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ACUPUNCTURE IN PAIN MANAGEMENT

Strengths and Weaknesses of a Promising Non-Pharmacologic Therapy in the Age of the Opioid Epidemic

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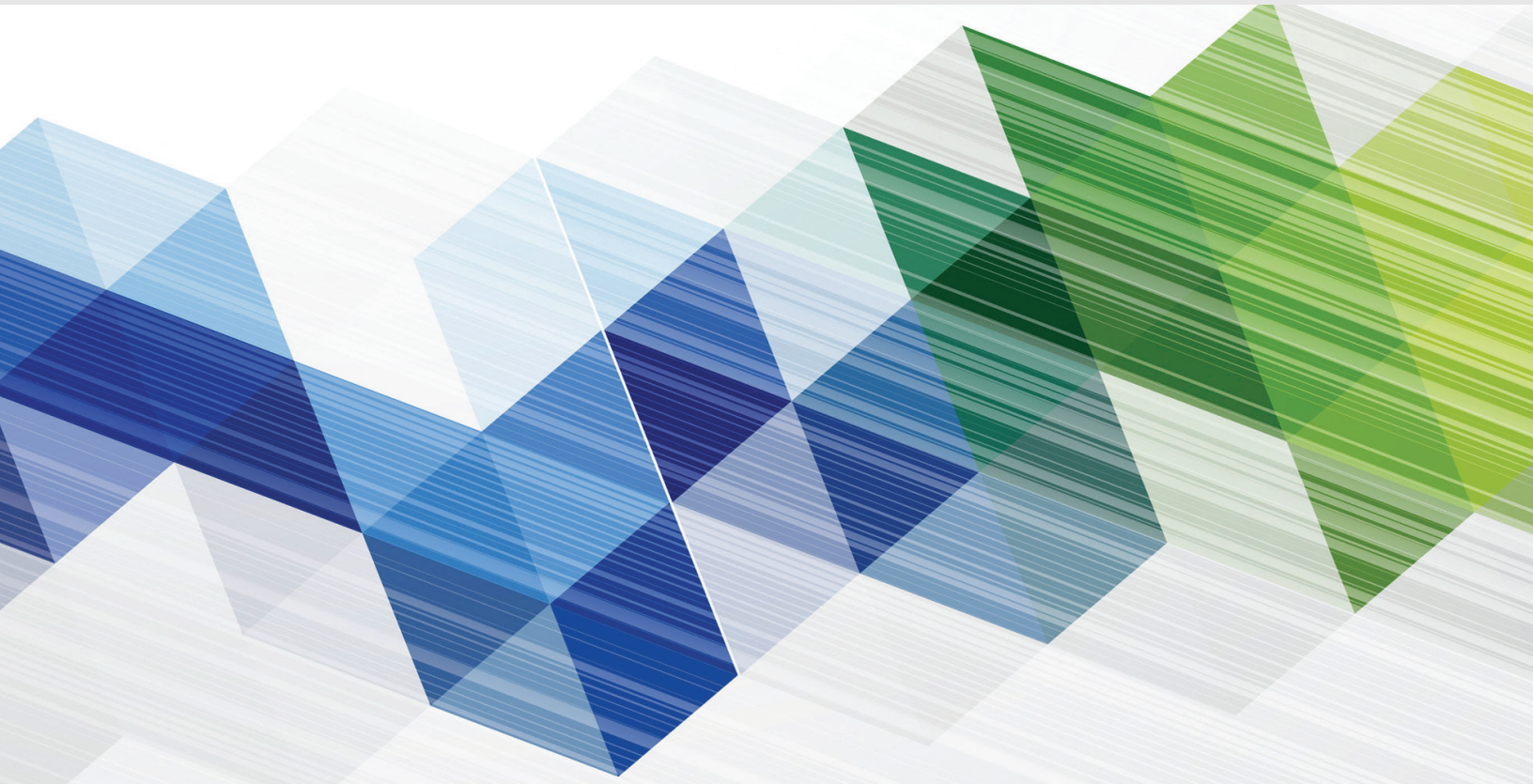

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EXECUTIVE SUMMARY

Stark evidence of the unfavorable benefit-to-harm ratio of opioids as well as other pain management drugs is leading policymakers to advise Health Care Providers (HCPs) to rely more on non-pharmacologic pain management approaches including so-called complementary or alternative therapies. These recommendations often mention acupuncture. Due to limited knowledge about acupuncture and concerns about limited insurance coverage, HCPs may find following this advice difficult.

This paper summarizes the most pertinent information regarding the potential of acupuncture in treating common pain conditions and reducing dependency on harmful medications. We review the current body of research as well as provide an overview of the potential benefits and limitations of expanding acupuncture's role in pain management.

FINDINGS

Recent quality research indicates that acupuncture:

1. Is as effective as—and sometimes moreso—than conventional pain management therapies.

2. Exhibits very low rates of adverse side effects.

3. Is or could be cost effective.

4. Scores higher than national benchmark averages in patient experience/satisfaction surveys.

However, limitations include:

1. Limited or inaccurate information regarding acupuncture held by the public, HCPs, health policymakers and health insurers is restricting demand for and access to acupuncture.

2. Low overall numbers and an uneven distribution of acupuncture service providers could make access to those services difficult in the event the demand rose significantly in a short period of time.

3. Cost concerns include limited insurance coverage as well as the greatly varying rates of provider fees for acupuncture services. These factors complicate calculating acupuncture's cost effectiveness

CONCLUSION

The evidence supports the conclusion that acupuncture has a favorable benefit-to-harm ratio in the treatment of common pain conditions and its expanded use could reduce dependency on opioids and other harmful medications. The greatest impediments to expanding acupuncture's use include a lack of accurate information about acupuncture services, cost factors, and the potential of limited access to qualified providers if demand were to rise significantly in a short period of time.

RECOMMENDATIONS:

1. Guidelines for HCPs managing patients with pain should unequivocally recommend acupuncture as an evidence-based therapy for common pain conditions.

2. HCPs should not let the concern over limits in insurance coverage for acupuncture services prevent them from recommending it.

3. The existing paucity in the number and the current disproportionate distribution of acupuncture providers should be addressed to meet rising demand.

4. Comparative cost effectiveness studies should be undertaken to help guide treatment protocols and determine where acupuncture is both most and least cost effective.

5. Governmental and philanthropic financial support grants should be established to support unbiased research into integrating the most promising non-pharmacologic pain management therapies into the practice of mainstream healthcare. This research should include pragmatic clinical effectiveness and workforce capabilities studies and lead to the development of guidelines that HCPs could utilize to aid their decision-making with regard to those therapies.

LIMITS OF THIS REPORT:

While we are confident in the strength of the evidence which finds that acupuncture is effective in common pain conditions, little reliable data on workforce and other associated cost factors for acupuncture services exists. Our recommendations on workforce and cost issues are based on limited data combined with anecdotal industry insider knowledge of those subjects.

CONTENTS

SECTION ONE: INCREASED INTEREST IN NON-PHARMACOLOGIC APPROACHES TO MANAGING PAIN

In March 2016, The Centers for Disease Control and Prevention (CDC) issued guidelines for prescribing opioids for chronic pain that included 12 recommendations. The first recommendation was that "Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain." Language advising the first-line use of non-drug therapies and non-opioid drugs for managing pain is now found in several guidelines being written or re-written in response to the North American opioid crisis. In February 2017, The American College of Physicians (ACP) issued guidelines for managing low back pain that went one step further when it recommended that for chronic low back pain "clinicians and patients should initially select non-pharmacologic treatment."

The ACP's recommendation of non-drug therapies as a first-line treatment for managing chronic pain even over non-opioid drugs reflects the evidence showing that the benefit-to-harm ratio of commonly used non-opioid pain management drugs is problematic and may not be as good as that for various non-drug therapies. Relying on non-opioid drugs alone, in other words, is not a viable solution to the opioid crisis.

In July 2017, The Joint Commission issued new standards relating to pain management for its 4,400 accredited hospitals; these new standards go into effect January 1, 2018. Those standards now specify that their accredited hospitals provide "non-pharmacologic pain treatment methods." The FDA is also considering language to its pain management blueprint advising HCPs to inform patients about non-pharmacologic therapies, including complementary therapies like acupuncture.

To say that the opioid crisis has spurred a new interest in non-pharmacologic therapies would be an understatement. However, challenges to implementing such policies are limiting how effectively they are being and will be carried out. When the CDC invited feedback to its proposed recommendations to its opioid prescribing guidelines, it received critical comments from many mainstream medical organizations. Several samples of those comments are presented in Appendix A.

Groups such as the American Medical Association, the American Society of Anesthesiologists, the American Academy of Physical Medicine & Rehabilitation, and many others pointed out that, while they agreed with the recommendation on using non-pharmacologic therapies, carrying out this recommendation would be difficult for their members to follow because of a lack of insurance coverage for those services and limited knowledge about how to utilize those therapies.

Another factor in how effectively these new recommendations/policies will be followed is how the evidence for the use of non-pharmacologic therapies will be interpreted, as many of these guidelines identify the need for these therapies to be "evidence-based."

In this report, we will address the main issues impacting the use of one of the most frequently mentioned and promising non-pharmacologic therapies—acupuncture. While we believe the evidence suggests acupuncture has tremendous positive potential for its expanded use in pain management, we are not suggesting that acupuncture has been proven superior to other non-pharmacologic pain management approaches. Although acupuncture is consistently at or near the top in studies comparing various non-pharmacologic therapies, too few comparative effectiveness studies have been undertaken to make a strong case for one of these therapies over the others; more research is needed to better rank such therapies.

SECTION TWO: THE EVIDENCE

A. OVERVIEW OF THE EVIDENCE

The last five to ten years has seen a significant increase in the number of research studies on acupuncture, and the quality of these trials has been improving. In just the last few years, several high quality trials have been published that are providing clearer insights into this practice than was the case in the past. In this section on acupuncture's effectiveness, only one study dates back as far as 2010, and 17 of the 24 studies we reference were published from 2015 to the present. Several of these studies are systematic reviews or meta-analyses. One landmark 2017 study is comprised of 136 systematic reviews, along with three network meta-analyses and nine reviews of reviews. After our section detailing the findings of these trials, we provide background information on several recent studies to underscore their significance.

We limited the focus of the data presented here to the most common pain conditions, as these are both the types of conditions for which patients typically use acupuncture and they are also the conditions for which opioids are most prescribed in North America. We add a section on acupuncture mechanism findings, as such studies strongly suggesting acupuncture stimulates important intrinsic biochemical changes, including the production of endogenous opioids and anti-inflammatory compounds.

We believe no other therapy has as much science behind it, suggesting it is possible to safely invoke such a range of natural pain-reducing internal chemistry. We also reference some cost-effectiveness studies on acupuncture for common pain conditions,

since cost is important when considering expanding the role of a therapy. In addition, such studies also underscore acupuncture's effectiveness. A therapy cannot be cost effective if it is not also clinically effective.

Before getting to this data, we offer a brief commentary on the ethics in interpreting and utilizing the evidence behind acupuncture, especially in light of the opioid crisis.

B. THE ETHICS OF INTERPRETING EVIDENCE IN THE AGE OF THE OPIOID CRISIS

While thousands of studies have been done on acupuncture over the last four decades, controversy remains over how to interpret that evidence. Much of that controversy has come from a vocal minority, active in the blogosphere, who insist research shows acupuncture to be "nothing more than a placebo." We will present current evidence which points to the opposite being true. However, understanding that the subject of acupuncture research can lead to heated, conflicting interpretations of the evidence, it is important to view that research in light of our current public health crisis: We find ourselves in the midst of an opioid epidemic that is killing scores of people and devastating communities. The gravity of this crisis makes it imperative that we seriously consider all possible solutions.

When the claim is made that acupuncture's effects are due to placebo, the effects being referred to are the positive clinical outcomes seen in thousands of research trials on tens of thousands of people. Those positive effects themselves are not controversial, as they have been clearly and consistently demonstrated. The only controversy is over how those effects are generated and, specifically, how clearly the active therapy outperforms the controls in controlled clinical trials.

In most two- or multi-arm controlled clinical trials, the "real" acupuncture will outperform the "sham" controls, but sometimes not to the extent some would deem as a "statistically significant" degree. When the real acupuncture does not outperform the sham controls to a statistically significant degree, it is often labeled as a negative trial, no matter how clinically effective the acupuncture may have been. For example, two of the better-known trials on acupuncture for chronic low back pain found it to be twice as effective

as conventional care[1-2]. The "conventional care" to which acupuncture was compared included physical/physio therapy and the use of commonly prescribed pain medications, including opioids. However, because the real acupuncture in these two trials did not outperform the sham acupuncture controls to a predetermined statistically significant degree, critics cite these trials as proof that acupuncture is only a placebo.

This sort of "glass half empty" interpretation of the evidence is wrong-headed, unethical and, frankly, considering the magnitude of the opioid crisis, highly dangerous. When evidence shows a relatively infrequently used therapy to be twice as effective as higher risk conventional care in the treatment of such a difficult-to-manage condition as low back pain, this should be seen as a positive outcome, not a negative one. We should not be holding back on a therapy like acupuncture just because a small, yet vocal, group believes the impressive pain reducing benefits seen in thousands of trials are due to placebo. The opioid crisis is a crisis of an unacceptable benefit-to-harm ratio in a commonly prescribed pain management therapy, and low back pain is one of the leading conditions for which opioids are prescribed. To find a way out of this, we need to identify and incorporate safer pain management approaches that are also effective.

If the likelihood of benefit is greater than the likelihood of harm, this is considered a positive benefit-to-harm ratio and a good recommendation. In this day of "evidence-based medicine," however, there is a need to undertake side-by-side comparisons of different therapies to measure their benefit-to-harm ratio in relation to each other. When comparing therapies for potentially life-threatening conditions, the likelihood of a higher rate of benefit may be worth a greater chance of harm. But when comparing therapies for common pain conditions that are largely self-limiting and not life threatening and whose severity is primarily gauged by the subjective assessment of the patient, ethics demands that a greater emphasis be placed on reducing potential harms, especially if those possible harms are more serious than the condition being treated. With an emphasis on the ethics of safety, we at the Acupuncture Now Foundation believe the strength of recommendations when comparing different pain management therapies should follow this order:

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[1] Haake M1, Müller HH, Schade-Brittinger C, Basler HD, Schäfer H, Maier C, Endres HG, Trampisch HJ, Molsberger A. German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. Arch Intern Med. 2007 Sep 24;167(17):1892-8.

[2] Cherkin DC, Sherman KJ, Avins AL, Erro JH, Ichikawa L, Barlow WE, Delaney K, Hawkes R, Hamilton L, Pressman A, Khalsa PS, & Deyo RA. A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain. Arch Intern Med. 2009 May 11; 169(9): 858–866. doi:10.1001/archinternmed.2009.65.

1. Less harm and greater benefit
2. Less harm and equal benefit
3. Less harm and slightly less benefit
4. Equal harm and slightly greater benefit
5. Slightly more harm but significantly greater benefit

Therapies that would be the most unethical to recommend follow this order:

1. Greater harm and less benefit
2. Greater harm and equal benefit
3. Equal harm and less benefit

As we will show, acupuncture typically demonstrates a superior benefit-to-harm ratio compared to most drugs conventionally used for treating common pain conditions and that fact alone should make the public, HCPs, and health policymakers take acupuncture seriously as a powerful resource in the fight against opioid dependency.

C. RESEARCH FINDINGS FOR THE EFFECTIVENESS AND MECHANISMS OF ACUPUNCTURE IN PAIN MANAGEMENT

(See Appendix B for references.)

CHRONIC PAIN

In 2014 the U.S. Veterans Affairs Evidence Map of Acupuncture found that acupuncture showed "evidence of positive effect" for chronic pain [1]. An individual patient data meta-analysis involving 17,922 patients treated with acupuncture for chronic pain found that acupuncture is effective for chronic pain and that "significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo" [2]. Another review of 6,376 patients with chronic pain found that 90% of the pain-relieving benefits of acupuncture persisted 12 months after treatment [3]. A review by the UK's National Institute for Health Research (NIHR) in 2017 concluded that acupuncture is more effective than both usual care and sham acupuncture for chronic pain based on "the most robust evidence from high-quality trials of acupuncture for chronic pain"[4].

ACUTE PAIN

In "Acute Pain Management: Scientific Evidence" published by the Australian and New Zealand College of Anesthetists and Faculty of Pain Medicine in 2015, NHMRC Level I evidence was identified from Cochrane reviews for acupuncture for labor pain, oocyte retrieval pain, primary dysmenorrhea, tension-type headaches and migraine, and from PRISMA reviews for postoperative pain, back pain and acute burns pain [5].

A number of studies have been conducted to explore the use of acupuncture for acute pain in emergency departments. These studies have included both auricular and body acupuncture [6-17]. A study which compared acupuncture with intravenous morphine in the management of acute pain in an emergency department found that acupuncture showed a significantly higher success rate than morphine (92% versus 78%) and shorter resolution time (16±8 minutes versus 28±14 minutes); there were 85 minor adverse events in the morphine group, 4 in the acupuncture group and no major adverse events [8]. The largest study to date was a multicenter randomized trial conducted in the emergency departments of four Melbourne hospitals comparing acupuncture, pharmacotherapy, and acupuncture plus pharmacotherapy for low back pain, ankle sprain, and migraine [17]. Acupuncture was found to be a safe and acceptable treatment and comparable (equivalent and non-inferior) to pharmacotherapy in analgesia [17].

LOW BACK PAIN

Recent reviews have found acupuncture to be an effective intervention for low back pain. In the Acupuncture Evidence Project, acupuncture was found to show "evidence of positive effect" for chronic low back pain and "evidence of potential positive effect" for acute low back pain [18]. In the Agency for Healthcare Research and Quality Comparative Effectiveness Review #169 titled "Non-Invasive treatment for Low Back Pain" it was found that there is moderate quality evidence for the effectiveness of acupuncture in chronic low back pain for both pain intensity and function, and low quality evidence for pain intensity and function in acute low back pain [19]. An updated American College of Physicians' Clinical Guideline on low back pain recommended acupuncture for both chronic low back pain (moderate quality evidence; strong recommendation) and for acute and sub-acute low back pain (low quality evidence; strong recommendation) [20]. The Scottish Intercollegiate Guidelines Network's guideline titled the "Management of Chronic Pain" also recommended acupuncture (Grade A recommendation) for chronic low back pain [21].

Two studies found that acupuncture is likely to be cost-effective for low back pain or chronic non-specific low back pain, respectively [22, 23].

Acupuncture has also been shown to be more effective than opioids for sciatica. In a network meta-analysis, Lewis et al. ranked acupuncture as the second most effective intervention in both global effect and reduction of pain intensity, while opioids were ranked 16th out of 20 interventions for global effect and 14th out of 18 interventions for reduction in pain intensity [24]. The reviewers concluded that the "findings of this review do not support the effectiveness of opioid medication, either for pain intensity or global effect" [24].

KNEE OSTEOARTHRITIS PAIN

Knee osteoarthritis pain was found to show "evidence of potential positive effect" in the U.S.VA Evidence map of acupuncture (2014) and "evidence of positive effect" in the Acupuncture Evidence Project [1, 18]. In a network meta-analysis comparing 22 interventions in 152 studies, acupuncture was found to be equal to balneotherapy and superior to sham acupuncture, muscle-strengthening exercise, Tai Chi, weight loss, standard care, and aerobic exercise (in ranked order) [25]. Acupuncture was also superior to standard care and muscle-strengthening exercises in a sub-analysis of moderate to high quality studies [25]. In a systematic review of 12 randomized controlled trials, acupuncture was found to significantly reduce pain intensity and to improve functional mobility and quality of life [26]. The reviewers concluded that "current evidence supports the use of acupuncture as an alternative for traditional analgesics in patients with osteoarthritis" [26]. A review by the UK's NIHR in 2017 concluded that "acupuncture is one of the more clinically effective physical therapies for osteoarthritis and is also cost-effective if only high-quality trials are analysed" [4]. The Scottish Intercollegiate Guidelines Network's guideline titled the "Management of Chronic Pain" also recommended acupuncture (Grade A recommendation) for osteoarthritis [21].

MIGRAINE PROPHYLAXIS

For migraine prophylaxis, acupuncture was rated as "effective" in the Australian DVA Review (2010) and "evidence of positive effect" in both the U.S. VA Evidence map of acupuncture (2014) and the Acupuncture Evidence Project [1, 18, 27]. Since March 2013 a narrative review of high quality randomized controlled trials and two systematic reviews, including a Cochrane systematic review update, have confirmed that acupuncture is superior to sham acupuncture and seems to be at least as effective as conventional preventative medication in reducing migraine frequency [28-30]. Moreover, acupuncture is described as "safe, long-lasting and cost effective" [28]. Evidence levels in these four reviews were moderate to high quality. UK's National Institute for Health and Care Excellence (NICE) has recommended acupuncture for migraine since 2012 [31].

HEADACHE (CHRONIC TENSION-TYPE AND CHRONIC EPISODIC)

Chronic tension-type headaches and chronic episodic headaches were rated as "evidence of positive effect" in both the U.S. VA Evidence map of acupuncture (2014) and the Acupuncture Evidence Project [1, 18]. The most recent Cochrane systematic review update confirmed that acupuncture is effective for frequent episodic and chronic tension-type headaches with moderate to low quality evidence [32]. A brief

review of systematic reviews and meta-analyses described acupuncture as having a "potentially important role as part of a treatment plan for migraine, tension-type headache, and several different types of chronic headache disorders" [33]. UK's National Institute for Health and Care Excellence (NICE) has recommended acupuncture for tension type headache since 2012 [31].

Studies in Germany and the UK found acupuncture for chronic headaches to be cost-effective [33].

POST-OPERATIVE PAIN

In the Acupuncture Evidence Project, post-operative pain was found to have "evidence of positive effect" [18]. A systematic review and meta-analysis of 13 RCTs in 2016 found that acupuncture, electro-acupuncture (EA), and transcutaneous electrical acupoint stimulation (TEAS) improved pain on day one after surgery and reduced opioid use [34]. A systematic review specifically on acute pain after back surgery reviewed five RCTs (three of which were high quality) and found encouraging but limited evidence for the efficacy of acupuncture [35]. An RCT on acupuncture for pain after total knee arthroplasty found that acupuncture was superior to sham in post-operative fentanyl use, time to first request for fentanyl and pain intensity [36].

MECHANISMS OF ACUPUNCTURE IN PAIN MANAGEMENT

Mechanisms underlying acupuncture analgesia have been extensively researched for over 60 years [37-40]. In animal models and human studies acupuncture and/or electroacupuncture has been shown to be effective for the alleviation of inflammatory, neuropathic, cancer, and visceral pain [37, 41].

a. Neural pathways

Ascending neural pathways involving Aδ, Aβ and C sensory fibers have been mapped, the mesolimbic loop of analgesia in the brain and brain stem has been identified and descending pathways have also been mapped [38].

b. Endogenous opioid & non-opioid mediators

Numerous mediators have been identified including opioid and non-opioid neuropeptides, serotonin, norepinephrine, dopamine, cytokines, glutamate, nitric oxide,

and gamma-amino-butyric-acid (GABA) [37, 38]. Acupuncture analgesia has been shown to involve several classes of opioid neuropeptides including enkephalins, endorphins, dynorphins, endomorphins and nociceptin (also known as Orphanin FQ) [38-40]. 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 [37, 42]. Adenosine has also been shown to play a role in acupuncture's effects on pain [43].

c. Neuroplasticity

Adverse neuroplasticity can present a challenge in pain management as neuroplastic changes can be associated with chronic severe pain that 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 [44-46]. This suggests that acupuncture may have an important role in treating chronic pain that involves adverse neuroplastic changes.

ADJUNCTIVE ACUPUNCTURE CAN REDUCE REQUIRED DOSAGES OF OPIOID-LIKE MEDICATION (OLM)

Some studies have reported reduced consumption of opioid-like medication (OLM) by more than 60% following surgery when acupuncture is used [47, 48]. A pilot RCT also showed a reduction of 39% in OLM use in non-malignant pain after acupuncture, an effect that lasted less than 8 weeks after acupuncture treatment ceased [49].

Given that acupuncture analgesia activates the production and release of endogenous opioids and activates μ, δ, andκ 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 [37]. For patients not yet prescribed OLM, acupuncture should be recommended prior to OLM prescription commencing. This would be in line with existing guidelines that recommend non-opiate alternatives that are safe and effective should first be exhausted before resorting to OLM.

D. EVIDENCE FOR THE SAFETY OF ACUPUNCTURE FOR PAIN MANAGEMENT

Condition	The Acupuncture Evidence Project (Mar 2013 - Sept 2016)	Comments
Acupuncture generally prior to this review	Zhang et al 2010 (Review of 98 case reports and 17 case series) [236] 'Various types of acupuncture-related adverse events have been reported in China. Similar events have been reported by other countries, usually as a result of inappropriate technique. Acupuncture can be considered inherently safe in the hands of well-trained practitioners.'	**Acupuncture can be considered inherently safe in the hands of well-trained practitioners.**
Ambulatory Anaesthesia	Liodden 2013 (Narrative review)[50]: Acupuncture may reduce preoperative anxiety, and postoperative pain, nausea, vomiting, shivering and emergence delirium. Acupuncture is safe and cost-effective. Acupuncture may be a beneficial adjunctive therapy for ambulatory anaesthesia.	Acupuncture **safe**, cost-effective and effective as an adjunctive therapy.
Low back pain	Nahin 2016 (4 RCTs; Excluded studies not performed in U.S.A or by U.S. researchers)[51]: Acupuncture superior to usual care; Acupuncture superior to sham in 1 RCT, but not superior in 2 RCTs. NIH (2016) Promise in the following for safety and effectiveness in treating pain: Acupuncture and yoga for back pain, acupuncture and tai chi for osteoarthritis of the knee [237]. Chou et al 2016 (Comparative effectiveness review) [47]: Serious adverse events were not reported in any trial.	Moderate to high quality evidence Cost effective. Promise in **safety** and effectiveness. Serious adverse events were not reported in any trial.
Migraine	Da Silva 2015 (Narrative review of large high quality RCTs)[28]: Acupuncture seems to be at least as effective as conventional preventative medication for migraine and is safe, long lasting, and cost-effective.	Moderate to high quality evidence, **safe** and cost-effective (including Cochrane update); 16 or more treatments more effective than 12 treatments or less.
Osteoarthritis of the Knee	Nahin 2016 (4 RCTs; Excluded studies not performed in U.S.A or by U.S. researchers)[51]. NIH 2016 [237]: Promise in the following for safety and effectiveness in treating pain: Acupuncture and yoga for back pain, acupuncture and tai chi for osteoarthritis of the knee.	Promise in **safety** and effectiveness.
Prostatitis pain/chronic pelvic pain syndrome	Chang 2016 (SR of 7 RCTs: 3 high quality studies, 1 moderate and 3 low)[52]Acupuncture superior to both sham and to usual care and safe, thus it should be offered when available.	Acupuncture superior to both sham and to usual care and **safe.**

Note: Extracted from Table 8 *in The Acupuncture Evidence Project;* endnotes may be found in Appendix B.

E. EVIDENCE FOR THE COST EFFECTIVENESS OF ACUPUNCTURE FOR PAIN MANAGEMENT

Condition	The Acupuncture Evidence Project (Mar 2013 - Sept 2016)	Comments
Ambulatory Anaesthesia	Liodden 2013 (Narrative review)[50]: Acupuncture may reduce preoperative anxiety, and postoperative pain, nausea, vomiting, shivering and emergence delirium. Acupuncture is safe and cost-effective. Acupuncture may be a beneficial adjunctive therapy for ambulatory anaesthesia.	Acupuncture safe, **cost-effective** and effective as an adjunctive therapy.
Chronic Pain	MacPherson 2016 (SR & MA of 29 trials) [3]The effects of a course of acupuncture treatment for patients with chronic pain do not appear 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.	"Studies of the cost-effectiveness of acupuncture should take our findings into account."
Dysmenorrhoea	Kim 2012 (Cost effectiveness analysis)[53]: Acupuncture is cost effective for dysmenorrhoea, allergic rhinitis, osteoarthritis & headache.	**Cost effective**
Headache	Kim 2012 (Cost effectiveness analysis)[53]: Acupuncture is cost effective for dysmenorrhoea, allergic rhinitis, osteoarthritis & headache. Coeytaux 2016 (Brief review of selected SRs and MAs)[33]: A potentially important role for acupuncture as part of a treatment plan for migraine, tension-type headache, and several different types of chronic headache disorders. Cost-effective in Germany and UK.	A potentially important role for acupuncture' as part of a treatment plan for migraine, tension-type headache, and several different types of chronic headache disorders. **Cost effective**
Low back pain	Taylor 2014 (Cost effectiveness analysis/MA)[23]: Cost effective for chronic low back pain. Andronis 2016 (SR of 33 studies)[22]: Likely to be cost effective.	Moderate to high quality evidence **Cost effective**, safe.
Migraine	Da Silva 2015 (Narrative review of large high quality RCTs[28]: Acupuncture seems to be at least as effective as conventional preventative medication for migraine and is safe, long lasting, and cost-effective.	Moderate to high quality evidence, safe and **cost-effective** (including Cochrane update); 16 or more treatments more effective than 12 treatments or less.
Neck Pain	Van der Velde 2015 (SR of 6 studies)[54]: Acupuncture plus usual medical care is cost-effective for neck pain and its associated disorders (NAD).	Moderate quality evidence (Cochrane update); Acupuncture plus medication is **cost-effective.**
Osteoarthritis	Kim 2012 (Cost effectiveness analysis)[53]: Acupuncture is cost effective for dysmenorrhoea, allergic rhinitis, osteoarthritis & headache.	**Cost-effective**

Note: Extracted from Table 7 *in The Acupuncture Evidence Project;* endnotes may be found in Appendix B.

SECTION THREE: FOUR MILESTONE STUDIES

We want to highlight four studies on acupuncture we believe are of particular importance to understanding the current state of the evidence as it pertains to pain management. Trying to understand the evidence behind acupuncture can be taxing as it seems to be riddled with contradictory findings. The biggest misunderstanding that must be clarified is the stigma that "all studies show acupuncture is no better than placebo." We have already presented dozens of studies including high quality multi-study reviews that have found just the opposite to be true.

In the four milestone studies presented here, we offer some background to the studies to help underscore why they are especially representative of the best current evidence on acupuncture. The first study, while not a controlled trial or review of trials, may in its own way be the most important study of all because it shows how actual acupuncture patients being treated in real-world settings by U.S.-based acupuncturists rate their experiences. This study includes a large subset of patients who were referred to a network of credentialed licensed acupuncturists by Physical Medicine physicians working within several pain management clinics.

A. AMERICAN SPECIALTY HEALTH PATIENT EXPERIENCE/SATISFACTION SURVEY

When an HCP is considering discussing acupuncture with his or her patients, objective data on how other patients rate their experience and satisfaction with obtaining acupuncture services would be helpful. Up until recently, very little data was available about the use of acupuncture under real world conditions in the U.S.. In 2016, a landmark two-year retrospective study was published by American Specialty Health (ASH), 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 network of 6,000 U.S. acupuncturists. The patients experiences reflected in this survey include both patients who were "self-referred" and a subset who were referred by their physician.

The survey utilized the "Clinician & Group Consumer Assessment of Healthcare Providers and Systems" (CG-CAHPS®) survey. All surveys officially designated as CAHPS surveys have been approved by the CAHPS Consortium, which is overseen by the U.S. Agency for Healthcare Research and Quality (AHRQ), the lead Federal agency charged with improving the safety and quality of America's health care system. CAHPS surveys are designed to provide a standardized tool to measure patients' experiences with healthcare providers, health plans, and health systems. Independent, accredited contractors administer surveys, and the results are compiled into a database establishing

national benchmarks. CAHPS is being widely adopted as *the* standard for measuring patient perceptions of the quality of care they receive from their HCPs.

The ASH study is titled "Does Acupuncture Provided Within a Managed Care Setting Meet Patient Expectations and Quality Outcomes?".[3] The majority of patients in this survey suffered musculoskeletal pain syndromes, with lower back and neck pain as the two most prevalent conditions.

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 ASH-contracted acupuncture providers by several pain management clinics in California. In order to be considered for a referral for acupuncture services, these patients must first be 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, before receiving treatment with acupuncture. In this subset of difficult-to-manage patients, an impressive 85% indicated their acupuncturist was successful in addressing their primary complaint.

While understanding that patient responses to surveys, even to a "gold standard" survey such as CG-CAHPS®, are not the same as findings from controlled clinical trials, the results of this survey show that even patients responding poorly to conventional pain management approaches report high levels of success when treated by acupuncturists who met ASH's credentialing standards.

[3] American Specialty Health. Does Acupuncture Provided Within a Managed Care Setting Meet Patient Expectations and Quality Outcomes?. (2016). http://files.clickdimensions.com/ashcompaniescom-a7oce/files/acupuncturecahps.pdf

These high success rates may be due in part to the fact that these patients received a full range of therapies—such as heat therapy, massage therapy and so forth—that many licensed acupuncturists typically provide, while acupuncture alone is studied in most clinical trials. In addition, these patients all had insurance coverage for acupuncture, which may have resulted in them receiving a higher number or greater frequency of treatments than might be the case for patients without insurance coverage or that patients may receive in controlled clinical trials. Whatever the reasons for the reported high rates of success with patients suffering difficult-to-manage pain, this study should encourage HCPs to consider referring such patients for acupuncture.

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- to10-point scale.
- 0.014% (13 out of 89,769) patients reported a minor adverse event and no serious adverse events were reported.

B. THE ACUPUNCTURE EVIDENCE PROJECT

The Acupuncture Evidence Project (AEP) is a landmark study commissioned by the Australian Acupuncture and Chinese Medicine Association.[4] One of the motivations for undertaking this project was to provide acupuncturists in Australia with the most up-to-date and scientifically rigorous evidence regarding the conditions for which acupuncture had been shown to be effective. Such a study was deemed to be needed due to truth in advertising regulations in Australia requiring medical providers who advertise their services to have evidence for claims of effectiveness, and the fact that acupuncture critics filed complaints about claims being made by acupuncturists regarding what acupuncture was effective in treating.

For this update, lead researcher John McDonald chose to build upon two previous highly regarded reviews of acupuncture research conducted by the Australian and U.S. Veterans Affairs Departments in 2010 and 2014 respectively. A total of 136 systematic reviews, including 27 Cochrane systematic reviews, were included in the review, along with three network meta-analyses, nine reviews of reviews, and 20 other reviews. The Acupuncture Evidence Project included pooled data from more than 1,000 randomized

[4] Australian Acupuncture and Chinese Medicine Association LTD. (2017). The Acupuncture Evidence Project: A comparative literature review.
http://www.acupuncture.org.au/OURSERVICES/Publications/AcupunctureEvidenceProject.aspx

controlled trials published in just the three-and-a-half-year period from March 2013 (the cut-off date for the U.S. VA study) to September 2016.

Evidence levels/quality were expressed using the four levels (with slight modification) from the U.S. VA Evidence Map of Acupuncture: "evidence of positive effect," "evidence of potential positive effect," "unclear," and "evidence of no effect" (changed in the AEP to "no evidence of effect" for greater clarity). The GRADE system terminology developed by the Cochrane Collaboration to identify the quality of evidence was also included where available—"high", "moderate", "low", and "very low" quality evidence. In short, the highest quality evidence was reviewed (systematic reviews and meta-analyses) using the most stringent methodology possible.

It is important to note that even the second and third levels—"evidence of potential positive effect" and "unclear"—all had numerous studies that found acupuncture to be effective. The reviews of the pooled studies for each of these conditions simply did not find as strong and unambiguous evidence for those conditions. However, compared to the U.S. and Australian VA reviews, more conditions were found to rate the highest level of evidence based on the latest research—a total of 8 conditions compared to 3 in the 2014 U.S. VA study—and 38 conditions are now graded as "evidence of potential positive effect" compared to 20 conditions in 2014. This shows a trend in the latest, highest-level research on acupuncture finding more definitive evidence of its effectiveness.

It is also important to consider that several of the eight conditions that had the highest level of evidence for acupuncture's effectiveness also happen to be among the very top conditions for which opioids are prescribed: chronic low back pain; knee osteoarthritis; chronic tension-type headache; post-operative pain; migraine prevention; and chemotherapy-induced nausea and vomiting; allergic rhinitis; and post-operative nausea and vomiting.

RESULTS

Of the 123 conditions reviewed, evidence of effect was found at various levels for 118 conditions. Six conditions were assessed as "no evidence of effect". The level of evidence had increased for 25 conditions since the previous reviews. The findings of this review are limited by the mounting evidence that sham/placebo controls used in acupuncture trials are not inert, which is likely to lead to a consistent underestimation of the true effect size of acupuncture interventions.

TABLE 1. SUMMARY OF LEVELS OF EVIDENCE USED IN THIS REVIEW

Level	Description	GRADE level (8)
Evidence of positive effect	Reviews with consistent statistically significant positive effects and where authors have recommended the intervention.	Moderate or high quality
Evidence of potential positive effect	Reviews reporting all individual RCTs or pooled effects across RCTs as positive, but the reviewers deeming the evidence insufficient to draw firm conclusions.	Moderate or high quality
Unclear/insufficient evidence	Conflicting evidence between reviews or between authors within a review, with reviewers summarising the evidence as inconclusive.	Low or very low quality; or conflicting levels of evidence within or between reviews
No evidence of effect	Reviews have consistently found little support for acupuncture.	Consistently low or very low quality

C. THE ACUPUNCTURE TRIALISTS' COLLABORATION

The Acupuncture Trialists' Collaboration was established in 2006 in an effort to make more accurate sense of the findings of acupuncture trials specifically on studies involving chronic pain. Some trials were reporting acupuncture to be superior to sham (placebo) acupuncture, while others showed evidence that acupuncture is superior to usual care but not sham, and still others concluded that acupuncture is no better than usual care. The collaboration obtained individual patient level data from the (at that time) more recent, larger, high quality randomized trials of acupuncture for chronic pain, standardized the data in order to combine it in a single data set, and then conducted analyses to address questions concerning both acupuncture effectiveness and acupuncture study design. One of the most important issues this review sought to better understand was the "effect size" of acupuncture; i.e., how much more effective "real" acupuncture was compared to sham or various types of usual care.

The trials selected involved headache and migraine, osteoarthritis, and back, neck and shoulder pain. Twenty-nine trials met inclusion criteria, 20 involving sham controls (n=5,230) and 18 non-sham controls (n=14,597). For sham controls, the researchers analyzed non-needle sham, penetrating sham needles, and non-penetrating sham needles. For non-sham controls, they analyzed non-specified routine care and protocol-guided care. Using meta-regression they explored impact of choice of control on effect of acupuncture.

The difference in effect size was −0.45 over usual care and −0.19 over penetrating needle sham *after* exclusion of outlying studies showing very large effects of acupuncture. However, when non-penetrating sham was used as a control, real acupuncture had about the same larger effect size found over usual care. While a gross oversimplification, effects sizes of 0.2 are often labeled as "small," 0.5 as "medium," and 0.8 as "large." Although the 0.19 effect size the Trialists' Collaboration found real acupuncture to have over sham is considered "small," it is still considered statistically significant.[5]

Acupuncture critics point to those small effect sizes as proof that acupuncture is nothing more than placebo. However, an effect size of near 0.2 is actually very close to what some commonly accepted medications have over placebo. One meta-analysis on Paracetamol (acetaminophen/Tylenol) found it to have an effect size of 0.21 over placebo, yet those same critics have not called for Tylenol to not be used. Not only is this a double standard over actual statistics between acupuncture and other accepted therapies, it is even more of a problem when considering that the penetrating needle sham used in many acupuncture studies is very likely causing some of the same neuro-chemical changes we detail in the section on acupuncture mechanisms. In other words, when comparing drugs like Tylenol to a placebo you can be sure the placebo you are using as a control is not causing the same effect of the active therapy you are trying to control against. You can't be sure of that with an acupuncture penetrating needle control so the true effect size of real acupuncture over an actual inactive control would surely be larger.

The Trialists' Collaboration findings were very straightforward: "Acupuncture was significantly superior to all categories of control group."

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[5] Hugh MacPherson, Emily Vertosick, George Lewith, Klaus Linde, Karen J. Sherman, Claudia M. Witt, Andrew J. Vickers, on behalf of the Acupuncture Trialists' Collaboration. (April 4, 2014). Influence of Control Group on Effect Size in Trials of Acupuncture for Chronic Pain: A Secondary Analysis of an Individual Patient Data Meta-Analysis http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0093739

D. AHRQ COMPARATIVE EFFECTIVENESS STUDY OF NON-EVASIVE TREATMENTS FOR LOW BACK PAIN

In February 2016, the AHRQ published a report titled "Noninvasive Treatments for Low Back Pain."[6] This report was part of the AHRQ's series of "Comparative Effectiveness Reviews. Such reviews "draw on completed scientific studies to make head-to-head comparisons of different health care interventions" and are "intended to help health care decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services."

This particular report is based on research conducted by the Pacific Northwest Evidence-based Practice Center and, at over 800 pages, is perhaps the most comprehensive head-to-head review ever undertaken of the wide range of noninvasive therapies commonly used for low back pain.

This comparative review looked at two primary questions: First, "What are the comparative benefits and harms of different pharmacological therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis?" And second, "What are the comparative benefits and harms of different nonpharmacological noninvasive therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis?" In asking those questions researchers measured both pain reduction and functional improvement and then the level of the "strength of evidence" behind their findings.

Twenty-five nonpharmacological interventions were compared including massage, physical therapy, manipulation, etc. Only three of those scored as high as "moderate" in both magnitude of effect for pain reduction and functional improvement. Those three were:

- Yoga versus usual care
- Progressive relaxation versus wait list control
- Acupuncture versus no acupuncture

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[6] Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt E. Noninvasive Treatments for Low Back Pain. Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 16-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2016. https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2178

Out of these three, only the acupuncture "strength of evidence" was rated as moderate for both pain reduction and functional improvement. This means that only "acupuncture vs. no acupuncture" had the highest rating across the board of "moderate" in all four possible categories.

In the case of the different pharmacological treatments for chronic low back pain only NSAIDs and Tramadol scored as high as a "moderate" for reducing pain and showed a "small" magnitude for improving function. Most drugs did not show any measurable reduction of pain or improvement of function, while the highly controversial opioids showed "small" effects for both pain and function. Only acupuncture was measured against medications for chronic low back pain and was found to have a "small" effect favoring acupuncture over medications for both pain and function.

This study is of major significance because it compares virtually all the common drug and non-drug therapies used in treating low back pain and was undertaken by the lead U.S. governmental agency whose mission is to provide objective evidence for policymakers, HCPs, and the public to use to make informed decisions regarding health care issues. The study found acupuncture to be at the top or very near the top of every measurement, including beyond sham controls, for the nearly 30 different therapies compared.

SECTION FOUR: SAFETY, COST EFFECTIVENESS AND THEIR INTERRELATIONSHIP

We included two tables from the "Acupuncture Evidence Project" listing several studies that found acupuncture to have high levels of safety and to be cost effective but we want to offer more information on those subjects here.

The most common adverse events found with acupuncture are bruising and bleeding, followed by transient pain and then dizziness or state of deep relaxation bordering on syncope. Virtually all of these "side-effects" are self-limiting and do not require any further treatment so it is questionable if they should even be labeled as a side effect/adverse reaction. Serious complications such as punctured organs, infections, or nerve injury do happen and are found in the literature, albeit at a very low rate. But most of those were the result of improper protocol (malpractice) from those ether poorly trained or not following professionally recognized standards of care. As malpractice insurance rates for licensed/certified acupuncturists cost approximately, $1,000 per year, it seems likely that those U.S.-trained practitioners are rarely practicing in an unsafe manner. A German study of 73,406 patients with chronic low back and chronic neck pain found only 0.6%

had adverse reactions requiring medication and/or follow-up by a physician and 0.03% required treatment in a hospital.[7]

Because adverse events associated with acupuncture that require any medical follow up are so rare, this adds to acupuncture's cost effectiveness as compared to other therapies especially drugs used to manage pain. When comparing cost effectiveness of more labor intensive hands-on therapies like acupuncture against conventional care such as pain management medications, calculating the cost of managing adverse events needs to also be considered, not just the upfront cost of delivering that care. How much are we spending today to manage the adverse impact of opioids? Billions of dollars, no doubt. Other popular pain management drugs also cause adverse reactions requiring medical follow up at a rate and cost that must be significantly higher than for acupuncture. And of course, this is not even considering the cost of human suffering seen as a result of these medications.

Unfortunately, there is little if any data on the costs of treating side effects of commonly used drugs such as those used in pain management. We will never know the true costs of different therapies until we factor in the cost of managing adverse events as well as the upfront costs. When both costs are factored in, the safer non-pharmacologic therapies like acupuncture start to look like a much better bargain than they may have seemed at first glance.

When it comes to cost for acupuncture, there is a wide range of charges seen for similar services. Some of those rate differences are due to the same factors seen in many industries such as the need to cover high overheads from higher cost of living areas but other factors seem more to be related to the number of patients being seen.

As we will discuss in the following section on workforce issues, many acupuncturists are seeing a low number of patients and this may well be influencing them to charge relatively higher rates. Rates near the $80-$100 per treatment range or more are not uncommon and patients are typically treated in individual treatment rooms. At the other end of the spectrum are practices following what is called "community acupuncture" practice models that treat several patients at once in larger rooms often in recliner chairs. There are about 170 such clinics in the U.S. that are part of the "People's Organization of Community Acupuncture" (POCA) that see a relatively higher volume of

[7] Witt C. Acupuncture safety and health economics study (ASH) - an observational study. http://www.claudia-witt.org/projects/methods/epidemiology/acupuncture-safety-and-health-economics-study-ash-an-observational-study/

patients, charge on a sliding scale of $15- $50 per treatment, and do not accept medical insurance reimbursements. POCA clinics deliver approximately one million treatments per year. In our section on four milestone studies, we highlighted a survey on patients managed by the insurance company ASH. They have a network of 6,000 credentialed acupuncturists and their payment for acupuncture is typically a per diem of $41 per treatment – a lower fee than many of these practitioners charge but is accepted in the expectation of referrals.

Considering the above, there is good reason to believe that if acupuncturists were to start to see a higher volume of patients because HCPs were following guidelines and referring their patients for non-pharmacologic therapies including acupuncture, the economies of scale could encourage a lower cost per treatment average than is seen today.

SECTION FIVE: WORKFORCE ISSUES

The evidence shows that acupuncture has the potential to play a much greater role in pain management than is currently the case. Furthermore, the potential for reducing dependency on opioids and other pain medications with the increased usage of acupuncture services is significant. However, one of the practical considerations that need to be addressed before an effort to significantly expand acupuncture's role in mainstream healthcare can be undertaken is that of workforce issues.

We regret that we are unable to provide comprehensive details regarding the numbers and distribution of acupuncturists in the U.S. We do our best to provide what data we could compile but the level of information on these issues are not as well researched as would be ideal.

The bottom line as we see it is that while some acupuncturists and acupuncture training programs are doing well financially, a good portion are not and are operating at well below capacity. If there were to be greater demand for acupuncture services, especially if this created salaried job positions for acupuncturists, there is a great deal of room to accommodate a higher demand, although some bottlenecks in meeting demand could occur especially in rural areas. We therefore believe workforce capacity concerns should not impede an effort to increase utilization of acupuncture services although we want to offer as much information on this subject as we can.

There are two significant uncertainties that cloud the picture of the workforce capabilities for expanding acupuncture services. The first is that there are greatly varying differences in the training of differing "acupuncturists" and just what services they offer. The second uncertainly is that even in the case of the more regulated and thus easier to count "licensed" or "certified" acupuncturists, no one knows how many of these who maintain their licensing/certification are actively practicing.

All of the states in the U.S. have laws that require some sort of licensing or certification for a healthcare provider to legally perform acupuncture. However, these laws vary considerably from state to state including whether or not they require those authorized to provide acupuncture to be registered with the state as such. This makes it impossible to get a count of all legally authorized acupuncture providers.

Most, but not all states, allow medical doctors and osteopaths to practice acupuncture without requiring them to undergo any formal training or examination in that subject. Some states allow chiropractors or naturopaths to perform acupuncture with some training but no required examination. Still other states allow podiatrists, dentists, physician's assistants, nurses, or even drug detox specialists to perform acupuncture in some restricted manner. Some of these are authorized without any required formal education or examination. Should everyone authorized by law to stick an acupuncture needle into a patient even with no required training be considered an "acupuncturist" and part of the potential workforce for providing that service?

At the other end of the spectrum are specialists usually titled as a licensed or certified acupuncturist. All but four states – Alabama, Oklahoma, South Dakota, and Wyoming – have laws authorizing acupuncture to be performed by a licensed/certified acupuncturist. All of these licensed/certified acupuncturists are required to have completed an accredited educational program and pass a formal examination. Consumers in the four states that do not have laws regulating acupuncture specialists can usually still find those specialists in their state. Most, but not all states require these licensed/certified acupuncturists to be registered in their state so some count of their numbers can be traced, although some of these practitioners may be registered in more than one state.

The latest figures we could find based on numbers from agencies in each state that regulate licensed/certified acupuncturists was from a 2013 survey. This showed 28,869 acupuncturists nationwide. That survey was part of the process of performing a job training analysis by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) which is undertaken every five years. The last published survey from

2013, found that 92% of licensed/certified acupuncturists worked in private practices. Again, no one knows how many of these practitioners are in active practice.

CHIROPRACTORS PRACTICING ACUPUNCTURE

Chiropractors are allowed to practice acupuncture in 34 states, while16 states require a separate acupuncture license. The additional training required for Chiropractors to practice acupuncture range from 100-300 hours. Some require an exam, others do not. There is no way to determine how many Chiropractors have met the requirements to practice acupuncture in those 34 states and out of those how many actually practice acupuncture.[8]

PHYSICIANS PRACTICING ACUPUNCTURE

The American Academy of Medical Acupuncture (AAMA) is the professional society of physicians (MDs and DOs) in North America who have incorporated acupuncture into their traditional medical practice. AAMA currently represents more than 1,300 physician acupuncturists in North America. Membership requirements for the Academy have been established in accordance with the "Limited" training guidelines established by the World Health Organization-recognized World Federation of Acupuncture and Moxibustion Societies for physicians practicing acupuncture. As most states allow MDs and DOs to practice acupuncture without additional training, certification or registration, it is impossible to estimate the number of physicians currently practicing acupuncture.

Although the lack of reliable data makes it impossible to calculate the number of those actively practicing acupuncture, between the licensed/certified acupuncture specialists, MDs and DOs, and Chiropractor fields alone, it seems reasonable to estimate there may be in excess of 50,000 professionals practicing acupuncture in the U.S. at this time in 2017. It would be very helpful if a more accurate count could be taken and especially a density map of where those practicing are located. A study looking at these issues would be helpful.

The Job Training Analysis published by the NCCAOM in 2013 also found 46% of the licensed/certified acupuncturists indicated they practiced less than 30 hours a week, and 69% less than 40 hours a week. 35% indicated these practice hours were due to a

[8] http://councilofchiropracticacupuncture.org/state-requirements.html

lack of patients and 38% indicated this was due to personal choice. 25% indicated they had other jobs as well as their acupuncture work. Of that 25% how many have other jobs out of financial necessity and would rather work more in their practice of acupuncture is uncertain.

With nearly 70% of licensed/certified acupuncturists practicing less than 40 hours a week and just 38% indicating this is due to personal choice, it seems clear there is room within the licensed/certified acupuncturist profession for a significant increase in patient load. This may be true for MDs, DOs, and chiropractors as well.

There are also over 60 Acupuncture/Chinese Medicine colleges operating in the U.S. with 57 of these being members of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM). All of the CCAOM's member schools have obtained either full accreditation or accreditation candidacy status with the Accreditation Commission for Acupuncture and Oriental Medicine , a national organization recognized by the U.S. Department of Education to accredit Acupuncture and Oriental Medicine schools and programs in the U.S.

As is the case with practicing licensed/certified acupuncturists, some of these schools appear stable and to be doing well financially, while others seem to be less stable. If there were to be a significantly increased demand for acupuncture services, these schools, like a good percentage of practicing acupuncturists, could no doubt ramp-up their capacity and start producing greater numbers of graduates. This would be especially true if salaried job positions, such as in Joint Commission certified hospitals or large integrative clinics were to materialize.

SECTION SIX: *CONCLUSION*

We mentioned in the introduction that several mainstream medical groups warned the CDC that following the guideline to encourage the use of non-pharmacologic therapies would be difficult to carry out due to a lack of insurance coverage and guidelines for their use. Our Foundation found nearly 20 such organizations that offered the CDC similar feedback and quotes from several of those are listed in Appendix A. The following one, from the "American Academy of Addiction Psychiatry and American Osteopathic Academy of Addiction Medicine" sums up these concerns most concisely:

"The guidelines emphasize using alternatives to the use of opioids, including non-opioid pharmacological approaches and behavioural health interventions. The 'elephant in the

room' is that such alternatives are time consuming, may not be adequately reimbursed, and that primary care clinicians often are not trained in the use of such approaches. While this is discussed, the guidelines may not be realistically implemented should the recommended changes in reimbursement and training fail to occur. Then what is the PCP to do? In many parts of the country, referral resources to behavioural health providers, those offering complementary and alternative medicine, pain management specialists etc. are not available. In short, a key concern is whether these guidelines are realistic and can they be implemented?"

We at ANF believe it is counterproductive to ignore these types of concerns as they were expressed by so many organizations representing the very HCPs to whom the guidelines are addressed. However, while acknowledging these concerns, we would urge HCPs to not let these issues prevent them from encouraging their patients to make use of these non-pharmacological services. It would, of course, be preferable to have insurance coverage and HCP training and guidelines in place before a policy of encouraging patients to use these services becomes widespread, but without seeing a significant increase in demand for these services, those who could address these issues may not feel the need to do so.

While there will be difficulties encountered for both patients and within the current healthcare industrial complex in making the transition from being a drug-centered system to one relying more on hands-on therapy to manage pain, there are highly professional individuals, organizations, and companies with expertise in these therapies ready to help integrate these "complementary" non-pharmacological therapies into more mainstream use. In the U.S., for example, the acupuncture profession has developed institutions for accrediting degree-granting colleges, licensing/certifications systems, and professional membership associations. There are also insurance companies that specialize in utilization management of non-pharmacological services employing evidence-based medical necessity review processes.

The "If you build it they will come" sentiment applies here: For decades specialists in non-pharmacological therapies have been doing their best with limited resources to build the infrastructure for integrating into the mainstream while waiting for the mainstream to come calling. There are ways to solve the problems those mainstream groups raise with the CDC if there is a will by mainstream institutions to make that happen. The Acupuncture Now Foundation looks forward to working with all groups and individuals interested in helping to make the benefits of acupuncture known and available to all.

APPENDIX A

Quotes from comments sent to the CDC regarding the problem of lack of guidelines and limited insurance coverage for non-pharmacologic therapies as compiled by The Acupuncture Now Foundation.

American Medical Association:
"Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider using opioid therapy if expected benefits for pain and/or function are anticipated to outweigh risks. In order to achieve this goal, public and private payer policies must be fundamentally altered and aligned to support payment for non-pharmacologic treatments and multimodal care."

Medical Board of California:
"While it is true that many non-pharmacologic modalities are effective for the treatment/control of chronic pain, the Guidelines fail to address the fact that many patients do not have access to these modalities, due to lack of insurance coverage or low availability. These Guidelines do not have to solve this problem, but it should mention that this may be an issue and educate on how to mitigate this situation."

American Society of Anesthesiologists:
"Insurance coverage: A major challenge in incorporating the Guideline in daily practice is that some of these recommendations may not be covered by the patient's insurance, which inhibits physicians' ability to treat patients using non-opioid approaches. We recommend that the Guideline clearly state that the federal government should encourage insurance coverage for therapies that would prevent opioid dose escalation or decrease. In addition, insurance coverage should include nonpharmacological therapies (all modalities available), and payers should reduce patient co-insurance and co-pays to encourage the use of non-pharmacological therapies."

American Pain Society:
"We agree that non-pharmacologic therapies are important tools in the management of many types of chronic pain. Unfortunately, many non-pharmacological therapies, are not reimbursed by Medicaid, Medicare or third-party payers. Support for such therapies in the guidelines might be useful for implementation of this recommendation. We believe that patients should have both pharmacological and non-pharmacological approaches available and reimbursed, as well as the availability of specialists when appropriate, for the management of their chronic pain."

American College of Physicians:
"The College also suggests that the Guideline document call for payment policy changes both within the public and private sector that will facilitate access to nonpharmacological therapies."

American Academy of Physical Medicine & Rehabilitation:
"Agree with recommendation for nonpharmacologic therapy and nonopioid therapy for chronic pain but concern is that primary care doctors have little experience integrating these successfully into practice. For the primary care world, there is little knowledge or experience with this. Also, reimbursement is poor and limited."

American Academy of Pain Management:
"We also note, in the narrative discussion, several mentions of challenges patients may have with obtaining adequate insurance coverage for non-pharmacologic therapies." "We suggest adding a paragraph specifically acknowledging and addressing all of these coverage challenges, adding suggestions for how providers can assist patients in obtaining these types of care if not covered by their insurance plans." "We further urge CDC to issue recommendations to the third-party payer community, listing the minimum benefits that should be offered in this context. The letter from the American Medical Association in response to the first draft of this guideline also mentioned this need. At a bare minimum, recommendations that payers provide universal coverage for the five types of nonpharmacologic care mentioned in the DoD/ VA pain guideline (physical manipulation, massage, acupuncture, biofeedback, and yoga) should be issued.

To fully support an integrative pain management model, providers such as acupuncturists, chiropractors and naturopathic physicians should be part of health insurance provider panels. These providers are well trained in non-pharmacologic approaches to treating chronic pain and can effectively collaborate with other providers on pain management teams to help reduce the use of opioids for initial treatment as well as to help with discontinuation of opioids in patients who have been on long-term opioid therapy."

Association of State and Territorial Health:
"Address reimbursement barriers for alternative treatments. The draft guideline states that 'non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.' Lack of reimbursement is a major barrier to including nonpharmacological approaches as a realistic treatment option for people with pain. Alternative treatments for pain management, including some physical modalities, relaxation and mind/body therapies, etc., are often not covered by health insurance plans, forcing an over-reliance in some cases on opioid medications. In order for this recommendation to be put into practice, ASTHO encourages CDC and other state and federal entities to develop a business model for reimbursement of nonpharmacologic therapies."

American Academy of Addiction Psychiatry and American Osteopathic Academy of Addiction Medicine:
"The 'elephant in the room' is that such alternatives are time consuming, may not be adequately reimbursed, and that primary care clinicians often are not trained in the use of such approaches. While this is discussed, the guidelines may not be realistically implemented should the recommended changes in reimbursement and training fail to occur. Then what is the PCP to do? In many parts of the country, referral resources to behavioral health providers, those offering complementary and alternative medicine, pain management specialists etc. are not available."

Providence Health:
"While we support the reference to nonpharmacologic therapy, we agree with other stakeholder comments that reforms to payment policy are needed to address barriers to access because services may not be covered by health insurance or coverage may be limited."

Alliance for Patient Access:
"For example, the CDC identifies non-pharmacological treatment as "preferred" despite the fact that many health plans have weak or nonexistent coverage for alternative pain management treatments."

Trust for Americas Health:
"Furthermore, many insurers don't adequately cover or reimburse for non-pharmacologic therapies such as acupuncture, biofeedback, relaxation, and other interactive, multimodal therapies. Payer policies—both public and private—would need to be fundamentally changed to support this recommendation."

APPENDIX B

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BIOGRAPHY

Dr. John McDonald, PhD commenced acupuncture studies in Australia in 1971, clinical practice in 1975 and teaching acupuncture in 1977. John has been a pioneer in developing acupuncture education in Australia in curriculum development and as a Dean, Department Head, senior lecturer and course coordinator in a number of colleges and universities. In 2006 John participated in the finalising of the World Health Organisation Western Pacific Region Standard for Acupuncture Point Locations. Among John's publications are the textbook "Zang Fu Syndromes: Differential Diagnosis and Treatment" co-authored with Dr Joel Penner from Los Angeles, seven peer-reviewed journal papers, 19 other journal papers, more than 30 health magazine articles and four videos. Recently John has, with Stephen Janz, co-authored a comparative literature review, The Acupuncture Evidence Project, sponsored and published by the Australian Acupuncture and Chinese Medicine Association of Australia Ltd (AACMA).

Currently, John is an Adjunct Senior-Lecturer in the School of Medicine at Griffith University (where he conducted his PhD research into the immunological mechanisms underpinning the effects of acupuncture in allergic rhinitis). John is also Vice-President for Research of the Acupuncture Now Foundation, a lecturer and member of the Curriculum Advisory Committee at the Endeavour College of Natural Health and a reviewer for various peer-reviewed journals including Nature, BMJ, Evidence-Based Complementary and Alternative Medicine and Journal of Acupuncture and Meridian Studies. John has also recently been appointed to the Editorial Board of Digital Chinese Medicine at Hunan University of Chinese Medicine.

Matthew Bauer, L.Ac., began his full-time practice of acupuncture and Chinese Medicine in 1986 and began working with several acupuncture organizations in the U.S. In 2014, Matthew founded the "Acupuncture Now Foundation" (ANF), a U.S. based international non-profit dedicated to offering reliable information regarding the practice of acupuncture. By drawing on the combined knowledge of acupuncturists the world over, the ANF hopes to help guide the development of the practice of acupuncture from an ancient art to an evidence based modern healthcare resource. Having served as a consultant in the managed care industry since 1998, Matthew helped to create the first managed care acupuncture-based credentialing and utilization guidelines and now serves on the Board of Directors of American Specialty Health Group, Inc. As a managed care consultant, Matthew took part in a think-tank with a dozen experienced Acupuncturists from the U.S., Mainland China, Taiwan, and Korea. That experience convinced Matthew of the need to find ways to gather experienced Acupuncturists together to share their knowledge to further the understanding of this ancient healing system. Matthew has authored dozens of articles and two books and has particular interest addressing the practical issues involved with bringing acupuncture into mainstream medicine.