupuncture, pharmacological treatment or Chinese herbs in primary dysmenorrhea	Systematic review of 27 randomized controlled trials in primary dysmenorrhea	Pain intensity (VAS, Menstrual Pain Reduction Score, other pain scores)	Acupuncture was superior to pharmacological treatment or Chinese herbs in pain relief	Only 5 out of 27 trials had low risk of bias
Chung et al, 2012	Acupoint stimulation versus non-acupoint stimulation or medication in primary dysmenorrhea	Systematic review of 30 randomized controlled trials (>3,000 subjects) and meta-analysis of 25 RCTs	Pain intensity, plasma PGF(2 $\alpha$ )/PGE(2) ratio	Acupoint stimulation was superior in short-term pain relief to stimulation on non-acupoints. Non-invasive stimulation of acupoints was more effective than invasive stimulation	Some trials were of low quality
Xu et al, 2014	Various forms of acupoint stimulation (including acupuncture, moxibustion and other methods) versus a variety of controls in primary dysmenorrhea	Meta-analysis of 20 randomized controlled trials (2,134 subjects) of acupoint stimulation for primary dysmenorrhea	Pain relief	Acupoint stimulation was more effective than controls for pain relief	Low to moderate quality evidence